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**Centers for Medicare & Medicaid Services' (CMS') First Biannual 2024 Healthcare  
Common Procedure Coding System (HCPCS) Public Meeting Agenda**

**Zoom Meeting - Remote participation  
Wednesday, May 29, 2024 9:00 am – 5:00 pm, eastern time (ET)**

8:45 am, ET:

- Zoom meeting login:

<https://cms.zoomgov.com/s/1605121459>

- Individuals who plan to speak as a primary or 5-minute speaker must register by emailing [HCPCS@cms.hhs.gov](mailto:HCPCS@cms.hhs.gov), by the published deadline. All attendees can access the virtual public meeting through the Zoom link above.

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 Level II 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 August 2024 and will be effective October 1, 2024, unless otherwise specified.

This agenda includes a summary of each HCPCS Level II code application being presented on Wednesday, May 29, 2024. The information provided in each summary reflects claims made by the applicant and should not be construed as a statement of fact or an endorsement by the federal government.

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**Agenda Item # 1**  
**Sparrow Ascent® - HCP231201M40EP**

**Topic/Issue**

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

Applicant's suggested language: XXXXX, “Transcutaneous auricular neurostimulation (tAN) device system for opioid withdrawal management”

**Summary of Applicant's Submission**

Spark Biomedical submitted a request to establish a new HCPCS Level II code to identify Sparrow Ascent®. Sparrow Ascent® received the Food and Drug Administration’s (FDA’s) 510(k) clearance on June 20, 2023. The Sparrow Ascent® is a non-invasive, wearable, battery-operated neurostimulation system designed to transcutaneously stimulate nerves on and/or around the auricle (ear) to reduce the symptoms associated with opioid withdrawal. Sparrow Ascent® is a battery operated, prescription device. The wearable neurostimulator can be used in both clinical environments (e.g., doctor's office, clinics, rehab centers etc.) and/or at home. The system is comprised of the following components: a disposable earpiece (which houses four cranial nerve electrodes), a reusable cable, and the reusable external pulse generator (EPG). The earpiece is self-applied and worn on and around the left or right ear. The earpiece electrodes are suspended in a hydrogel adhesive casing. The targeted regions include the auricular branch of the vagus nerve and the auriculotemporal nerve, a branch of the trigeminal nerve. Arranged in a multipolar configuration, the Sparrow Ascent® system provides dual-frequency biphasic stimulation. Channels/circuits are formed between pairs of electrodes by alternating the poles. The Sparrow Ascent® system is designed to be worn up to 24 hours a day, for as many days as needed, to reduce opioid withdrawal symptoms. Transcutaneous auricular neurostimulation therapy can be self-administered, unsupervised in the patient’s home. Users can tailor the strength of stimulation via the EPG (which also serves as the patient controller) throughout the withdrawal episode of care. The Sparrow Ascent® stimulator has an expected useful life of 3 years or greater. The stimulator is powered by AAA batteries, these can be replaced as needed based on power consumption. The ergonomically designed disposable earpieces housing the electrodes are changed out daily by the user. The Sparrow Ascent® device is not useful in the absence of opioid withdrawal symptoms.

**CMS Preliminary HCPCS Coding Recommendation**

Establish a new HCPCS Level II code EXXXX, “Transcutaneous electrical nerve stimulator for nerves in the auricular region” to describe Sparrow Ascent®.

**Preliminary Medicare Benefit Category Determination**

No determination.

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. Our initial review found that the Sparrow Ascent® System may not meet these conditions as follows:

**Expected life of at least 3 years** – As stated in the application, the Sparrow Ascent® patient controller and cable have a service life of three years from the date of manufacture. However, supporting materials in the application mention a service life of two years from the date of manufacture. DME is a benefit for rental of equipment and the three-year minimum lifetime requirement is intended to specify that durable equipment is equipment that can withstand repeated use over an extended period of time. The three-year minimum lifetime requirement represents a minimum threshold for a determination of durability and is calculated based upon the date of use as opposed to manufacture date or when the equipment is sold to a supplier. For this reason, our initial review found the Sparrow Ascent® may not meet the required expected life of at least three years. While we received some additional clarification from the applicant during our initial review process, our review of the lifetime durability testing presented by the applicant in support that the device has a lifetime of at least three years raised the following additional comments/questions about the results:

1. According to the definition of Mean Time Between Failures (MTBF), an MTBF of 19.2 years implies that, on average, the time between failures within the tested group is 19.2 years. However, MTBF alone doesn't indicate the device's service life. How was it determined that the device can endure repeated use for at least 3 years?
2. The sample size for the testing appears to be for one pulse generator. What is the rationale for the small sample size?
3. The report does not appear to include durability testing information related to the housing components of the device and seems to primarily include components of the circuit board. What was the testing criteria for the device housing?

### **Preliminary Medicare Payment Determination**

No determination.

**Agenda Item # 1**  
**Sparrow Ascent® Earpiece Kit - HCP231201AU2B3**

**Topic/Issue**

Request to establish a new HCPCS Level II code to identify Sparrow Ascent® Earpiece Kit.

Applicant's suggested language: XXXXX, “Four week supply for use of device coded at XXXXX”

**Summary of Applicant's Submission**

Spark Biomedical submitted a request to establish a new HCPCS Level II code to identify the Sparrow Ascent® Earpiece Kit. The Sparrow Ascent® is a wearable neurostimulation stimulator system which consists of a patient controller (a battery-operated neurostimulation pulse generator) that connects to a cable that connects to a disposable earpiece. The patient controller and cable combination are the durable components of this device. It is the external pulse generator that initiates the electrical pulses, which is the medically necessary function of the Sparrow Ascent® and allows the device to provide its neurostimulation therapy. The Sparrow Ascent Earpiece is a component necessary for the effective use of the Sparrow Ascent neurostimulation pulse generator. The earpiece is an ergonomically designed, wearable stimulation interface designed to be worn around the left or right (user’s choice) ear for up to 24 hours. Both the outer and inner parts are designed to be flexible and adjustable to fit various sized ears. The disposable earpiece is designed to stay adhered to the skin and provide electrical connectivity for up to 24 hours. The earpiece can be self-applied, positioning the electrodes to stimulate three key dermatome regions. The electrodes are located on the cymba concha, on the temporomandibular joint region, just anterior to the tragus, and behind the auricle. Sparrow Ascent® earpieces are daily disposable and should be changed out every 24 hours. Earpieces are not intended to be cleaned or reused. The Sparrow Ascent® Left Earpiece Kit and Right Earpiece Kit are separate earpiece kits for replacement or longer-term use if additional treatment is prescribed. Each kit contains 28 disposable left or right earpieces and 28 alcohol wipes.

**CMS Preliminary HCPCS Coding Recommendation**

Establish a new HCPCS Level II code AXXXX, “Supplies for transcutaneous electrical nerve stimulator, for nerves in the auricular region, per month” to describe the Sparrow Ascent® supplies.

**Preliminary Medicare Benefit Category Determination**

No determination.

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. Our initial review found that the Sparrow Ascent® System may not meet these conditions as follows:

**Expected life of at least 3 years** – As stated in the application, the Sparrow Ascent® patient controller and cable have a service life of three years from the date of manufacture. However, supporting materials in the application mention a service life of two years from the date of manufacture. DME is a benefit for rental of equipment and the three-year minimum lifetime requirement is intended to specify that durable equipment is equipment that can withstand repeated use over an extended period of time. The three-year minimum lifetime requirement represents a minimum threshold for a determination of durability and is calculated based upon the date of use as opposed to manufacture date or when the equipment is sold to a supplier. For this reason, our initial review found the Sparrow Ascent® may not meet the required expected life of at least three years. While we received some additional clarification from the applicant during our initial review process, our review of the lifetime durability testing presented by the applicant in support that the device has a lifetime of at least three years raised the following additional comments/questions about the results:

1. According to the definition of Mean Time Between Failure (MTBF), an MTBF of 19.2 years implies that, on average, the time between failures within the tested group is 19.2 years. However, MTBF alone doesn't indicate the device's service life. How was it determined that the device could endure repeated use for at least 3 years?
2. The sample size for the testing appears to be for one pulse generator. What is the rationale for the small sample size?
3. The report does not appear to include durability testing information related to the housing components of the device and seems to primarily include components of the circuit board. What was the testing criteria for the device housing?

### **Preliminary Medicare Payment Determination**

No determination.

**Agenda Item # 2**  
**iCare HOME2 Tonometer - HCP2312208153N**

**Topic/Issue**

Request to establish a new HCPCS Level II code to identify iCare HOME2 Tonometer.

Applicant's suggested language: XXXXX, "Tonometer, rebound, handheld"

**Summary of Applicant's Submission**

iCare Finland Oy submitted a request to establish a new HCPCS Level II code to identify iCare HOME2 Tonometer. The iCare HOME2 Tonometer received the Food and Drug Administration's (FDA's) 510(k) clearance on January 25, 2022. The iCare HOME2 Tonometer is a handheld, battery-operated device that measures intraocular pressure (IOP) in the patient's home using the rebound method and that does not require topical anesthesia. IOP is one of the main risk factors for the development and progression of glaucoma and the only modifiable risk factor. Studies have demonstrated that more rapid progressors for glaucomatous damage are those with greater IOP spikes and that not only IOP spikes but also IOP fluctuations are independent risk factors for progression to vision loss (Cvenkel et al. 2019, Asrani et al. 2000, Gao et al. 2011, Kim et al. 2018, Musch et al. 2009). Numerous publications have also demonstrated that these IOP spikes and fluctuations cannot be adequately measured through single point-in-time measurements in the physician office (Kratz et al. 2023, McGlumphy et al. 2021, Kim et al. 2018, Levin et al. 2022). Studies show that up to two-thirds of patients with glaucoma have IOP spikes and IOP fluctuations outside of office hours, however these spikes and fluctuations can be captured with remote patient monitoring using the iCare HOME2 Tonometer (Barkana et al. 2006, Nakakura et al. 2006, McGlumphy et al. 2021, Cvenkel et al. 2019). The iCare HOME2 Tonometer can measure IOP outside of the physician's office and office hours, thereby enabling the physician to assess real-world IOP spikes and fluctuations over a 24-hour period for several days to weeks, as required to inform clinical decision making. With the iCare HOME2 Tonometer being used by patients suspected to have glaucoma as well as by patients with known glaucoma, IOP measurements can now be taken at home at various times of the day and night and used to better identify these IOP risk factors that will impact care and treatment management. These data provide the patient's physician with critical IOP information that can result in a more appropriate glaucoma treatment plan (Liu et al. 2020, Levin et al. 2022). Studies have shown that home monitoring of IOP resulted in glaucoma treatment changes for over 50% of patients (Sood et al. 2016, Hughes et al. 2003, Levin et al. 2022). Additionally, gathering nyctohemeral IOP information with the iCare HOME2 Tonometer may be useful to set a baseline measurement of the patient's IOP, when choosing a suitable medication, pre-surgery to determine the preferred surgical timing and approach, post-surgery to confirm the ongoing effectiveness of the surgery, and with sustained-release implants to assess when they are losing efficacy (Liu et al. 2020, Levin et al. 2022, Rojas et al. 2020, Awadalla et al. 2019).

**CMS Preliminary HCPCS Coding Recommendation**

The iCare HOME2 Tonometer can measure IOP outside of the physician's office and office hours, thereby enabling the physician to assess real-world IOP spikes and fluctuations over a 24-hour period for several days to weeks, as required to inform clinical decision making. Our

understanding is that iCare HOME2 Tonometer is intended as an adjunct to the routine clinical monitoring of IOP. We have not identified a specific need for this iCare HOME2 Tonometer 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 # 2**  
**iCare HOME2 Tonometer Probe - HCP231220WWK6M**

**Topic/Issue**

Request to establish a new HCPCS Level II code to identify iCare HOME2 Tonometer Probe.

Applicant's suggested language: XXXXX, "Single-use probe for use with handheld tonometer device, each"

**Summary of Applicant's Submission**

iCare Finland Oy submitted a request to establish a new HCPCS Level II code to identify iCare HOME2 Tonometer Probe. The iCare HOME2 Tonometer Probe received the Food and Drug Administration's (FDA's) 510(k) clearance on March 21, 2017. The iCare HOME2 Tonometer Probe is used to self-measure intraocular pressure (IOP) in the home with the iCare HOME2 Tonometer (a separate HCPCS Level II code application has been submitted above). The iCare HOME2 Tonometer requires the use of the Tonometer Probe. The iCare HOME2 Tonometer is a handheld, battery-operated device that measures intraocular pressure (IOP) in the patient's home using the rebound method and that does not require topical anesthesia. Measurements for a typical patient suspected of having glaucoma or diagnosed with glaucoma are performed 4-6 times a day for approximately 1-2 weeks, as per current clinical guidelines for IOP measurement for patients suspected of having glaucoma and patients with glaucoma. Each IOP measurement requires the use of one single-use probe. IOP is one of the main risk factors for the development and progression of glaucoma and the only modifiable risk factor. The iCare HOME2 Tonometer can measure IOP outside of the physician's office and office hours, thereby enabling the physician to assess real-world IOP spikes and fluctuations over a 24-hour period for several days to weeks, as required to inform clinical decision making. With the iCare HOME2 Tonometer being used by patients suspected to have glaucoma as well as by patients with known glaucoma, IOP measurements can now be taken at home at various times of the day and night and used to better identify these IOP risk factors that will impact treatments, care and management. These data provide the patient's physician with critical IOP information that can result in a more appropriate glaucoma treatment plan (Liu et al. 2020, Levin et al. 2022). Studies have shown that home monitoring of IOP resulted in glaucoma treatment changes for over 50% of patients (Sood et al. 2016, Hughes et al. 2003, Levin et al. 2022). Additionally, gathering nyctohemeral IOP information with the iCare HOME2 Tonometer may be useful to set a baseline measurement of the patient's IOP, when choosing a suitable medication, pre-surgery to determine the preferred surgical timing and approach, post-surgery to confirm the ongoing effectiveness of the surgery, and with sustained-release implants to assess when they are losing efficacy (Liu et al. 2020, Levin et al. 2022, Rojas et al. 2020, Awadalla et al. 2019).

**CMS Preliminary HCPCS Coding Recommendation**

The iCare HOME2 Tonometer can measure IOP outside of the physician's office and office hours, thereby enabling the physician to assess real-world IOP spikes and fluctuations over a 24-hour period for several days to weeks, as required to inform clinical decision making. Our understanding is that iCare HOME2 Tonometer is intended as an adjunct to the routine clinical monitoring of IOP. We have not identified a specific need for this iCare HOME2 Tonometer Probe 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 # 3**  
**MysteryVibe Crescendo 2 - HCP231231B8WQX**

**Topic/Issue**

Request to establish a new HCPCS Level II code to identify MysteryVibe Crescendo 2.

Applicant's suggested language: XXXXX, "Pelvic floor genital vibrator, a non-implantable, adjustable stimulator"

**Summary of Applicant's Submission**

MysteryVibe LLC submitted a request to establish a new HCPCS Level II code to identify MysteryVibe Crescendo 2. MysteryVibe Crescendo 2 is a class II device, exempt from the premarket notification procedures by the Food and Drug Administration (FDA). Crescendo 2 is a non-implantable, pelvic floor genital vibrator, and adjustable stimulator. The Crescendo 2 is a handheld rechargeable device intended to control and relax the pelvic muscles to treat pelvic pain. MysteryVibe Crescendo 2 has customizable frequency, waveform, and intensity. Chronic pelvic pain (CPP) is persistent pain in the pelvic area lasting 3-6 months or longer. Pain may be constant, dull, sharp, or cramping, accompanied by pressure or heaviness in the pelvis. CPP can range from mild to severe and can impact work, sleep, or exercise. Symptoms may include frequent urination, bloating, upset stomach, and bowel issues. The Crescendo 2 device fulfills the flexible spending account (FSA) and Health Reimbursement Arrangement (HRA) compliance standards of a 90% rule. MysteryVibe LLC accepts FSA/HRA payments for qualified prescriptions or eligible healthcare items. Currently, 98% of Crescendo's sales are based on recommendations and prescriptions from obstetricians and gynecologists, pelvic floor therapists, and urologists. The patient brings the device and their physical therapist trains them on how to use it.

**CMS Preliminary HCPCS Coding Recommendation**

CMS has not identified a program operating need for Medicare or other payers to establish a unique HCPCS Level II code to describe a pelvic floor genital vibrator to treat pelvic pain. We would like to understand how the MysteryVibe Crescendo 2 device achieves medical outcomes. It is evident from the manufacturer's website<sup>1</sup> that this device has a broad range of uses for other indications, including "all-time best sex toy, and boost your sex life." Also, this device is advertised for solving arousal, pain, and dryness issues. 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 to describe the MysteryVibe Crescendo 2.

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<sup>1</sup> <https://mysteryvibe.com/>

**Agenda Item # 4**  
**myPTM™, Personal Therapy Manager - HCP231221EK8Q5**

**Topic/Issue**

Request to establish a new HCPCS Level II code to identify myPTM™, Personal Therapy Manager.

Applicant's suggested language: XXXXX, "Patient programmer (external) for use with implantable programmable infusion pump, replacement only"

**Summary of Applicant's Submission**

Medtronic submitted a request to establish a new HCPCS Level II code to identify myPTM™, Personal Therapy Manager. myPTM™ was approved by the Food and Drug Administration (FDA) under a premarket approval on July 31, 2018. The myPTM™ is intended for use with the SynchroMed™ II infusion pump. The SynchroMed™ II is prescribed for a patient with intractable chronic pain, including cancer-related pain. Unlike oral pain medications that must be absorbed systemically, intrathecal drug delivery system (IDDS) delivers physician-prescribed doses of medication directly to the intrathecal space (a fluid-filled area in the spinal column through which pain signals travel). Intrathecal drug delivery enables patients to experience pain relief using a fraction of an oral medication dose, which can minimize the side effects and dependency based on pain medication taken orally. The myPTM™ components are prescribed by physicians as an option to the IDDS system. The prescribing clinician determines whether a patient receives a myPTM™ to optimize their therapy. myPTM™ allows a patient to activate delivery of physician-programmed supplemental doses of medication when experiencing pain not adequately managed by the pre-specified pump flow rate (i.e., dosage, usually in micrograms per day). The myPTM™ Personal Therapy Manager system includes the handset, communicator, and myPTM™ app. myPTM™ uses an icon-based touch-screen interface and on-screen graphics and audible tones that direct patient interaction. When the activator button on the handset is pressed by the patient, a message is sent by telemetry via the communicator to the implanted pump which releases a preprogrammed dose of drug. Given the average lifetime of an IDDS implant is typically longer than the myPTM™ reasonable useful life of approximately five years, many patients will require replacements of the myPTM™ over the lifetime of the IDDS implant.

**CMS Preliminary HCPCS Coding Recommendation**

Due to the relatively low volume of implanted intrathecal drug delivery systems, CMS believes the rare instance of needing a replacement system for external parts does not require a unique HCPCS Level II code. As such, existing code HCPCS Level II code A9999, "Miscellaneous dme supply or accessory, not otherwise specified," can be utilized for the myPTM™.

**Preliminary Medicare Benefit Category Determination**

The benefit category determination for claims submitted using HCPCS Level II code A9999 are made by the A/B Medicare Administrative Contractors (MACs) on an individual, claim-by-claim basis.

### **Preliminary Medicare Payment Determination**

The payment determination for claims submitted using HCPCS Level II code A9999 are made by the A/B MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

**Agenda Item # 5**  
**InTandem - HCP231229HB5QU**

**Topic/Issue**

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

Applicant's suggested language: EXXXX, "Gait modulation system, rhythmic auditory stimulation, closed loop, including all components and accessories"

**Summary of Applicant's Submission**

MedRhythms Inc. submitted a request to establish a new HCPCS Level II code to identify InTandem. InTandem is a class II device, exempt from the premarket notification procedures by the Food and Drug Administration (FDA). InTandem delivers rhythmic auditory stimulation (RAS), using real-time gait data from shoe-worn sensors, a durable control unit containing proprietary RAS based treatment algorithms in a closed-loop system to unconsciously improve gait quality and speed in patients with stroke-related gait impairments. RAS targets automatic processes in the brainstem, cerebellum, and spinal cord to induce auditory motor entrainment (the unconscious synchronization of the auditory and motor systems). InTandem is intended for patients who are six months or more post stroke event for gait impairment, specifically, slow walking speed, asymmetry, and effortful gait. In clinical literature, these factors are associated with fall risk, reduced ability to perform ambulation-related activities of daily living, and long-term health outcomes, including frequent hospitalizations and mortality. InTandem is typically used three times per week for 30 minutes each session. InTandem consists of three components: the shoe-worn sensors, a durable control unit preloaded RAS software with a locked music library, and a bone-conduction headset. The sensors collect baseline information about the patient's gait, which is processed by the control unit with the proprietary RAS based treatment algorithms to automatically adjust the music-based rhythmic cues in real time, per the RAS protocol. Depending on patient response, the control unit may overlay a synchronized rhythm track to engage the auditory-motor response more strongly or slow the tempo. When auditory-motor entrainment is reestablished with sufficient quality of gait, the control unit will automatically detect and increase the tempo. InTandem is a prescription only medical device.

**CMS Preliminary HCPCS Coding Recommendation**

The applicant included a letter from Point32Health to support the request for a HCPCS Level II code. CMS acknowledges the letter from Point32Health; however, there is no indication of a program need and no evidence of a need from other insurers for a HCPCS Level II code. We would like to understand how InTandem is a class II device, exempt from the premarket notification procedures by the FDA, but indicated in the application summary as "InTandem is the only FDA authorized medical device that delivers Rhythmic Auditory Stimulation in the home setting." CMS has the following questions for the applicant:

1. Could a patient use the auditory aspect without the clip attachment?
2. The applicant indicated that there are differences between InTandem music list and a commercial playlist. The studies provided compared InTandem to an active control, described as walking practice supervised by clinical investigators. Essentially, this

comparison was between no music and music. Are there any studies demonstrating how these differences contribute to treatment efficacy?

3. It seems that rhythmic auditory stimulation (RAS) methods, using only a metronome without music, may have similar effectiveness in gait training compared to this device. Therefore, the added significance of incorporating music does not appear to demonstrate greater efficacy in improving gait. Explain how InTandem differs from metronome for gait rehabilitation in patients post-stroke.
4. We would like to understand the distinctiveness of the music therapy for patients with a stroke compared to other types of music therapies for different diagnoses.
5. Are there other uses for the product besides this therapy? For instance, could it be used by patients that did not experience a stroke?

**Agenda Item # 6**  
**IpsiHand™ Upper Extremity Rehabilitation System - HCP230701PDW27**

**Topic/Issue**

Request for Medicare payment determination for IpsiHand™ Upper Extremity Rehabilitation System.

**Summary of Applicant's Submission**

Neuroolutions Inc. submitted a request to establish a new HCPCS Level II code to identify Neuroolutions IpsiHand™ Upper Extremity Rehabilitation System (IpsiHand™). IpsiHand™ received the Food and Drug Administration's (FDA's) De Novo clearance on April 23, 2021. Neuroolutions began marketing IpsiHand™ in 2022 and first sales of the IpsiHand™ were completed in early 2023. IpsiHand™ is the first and only brain-computer interface (BCI) controlled therapy to be awarded an FDA market authorization. IpsiHand™ is a class II medical device, available by prescription only, that consists of a biometric electroencephalogram (EEG) headset, a powered upper extremity range of motion assist device, and a microprocessor control unit containing therapy software. IpsiHand™ allows for delivery of thought-actuated therapy for chronic upper extremity disability in patients with strokes. IpsiHand™ is indicated for use in patients with chronic strokes (6 months or more post-stroke) who are 18 years or older, undergoing stroke rehabilitation to facilitate muscle re-education and for maintaining or increasing range of motion in the upper extremities. The device is locked, which means that it can only be used for treatment of the specified clinical indication by the patient. IpsiHand™ promotes Hebbian learning, a process of tightly coupling motor intent brain signals with hand sensory feedback to induce synaptic plasticity and remodel the brain. A patient is prompted to visualize hand movements; the system detects their intention to move non-invasively using the EEG and instructs the handpiece to complete the intended motion. Handpiece-actuated motion is synchronized with the proprioceptive sensory feedback felt by the patient. The therapeutic effect is accomplished by the patient completing therapy modules where they repeatedly visualize moving their affected hand and the system completes the desired motion. IpsiHand™ is self-administered in the patient's home in one-hour modules for five days per week. Patients who completed 12-weeks of therapy showed an average increase of 7.7 points on the Upper Extremity Fugl-Meyer assessment. It is important to note that the functional gains that are achieved using IpsiHand™ are maintained beyond the completion of therapy. The overall required duration of therapy varies from patient to patient, depending on the severity of the initial impairment. Therapy with IpsiHand™ should continue until functional gains in the upper extremity have plateaued which may take years to achieve. The therapy is not delivered as part of a clinician service.

**CMS HCPCS Coding Determination**

CMS established HCPCS Level II code E0738, "Upper extremity rehabilitation system providing active assistance to facilitate muscle re-education, include microprocessor, all components and accessories" to describe IpsiHand™ Upper Extremity Rehabilitation System, effective April 1, 2024.

**Medicare Benefit Category Determination**

CMS determined that IpsiHand™ is Durable Medical Equipment, effective April 1, 2024.



## Preliminary Medicare Payment Determination

In accordance with Medicare regulations at 42 CFR § 414.238, fee schedule amounts for new HCPCS Level II 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.

CMS has identified two HCPCS Level II codes to compare against the IpsiHand™ Upper Extremity Rehabilitation System as shown in the below comparability table. HCPCS Level II codes L8702 ("Powered upper extremity range of motion assist device, elbow, wrist, hand, finger, single or double upright(s), includes microprocessor, sensors, all components and accessories, custom fabricated") and L8701 ("Powered upper extremity range of motion assist device, elbow, wrist, hand with single or double upright(s), includes microprocessor, sensors, all components and accessories, custom fabricated") describe custom-fitted powered myoelectric elbow-wrist-hand braces designed to assist upper extremity joint motion in a weakened body member to improve the user's functional activities of daily living. Subtracting HCPCS Level II code L8701 from HCPCS Level II code L8702 would isolate for payment purposes just the portion of HCPCS Level II code L8702 that provides the motor activated hand grasp which we compared against the IpsiHand™ handpiece. Our analysis strove to compare the IpsiHand™ handpiece against the three-jaw chuck grasp mechanism found in devices described by HCPCS Level II code L8702 where the thumb opposes both the middle and index fingers. We did not identify any other codes that would describe other parts of the IpsiHand™ system or find the two L codes comparable with respect to their physical, electrical and mechanical components and intended use.

	<b>E8702-8701</b>	<b>Ipsi™ Handpiece</b>
<b>Physical Components</b>	E8702 (elbow -wrist-hand-finger device): Single Uprights, Straps, Cuffs  E8701(elbow-wrist-hand device): Single Uprights, Straps, Cuffs	Arm-Wrist-hand-finger device: Straps, Loops
<b>Mechanical Components</b>	E8702: Joints (fixed or variable motion), finger grasp  E8701: Joints (fixed or variable motions)	Joints: Robotic Fixed, finger grasp
<b>Electrical Components</b>	E8702: Battery Powered, Joint Motors, Microprocessor, EMG (electromyography) Sensors, Cables  E8701: Battery Powered, Joint Motors, Microprocessor, Sensors, Cables	Battery powered, Microcontroller, EEG (electroencephalographic) Sensors
<b>Function and Intended Use</b>	E8702: Elbow-wrist-hand device with 3-jaw chuck grasping function and finger closing capability.	Arm-Elbow-hand- finger device with 3-finger pincer grip mechanism with one degree of freedom.

	<b>E8702-8701</b>	<b>Ipsi™ Handpiece</b>
	E8701: Elbow-wrist- hand device with 3-jaw chuck grasping function.  E8701 and E8702: To enable a patient to initiate and control movement of a partially paralyzed arm using the patient's own muscle signals to manage daily tasks.	To facilitate muscle re-education and maintaining or increasing the range of motion in the upper extremities in chronic stroke patients (>6 months post-stroke) undergoing stroke rehabilitation
<b>Additional Aspects and Features</b>	Device is used as a supportive and assistive device in everyday tasks.	Three modes: Brain Computer Interface (BCI) or ‘thought’ mode; the Volitional mode; the Continuous Passive Motion (CPM)  Therapy provided in one-hour modules completed five days per week

As described above, while some aspects of the IpsiHand™ handpiece may be similar, we did not find the difference between HCPCS Level II codes L8702 and L8701 to be comparable nor did we find existing codes that capture the complete, overall function of the IpsiHand™ Upper Extremity Rehabilitation System. For example, we could not identify existing codes that would account for the EEG electrodes found on the IpsiHand™ headset. Since we were unable to identify codes that adequately compare to the features of the IpsiHand™ system, we have determined that the gap-filling methodology is appropriate for establishing fees for this code.

To gap-fill the fee schedule amount for HCPCS Level II code E0738, we used commercial pricing for the IpsiHand™ Upper Extremity Rehabilitation System from the Federal Supply Schedule of \$30,000. The annual deflation factors are specified in program instructions and the deflated amounts are then increased by the update factors specified in section 1834(a)(14) of the Act for DME. The 2024 average non-rural capped rental fee schedule amount for HCPCS Level II code E0738 would be approximately \$1,952.78 for months 1 through 3 and approximately \$1,464.59 for months 4 through 13 for a total of \$20,504.24 after 13 months of continuous use.

Pricing Indicator = 36

**Agenda Item # 7**  
**Motus Hand and Motus Foot - HCP230314K8EQG**

**Topic/Issue**

Request for Medicare payment determination for Motus Hand and Motus Foot.

**Summary of Applicant's Submission**

Motus Nova submitted a request to establish a new HCPCS Level II code to identify the Motus Hand and the Motus Foot. The Motus Hand and the Motus Foot are exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The Motus Hand and Foot are devices comprised of a robotic exoskeleton and a dedicated computer with interactive interface to provide biofeedback on a patient's performance. The Motus devices are for individuals who experienced a stroke to use at home or in the clinic; they guide patients through therapeutic activities, provide intuitive robotic assistance to augment weakness, thereby helping patients engage in high-dose repetitive task practice, and generate personalized statistics. They are for non-invasive, external use only and are intended to assist patients with engaging in rehabilitative exercises.

**CMS Preliminary/Final HCPCS Coding Determination**

CMS established a new HCPCS Level II code E0739, "Rehab system with interactive interface providing active assistance in rehabilitation therapy, includes all components and accessories, motors, microprocessors, sensors" to describe Motus Hand and the Motus Foot, effective April 1, 2024. Within the HCPCS Level II code set, "rehab" is spelled out to read "rehabilitation." As such, we recommend to:

Revise existing HCPCS Level II code E0739, "Rehab system with interactive interface providing active assistance in rehabilitation therapy, includes all components and accessories, motors, microprocessors, sensors" to instead read "Rehabilitation system with interactive interface providing active assistance in rehabilitation therapy, includes all components and accessories, motors, microprocessors, sensors" to describe Motus Hand and the Motus Foot.

**Medicare Benefit Category Determination**

CMS determined that the Motus Hand and Motus Foot are Durable Medical Equipment, effective April 1, 2024.

**Preliminary Medicare Payment Determination**

In accordance with Medicare regulations at 42 CFR § 414.238, fee schedule amounts for new HCPCS Level II 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. CMS identified the following HCPCS Level II codes to describe the Motus Hand and the Motus Foot: E1806 ("Static progressive stretch wrist device, flexion and/or extension, with or without range of motion adjustment, includes all components and accessories"), E1816

("Static progressive stretch ankle device, flexion and/or extension, with or without range of motion adjustment, includes all components and accessories"), E0650 ("Pneumatic compressor, non-segmental home model") and E0655 ("Non-segmental pneumatic appliance for use with pneumatic compressor, half arm").

The four HCPCS Level II codes were compared to the Motus Hand and Foot as shown in the below comparability table. The Motus Hand and Foot are devices comprised of either a hand or foot controller and a touchscreen power source with interactive interface for providing biofeedback on a patient’s performance. HCPCS Level II codes E1806 and E1816 describe the Motus Hand and Foot controllers, respectively, as they are also mechanical devices that assist with flexion, extension, dorsiflexion and plantarflexion. The HCPCS Level II code E0655, describing a pneumatic bladder, represents the Motus controller's pneumatic actuator and the pneumatic compressor. HCPCS Level II code E0650 describes the Motus pneumatic pump. We did not identify any other codes that would describe other components of the Motus Hand or the Motus Foot for comparison.

	<b>E0650</b>	<b>E1806/E1816</b>	<b>E0655</b>	<b>Motus Hand and Motus Foot</b>
<b>Physical Components</b>	Pump or Control Unit  Wraps	Cuffs  Straps  Pads	Pump  Arm Wraps/Sleeves  Straps/Harness  Zippers	A Locked Touch Screen console  Pump  Hand or Foot Controller  Actuator
<b>Mechanical Components</b>	Pneumatic Pump	Wrist/Ankle Mechanical Joints	Pneumatic Pump  Segmental or Sequential Gradient Pressure  Non-Peristaltic	Pneumatic Pump  Pneumatic Actuator
<b>Electrical Components</b>	Battery			Processors  Bio-feedback Sensors
<b>Function and Intended Use</b>	To provide timed periods of pressurized air to the affected area through a Single Outflow Port	To provide static stretching with stress relaxation to elongate contracted tissue  Designed for the prevention and treatment of joint contractures with	To provide gradient sequential or segmental gradient compression  Designed for the treatment of chronic venous	To deploy pneumatic artificial muscles for simulating dorsal muscle contraction and relaxation  Designed for patients who have

	<b>E0650</b>	<b>E1806/E1816</b>	<b>E0655</b>	<b>Motus Hand and Motus Foot</b>
	Designed for the treatment of lymphedema or Chronic Venous Insufficiency with venous stasis ulcers	the goal to maintain or restore range of motion.	stasis ulcers and venous insufficiency	had strokes or conditions that lead to upper limb movement disorders including but not limited to: muscle tightness (tone), spasticity, weakness, or motor control deficits
<b>Additional Aspects and Features</b>	Pressure range 30-90 mm/Hg  Used by successive patients	Foam liner can be used.  Bidirectional to be used in flexion/extension (for wrist braces) and dorsiflexion/plantarflexion (for ankle braces)  Used by successive patients	Pressure range 20-80 mm/Hg  Used by Single patients	Portable  Used by successive patients.

While some aspects of the Motus Hand and Motus Foot may be similar to existing HCPCS Level II codes, we did not find codes that would describe the complete overall function of the Motus Hand and Foot devices. Since we were unable to identify codes that adequately compare to the features of the Motus Hand and Motus Foot, we have determined that the gap-filling methodology is appropriate for establishing fees for this code.

To gap-fill the fee schedule amount for HCPCS Level II code E0739, we used commercial pricing that averaged to \$15,000 for the Motus Hand and the Motus Foot. The annual deflation factors as specified in program instructions were applied and the deflated amounts are then increased by the update factors specified in section 1834(a)(14) of the Act for DME. The 2024 average non-rural capped rental fee schedule amount for HCPCS Level II code E0739 would be approximately \$1,099.71 for months 1 through 3 and approximately \$2,824.78 for months 4 through 13 for a total of \$11,546.93 after 13 months of continuous use.

Pricing Indicator = 36

**Agenda Item # 8**  
**Vivally® System, Hardware Control Unit - HCP240102XXG03**

**Topic/Issue**

Request to establish a new HCPCS Level II codes to identify the durable controller kit component of the Vivally® System with a hardware control unit.

Applicant's suggested language: EXXXX, “Transcutaneous tibial nerve stimulator with EMG-sensing, closed-loop operation, for urinary control, controlled by hardware control unit”

**Summary of Applicant's Submission**

Avation Medical submitted a request to establish a new HCPCS Level II code to identify the Vivally® System with hardware control unit. The Vivally® System received the Food and Drug Administration’s (FDA’s) 510(k) clearance on April 3, 2023. The Vivally® System is a wearable neuromodulation system for home use to treat patients with urge urinary incontinence and urinary urgency caused by overactive bladder syndrome. Using proprietary algorithms and electromyographical (EMG) sensors, the Vivally® System detects the level of energy being delivered to the tibial nerve during stimulation, enabling the System to evaluate the level of tibial nerve activation and autonomously adjust stimulation parameters to ensure optimal therapeutic output in a true real-time, closed-loop operation. The Vivally® System is supplied in two configurations: the Vivally® System with hardware control unit, which uses a dedicated device to initiate therapy sessions; and the Vivally® System (without hardware control unit), which uses an app on the patient’s smartphone to initiate sessions. The Vivally® System with hardware control unit is comprised of a controller kit, including a rechargeable smart controller (stimulator) with proprietary closed-loop control algorithms, charging accessories, and a hardware control unit (a dedicated device with software to use the Vivally® System); a reusable garment with embedded stimulation and EMG-sensing electrodes; and reusable gel cushions. Vivally® System is prescribed by a clinician following a clinical evaluation, which includes a personalized calibration service performed by the physician using a physician Vivally® System kit designed for in-office personalization of the Vivally® therapy. Personalization establishes an EMG target and range of neuromodulation energy. The lower limit is associated with the detection of an EMG signal to indicate nerve activation, and the upper limit ensures that therapy is comfortable. The Vivally® Patient Kit is delivered to the patient’s home. Vivally® System is used by the patient at home for 30 minutes each therapy session, as prescribed. The controller provides electrical stimulation through two transmission electrodes embedded in the garment. The controller also measures the EMG signal from the patient’s foot via three additional EMG sensing electrodes embedded on the garment. During therapy, the Vivally® System automatically adjusts the stimulation output to achieve the EMG target value. This closed loop feature ensures a consistent therapeutic delivery to the patient, enhancing the usability and effectiveness of the stimulation.

**CMS Preliminary HCPCS Coding Recommendation**

Existing HCPCS Level II code E0736, “Transcutaneous tibial nerve stimulator” describes the controller kit component of the Vivally® System with hardware control unit.

## **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. During the benefit category determination process for multi-component devices, CMS has a longstanding policy of first determining which specific component provides the medically necessary function of rendering direct treatment (CMS-1577-F, November 10, 2011). 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 non-durable, even if other components of that device are durable. The Vivally® System components consist of a Controller, a Garment, and Gel cushions. According to the applicant, the Controller provides electrical stimulation through two transmission electrodes embedded in the Garment. The Controller also measures the EMG signal from the patient's foot via three additional EMG sensing electrodes embedded in the Garment. Of the three components, the Controller component is the sole component that provides a medically necessary function because it is the component that initiates the therapy session. The Controller meets all five of the conditions that must be met in order for equipment to be classified as DME.

### **Preliminary Medicare Payment Determination**

In accordance with regulations at § 414.238(b), fee schedule amounts for new HCPCS Level II 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. If there are no items with existing fee schedule amounts that are comparable to the items and services under the new code, the fee schedule amounts for the new code are established in accordance with paragraph (c) of this section.

We undertook a comparability analysis and have determined that the Vivally® Hardware Controller is comparable to HCPCS Level II code E0720. We provide the below comparability analysis that details our comparison of the two codes.

	<b>E0720</b>	<b>Vivally® Hardware Controller</b>
<b>Physical Components</b>	Control Unit	Control Unit
<b>Mechanical Components</b>	-	-
<b>Electrical Components</b>	Rechargeable Battery Biphasic waveforms	Battery Biphasic waveforms
<b>Function and Intended Use</b>	Nerve stimulation through transcutaneous electrical stimulation of the tibial nerve or pelvic floor function  To treat patients with the conditions of urinary urgency and incontinence.	Nerve stimulation through transcutaneous electrical stimulation of peripheral nerves  To treat patients with acute and chronic injuries and pain
<b>Additional Aspects and Features</b>	Fixed pulse frequency of 20 Hz	Low frequency usually below 300HZ

CMS recognizes the new indications through our preliminary valuation to compare the technology to HCPCS Level II code E0720 devices prior to competitive bidding, when devices to treat a range of conditions like insomnia, depression, anxiety, pain, and in this case, urinary incontinence, were not available to suppliers engaging in the competitive bidding program. As such, CMS would establish the fees for HCPCS Level II code E0736 using fees for HCPCS Level II code E0720 that were not adjusted using information from the DMEPOS Competitive Bidding Program.

Based on this preliminary determination, the average 2024 fee schedule amount for HCPCS Level II code E0736 would be based on the unadjusted purchase fee schedule amounts for HCPCS Level II code E0720 of approximately \$477.98 on average. Since the purchase price for this item are more than \$150, payment for this device would be made on a capped rental basis in accordance with 42 CFR §414.229, with the capped rental fee schedule amounts for months 1 through 3 based on 10 percent of the purchase price or approximately \$47.80 on average. The capped rental fee schedule amounts for months 4 through 13 based on 7.5 percent of the purchase price or approximately \$35.85 on average. Total payments after 13 months would be approximately \$501.88 on average.

Pricing Indicator = 36



## **Agenda Item # 8**

### **Vivally® System, Controlled by a Smartphone Application - HCP2401027WJEG**

#### **Topic/Issue**

Request to establish a new HCPCS Level II code to identify the Vivally® System that is controlled by a smartphone application.

Applicant's suggested language: EXXXX, "Transcutaneous tibial nerve stimulator with EMG-sensing, closed-loop operation, for urinary control, controlled by phone application"

#### **Summary of Applicant's Submission**

Avation Medical submitted a request to establish a new HCPCS Level II code to identify the Vivally® System (without hardware control unit), which uses a smartphone application on the patient's own device to initiate and manage therapy. The Vivally® System received the Food and Drug Administration's (FDA's) 510(k) clearance on April 3, 2023. The Vivally® System is a wearable neuromodulation system for home use to treat patients with urge urinary incontinence and urinary urgency caused by overactive bladder syndrome. Using proprietary algorithms and electromyographical (EMG) sensors, the Vivally® System detects the level of energy being delivered to the tibial nerve during stimulation, enabling the System to evaluate the level of tibial nerve activation and autonomously adjust stimulation parameters to ensure optimal therapeutic output in a true real-time, closed-loop operation. The Vivally® System is supplied in two configurations: the Vivally® System with hardware control unit, which uses a dedicated device to initiate therapy sessions; and the Vivally® System (without hardware control unit), which uses an app on the patient's smartphone to initiate sessions. The Vivally® System is comprised of a controller kit, including a rechargeable smart controller (stimulator) with proprietary closed-loop control algorithms, charging accessories, and access to a software application to initiate and manage therapy sessions with the Vivally® System; a reusable garment with embedded stimulation and EMG-sensing electrodes; and reusable gel cushions. Vivally® System is prescribed by a clinician following a clinical evaluation, which includes a personalized calibration service performed by the physician using a physician Vivally® System kit designed for in-office personalization of the Vivally® therapy. Personalization establishes an EMG target and range of neuromodulation energy. The lower limit is associated with the detection of an EMG signal to indicate nerve activation, and the upper limit ensures that therapy is comfortable. Vivally® is used by the patient at home for 30 minutes each therapy session, as prescribed. The Controller provides electrical stimulation through two transmission electrodes embedded in the garment. The controller also measures the EMG signal from the patient's foot via three additional EMG sensing electrodes embedded on the garment. During therapy, the Vivally® System automatically adjusts the stimulation output to achieve the EMG target value. This closed loop feature ensures a consistent therapeutic delivery to the patient, enhancing the usability and effectiveness of the stimulation.

#### **CMS Preliminary HCPCS Coding Recommendation**

CMS has not identified a program operating need to establish a unique HCPCS Level II code to describe the Vivally® System configuration controlled by smartphone application. CMS' determination is based on the device characteristics presented for review that rely on a smartphone. 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 to describe the Vivally® System configuration controlled by the smartphone application.

**Agenda Item # 8**  
**Vivally® System, Gel Cushion - HCP24010291273**

**Topic/Issue**

Request to establish a new HCPCS Level II code to identify the gel cushion of the Vivally® System.

Applicant's suggested language: AXXXX, “Hydrogel interfaces for tibial nerve stimulation system with EMG-sensing for closed-loop operation, for urinary control, reusable”

**Summary of Applicant's Submission**

Avation Medical submitted a request to establish a new HCPCS Level II code to describe the gel cushion of the Vivally® System. The Vivally® System received the Food and Drug Administration’s (FDA’s) 510(k) clearance on April 3, 2023. The Vivally® System is a wearable neuromodulation system for home use to treat patients with urge urinary incontinence and urinary urgency caused by overactive bladder syndrome. The Vivally® System is comprised of a controller kit, including a rechargeable smart controller (stimulator), charging accessories, and depending on configuration, either a hardware control unit (Vivally® System with hardware control unit) or access to a Vivally® mobile software application; a reusable garment; and reusable gel cushions. The gel cushions are a necessary supply used with the Vivally® System to ensure sufficient/consistent signal conduction. They are uniquely designed for re-usability with minimal adhesive to prevent skin reaction. The gel cushions are shaped specifically for use with the embedded electrodes in the garment to ensure proper placement and eliminate user variation. Avation Medical utilized a proprietary cross-linking process that provided the necessary physical structure, such that they maintain their shape and form after removal or reuse. Prior to using the Vivally® System, the gel cushions should be properly adhered to the garment by fully covering the electrode pad. Two gel cushions are placed inside the garment by removing the coverings and then placing the sticky side of the gel cushions down on the electrode pad. Gel cushions should be replaced every 30 days, or if they are excessively dry or dirty, if they no longer adhere to the garment, or if therapy feels less comfortable than usual.

**CMS Preliminary HCPCS Coding Recommendation**

Existing HCPCS Level II code A4595, “Electrical stimulator supplies, 2 lead, per month, (e.g., tens, nmes)” describes the gel cushion component of the Vivally® System.

**Preliminary Medicare Benefit Category Determination**

**Durable Medical Equipment**

During the benefit category determination process for multi-component devices, CMS has a longstanding policy of first determining which specific component provides the medically necessary function of rendering direct treatment. The Vivally® System components consist of a Controller, a Garment, and Gel cushions. Of the three components the Controller component is the sole component that provides a medically necessary function. The Vivally® System Gel Cushions meet the definition of DME because the Vivally® System Controller

meets all of the conditions listed in Medicare regulations at title 42 Code of Federal Regulations (CFR) 414.202, and thus is DME.

Chapter 15, section 110.3 of the Medicare Benefit Policy Manual (CMS Pub. 100-02) states payment may be made for suppliers that are necessary for the effective use of DME. The gel cushions would be considered a supply, necessary for the effective use of DME.

### **Preliminary Medicare Payment Determination**

The payment rules and pricing associated with the existing HCPCS Level II code A4595 apply to this product, if covered.

Pricing Indicator = 34

**Agenda Item # 8**  
**Vivally® System, Garment - HCP2401029GHMA**

**Topic/Issue**

Request to establish a new HCPCS Level II codes to identify the EMG-sensing garment of the Vivally® System.

Applicant's suggested language: AXXXX, “Form fitting conductive garment with EMG-sensing and stimulation electrodes for closed-loop electrical stimulation, for urinary control”

**Summary of Applicant's Submission**

Avation Medical submitted a request to establish a new HCPCS Level II code to identify electromyographical (EMG) sensing garment of the Vivally® System. The Vivally® System received the Food and Drug Administration’s (FDA’s) 510(k) clearance on April 3, 2023. The Vivally® System is a wearable neuromodulation system for home use to treat patients with chronic bladder conditions of urge urinary incontinence and urinary urgency caused by overactive bladder syndrome. The Vivally® System is comprised of a controller kit, including a rechargeable smart controller (stimulator), charging accessories, and depending on configuration, either a hardware control unit (Vivally® System with hardware control unit) or access to a Vivally® mobile software application; a reusable garment with embedded stimulation and EMG-sensing electrodes; and reusable gel cushions. The garment of the Vivally® System includes stimulation electrodes and EMG-sensing electrodes necessary in a form-fitting garment necessary for use of the Vivally® System. The garment comes in multiple sizes and is used with the controller to provide electrical stimulation to the tibial nerve for urinary control. The EMG-sensing capability of the electrodes are embedded within the garment. The size, shape, and fit of the Vivally® garment is scientifically and clinically designed to account for anatomical variation and patient movement. The correct Vivally® garment size will allow for a snug fit, with the hole on the side of the Vivally® garment aligned with the medial malleolus (inner ankle bone) and the gel cushions in contact with the skin. The garment material was selected to be breathable and durable, providing the optimal combination of structure, washability, and flexibility. A process was developed to ensure proper imprinting of multiple layers of the electrode array onto the garment, to last at least one year of use.

**CMS Preliminary HCPCS Coding Recommendation**

Existing HCPCS Level II code A4595, “Electrical stimulator supplies, 2 lead, per month, (e.g., tens, nmes)” describes the EMG-sensing garment of the Vivally® System.

**Preliminary Medicare Benefit Category Determination**

Durable Medical Equipment

During the benefit category determination process for multi-component devices, CMS has a longstanding policy of first determining which specific component provides the medically necessary function of rendering direct treatment. The Vivally® System components consist of a Controller, a Garment, and Gel cushions. Of the three components the Controller component is the sole component that provides a medically necessary function. The Vivally®

System Garment meets the definition of DME because the Vivally® System Controller meets all of the conditions listed in Medicare regulations at title 42 Code of Federal Regulations (CFR) 414.202, and thus is DME.

Chapter 15, section 110.3 of the Medicare Benefit Policy Manual (CMS Pub. 100-02) states payment may be made for suppliers that are necessary for the effective use of DME. The garment would be considered a supply, necessary for the effective use of DME.

### **Preliminary Medicare Payment Determination**

The payment rules and pricing associated with the existing HCPCS Level II code A4595 apply to this product, if covered.

Pricing Indicator = 34

**Agenda Item # 9**  
**ZIDA Wearable Neuromodulation System - HCP230703TF2YL**

**Topic/Issue**

Request for Medicare payment determination for ZIDA Wearable Neuromodulation System's Control Unit.

**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 Final HCPCS Coding Determination**

CMS established HCPCS Level II code E0736, "Transcutaneous tibial nerve stimulator" to describe the ZIDA Wearable Neuromodulation control unit, effective April 1, 2024.

## Medicare Benefit Category Determination

CMS determined that the ZIDA Wearable Neuromodulation control unit is Durable Medical Equipment, effective April 1, 2024.

## Preliminary Medicare Payment Determination

In the Second Biannual 2023 HCPCS Level II coding cycle, we deferred our payment determination for the ZIDA Wearable Neuromodulation control unit. With further analysis, we are now able to establish a preliminary payment determination. We establish fee schedule amounts for new HCPCS Level II codes for items and services without a fee schedule pricing history in accordance with regulations at 42 CFR § 414.238. For new HCPCS Level II codes for items and services without a fee schedule pricing history we use the existing fee schedule amounts for comparable items when these items 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. With further analysis of the ZIDA Wearable Neuromodulation control unit, we have concluded that it is comparable to HCPCS Level II code E0720 (Transcutaneous electrical nerve stimulation (TENS) device, two lead, localized simulation) with respect to the physical and electrical components and the function (nerve stimulation through transcutaneous electrical stimulation). See below table. We note that although an application for a HCPCS Level II code, benefit category, and payment determination may be made by a specific company for a particular item, we must establish payment amounts based on pricing information available for all items that would be included in the Product Classification List (PCL).

	<b>E0720</b>	<b>Zida Control Unit</b>
<b>Physical Components</b>	Control Unit	Control Unit
<b>Mechanical Components</b>	-	-
<b>Electrical Components</b>	Battery Biphasic waveforms	Battery Monophasic square waves
<b>Function and Intended Use</b>	Nerve stimulation through transcutaneous electrical stimulation of peripheral nerves  To treat patients with acute and chronic injuries and pain	Nerve stimulation through transcutaneous electrical stimulation of the posterior tibial nerve (TTNS) near the ankle  To treat patients with an overactive bladder (OAB) and associated symptoms of urinary urgency, urinary frequency, and urge incontinence.
<b>Additional Aspects and Features</b>	Low frequency usually below 300HZ	Fixed pulse frequency of 20 Hz

CMS recognizes the new indications through our preliminary valuation to compare the technology to HCPCS Level II code E0720 devices prior to competitive bidding, when devices to treat a range of conditions like insomnia, depression, anxiety, pain, and in this case, urinary incontinence, were not available to suppliers engaging in the competitive



bidding program. As such, CMS would establish the fees for HCPCS Level II code E0736 using fees for HCPCS Level II code E0720 that were not adjusted using information from the DMEPOS Competitive Bidding Program.<sup>2</sup>

Based on this preliminary determination, the average 2024 fee schedule amount for HCPCS Level II code E0736 would be based on the unadjusted purchase fee schedule amounts for HCPCS Level II code E0720 of approximately \$477.98 on average. As the price used in calculating the fee schedule amounts is greater than \$150 in the base period, payment would be made on a capped rental basis in accordance with our regulations at 42 CFR 414.229. Our preliminary determination is that the capped rental fee schedule amount would be approximately \$47.80 on average for months 1 through 3, and approximately \$35.85 on average for months 4 through 13, resulting in a total capped payment of \$501.88 should there be 13 months of continuous use.

Pricing Indicator = 36

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<sup>2</sup> CMS has similarly applied comparability using unadjusted fee schedule amounts for Alpha-Stim® Cranial Electrotherapy Stimulation, 19.117, the Monarch eTNS System®, 20.070, and the gammaCore Sapphire™, 20.173.

**Agenda Item # 10**  
**Flyte® System Controller - HCP24010236LW3**

**Topic/Issue**

Request to establish a new HCPCS Level II code to identify Flyte® System Controller.

Applicant's suggested language: XXXXX, “Non-implanted intravaginal device for transvaginal delivery of mechanotherapy to the pelvic floor muscle system, controller”

**Summary of Applicant's Submission**

Pelvital USA, Inc. submitted a request to establish a new HCPCS Level II code to identify Flyte® System Controller. The Flyte® System received the Food and Drug Administration’s (FDA’s) 510(k) clearance on December 29, 2023. The Flyte® System is a non-sterile, vaginal device intended to strengthen the pelvic floor muscles during normal Kegel exercises. The Flyte® System is indicated for the treatment of stress urinary incontinence. The Flyte® System is designed for in-home use and consists of a hand-held Flyte® System Controller and Wand. The Flyte® System Controller consists of a 3.7V Lithium-ion Polymer rechargeable battery with a capacity of 700-750 milliampere-hour and built-in safety protection. The Flyte® System Controller also contains a printed circuit board assembly used to control the motor speed and frequency and to provide the user with visual feedback information. The Flyte® System has a mechanism of action referred to as mechanotherapy. Specifically, the Flyte® System takes advantage of the natural mechanotransduction properties of muscle cells to strengthen the pelvic floor muscle when delivering mechanical vibrations during pelvic floor contractions. The standard treatment is 5 minutes per day for 6-12 weeks followed by maintenance as directed by a clinician (for example, once weekly for 12 months). The Flyte® System Controller, is packaged together with a charger cord, charging block, and the removable cord that connects the Controller to the Flyte® System Wand.

**CMS Preliminary HCPCS Coding Recommendation**

CMS has not identified a program operating need for Medicare or other payers to establish a new unique HCPCS Level II code to describe Flyte® System Controller. CMS would like to better understand how the Flyte® System vibrating motor directly affects and strengthens the pelvic muscle. CMS would welcome information from the applicant and other insurers to demonstrate a claims processing need for a HCPCS Level II code.

**Preliminary Medicare Benefit Category Determination**

Note: In the event the applicant and other insurers demonstrate a claims processing need for a HCPCS Level II code and a new code is established, we consider the Flyte® System Controller to not be in a Medicare DMEPOS benefit category.

During the benefit category determination process for multi-component devices, CMS has a longstanding policy of first determining which specific component provides the medically necessary function of rendering direct treatment (CMS-1577-F, November 10, 2011). The Flyte® System’s components consist of an external hand-held Controller disk and the vaginal probe Wand. Of the two components, the Wand component is the sole component that provides a medically necessary function. While the Controller component pilots the Wand as

a hand-held external component, it is the Wand that delivers the mechanical pulses while the pelvic floor muscles are voluntarily contracting. However, the vaginal probe Wand is not intended to withstand repeated use by successive patients and does not meet the 3-year useful lifetime requirement of the DME benefit category. Therefore, the Flyte® System Controller cannot be defined as durable medical equipment.

This determination is consistent with previous decisions that were provided for other multi-component systems such as the Omnipod Insulin Delivery System (in which the disposable pod pumps the insulin), the VIBRANT® System (in which the disposable capsule stimulates the colon), and the Altera® Nebulizer (in which the disposable handset nebulizes the medicine). These systems do not meet the definition of durable medical equipment because they rely on disposable components of the system to provide the medically necessary function.

### **Preliminary Medicare Payment Determination**

No Medicare payment. Pricing Indicator = 00

**Agenda Item # 10**  
**Flyte® System Wand - HCP240102C74P1**

**Topic/Issue**

Request to establish a new HCPCS Level II code to identify Flyte® System Wand.

Applicant's suggested language: XXXXX, “Non-implanted intravaginal device for transvaginal delivery of mechanotherapy to the pelvic floor muscle system, wand”

**Summary of Applicant's Submission**

Pelvital USA, Inc., submitted a request to establish a new HCPCS Level II code to identify Flyte® System Wand. The Flyte® System received the Food and Drug Administration’s (FDA’s) 510(k) clearance on December 29, 2023. The Flyte® System is a non-sterile, vaginal device intended to strengthen the pelvic floor muscles during normal Kegel exercises. The Flyte® System is indicated for the treatment of stress urinary incontinence. The Flyte® System is designed for in-home use and consists of a hand-held Flyte® System Controller and a Wand. The Flyte® System Wand contains an accelerometer and gyroscope which enable the controller to generate the visual feedback information. The Flyte® System Wand also houses the motor and weight used to generate the mechanical vibrations. The Flyte® System Wand is available in large and small sizes, the housing is cylindrical and is made of Acrylonitrile Butadiene Styrene plastic. The Flyte® System Wand is the only part of the device that directly contact the user’s vaginal cavity (mucosal membrane contact) and is covered entirely with a biocompatible medical-grade silicone sheath. The Flyte® System Wand is placed in the vagina and delivers a series of mechanical vibrations while the pelvic floor muscles are voluntarily contracting. The Flyte® System has a mechanism of action referred to as mechanotherapy. Specifically, the Flyte® System takes advantage of the natural mechanotransduction properties of muscle cells to strengthen the pelvic floor muscle when delivering mechanical vibrations during pelvic floor contractions. The standard treatment is 5 minutes per day for 6-12 weeks followed by maintenance as directed by a clinician (for example, once weekly for 12 months). The Flyte® System Controller, is packaged together with a charger cord, charging block, and the removable cord that connects the Controller to the Flyte® System Wand.

**CMS Preliminary HCPCS Coding Recommendation**

CMS has not identified a program operating need for Medicare or other payers to establish a new unique HCPCS Level II code to describe Flyte® System Wand. CMS would like to better understand how the Flyte® System vibrating motor directly affects and strengthens the pelvic muscle. CMS would welcome information from the applicant and other insurers to demonstrate a claims processing need for a HCPCS Level II code.

**Preliminary Medicare Benefit Category Determination**

Note: In the event the applicant and other insurers demonstrate a claims processing need for a HCPCS Level II code and a new code is established, we consider the Flyte® System Wand to not be in a 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. During the benefit category determination process for multi-component devices, CMS has a longstanding policy of first determining which specific component provides the medically necessary function of rendering direct treatment (CMS-1577-F, November 10, 2011). The Flyte® System's components consist of an external hand-held Controller disk and the vaginal probe Wand. Of the two components, the Wand component is the sole component that provides a medically necessary function. While the Controller component pilots the Wand as a hand-held external component, it is the Wand that delivers the mechanical pulses while the pelvic floor muscles are voluntarily contracting. However, the vaginal probe Wand, the subject of this application, does not meet two of the conditions that must be met for equipment to be classified as DME:

**Can withstand repeated use** – The Wand is not intended for use by successive patients and thus cannot withstand repeated use.

**Has an expected life of at least 3 years** - As stated in the application, the Flyte® System's Wand component does not have an expected useful life of at least 3 years.

Therefore, the Flyte® System Wand cannot be defined as durable medical equipment.

CMS does not question the efficacy, utility, or usefulness of similar disposable devices; however, they do not meet the definition of DME. For an item such as the Flyte® System Wand to be covered by Medicare, a change in the law would be needed to create a benefit category for disposable medical devices.

This determination is consistent with previous decisions that were provided for other multi-component systems such as the Omnipod Insulin Delivery System (in which the disposable pod pumps the insulin), the VIBRANT® System (in which the disposable capsule stimulates the colon), and the Altera® Nebulizer (in which the disposable handset nebulizes the medicine). These systems do not meet the definition of durable medical equipment because they rely on disposable components of the system to provide the medically necessary function.

### **Preliminary Medicare Payment Determination**

No Medicare payment. Pricing Indicator = 00

**Agenda Item # 11**  
**NTX-100 Tonic Motor Activation (TOMAC) System - HCP231231EPL6H**

**Topic/Issue**

Request to establish a new HCPCS Level II code to identify NTX-100 Tonic Motor Activation (TOMAC) System.

Applicant's suggested language: EXXXX, "External lower extremity nerve stimulator, tonic motor activation for Restless Legs Syndrome, bilateral"

**Summary of Applicant's Submission**

Noctrix Health Inc. submitted a request to establish a new HCPCS Level II code to identify the NTX-100 Tonic Motor Activation (TOMAC) System. The NTX-100 TOMAC System received the Food and Drug Administration's (FDA's) De Novo clearance on April 17, 2023. The NTX-100 TOMAC System delivers electrical stimulation to specific fibers of the peroneal nerve in both legs to relief symptoms for patients with primary drug refractory restless legs syndrome (RLS). RLS is a neurological disorder that causes uncomfortable sensations in the legs and an irresistible urge to move them, mostly in the evening and are most intense at night when resting. RLS can severely disrupt sleep, making it difficult to fall asleep or return to sleep after waking up. Moving the legs or walking typically relieves the discomfort, but the sensations often recur once the movement stops. Chronic sleep deprivation caused by RLS could increase the risk of dementia, heart failure, hypertension, and diabetes mellitus. The typical treatment of RLS consists of medications such as gabapentin, dopamine agonists, and off-label opioids. The use of NTX-100 TOMAC System is recommended when patients have symptoms. The NTX-100 TOMAC System delivers 30-minute stimulation session and automatically turns off. Patients can initiate a second treatment session if the symptoms RLS wake them up from sleep. NTX-100 TOMAC System consists of bilateral therapy delivery units (Therapy Bands), applied to each leg and proprietary charge dispersing interfaces, deliver electrical stimulation that is compatible, delivering high current (30 mA) for efficacy at a high frequency (4000 Hz) for comfort during sleep. Therapy Bands also incorporate a gyroscope, accelerometer, and impedance-sensing components to ensure safety and consistent stimulation during sleep and related leg movements. Device controls incorporated into the Therapy Bands allow the patient to initiate therapy and adjust stimulation strength as needed.

**CMS Preliminary HCPCS Coding Recommendation**

Establish a new HCPCS Level II code EXXXX, "External lower extremity nerve stimulator for restless legs syndrome, each" to describe NTX-100 Tonic Motor Activation (TOMAC) System.

CMS notes that while the device is often supplied as a pair of two units, we have proposed to establish a code for a single unit, since RLS may affect one limb and at any given time, one unit of the device could need replacement.

**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.

The NTX-100 Tonic Motor Activation System meets all five of the conditions that must be met in order for equipment to be classified as DME.

### **Preliminary Medicare Payment Determination**

In accordance with regulations at 42 CFR 414.238(c), fee schedule amounts for items and services without a fee schedule pricing history described by new HCPCS Level II 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 purchase price used in calculating the fee schedule amounts is greater than \$150, then payment would be made on a capped rental basis in accordance with our regulations at 42 CFR 414.229. If the only available price information is from a period other than the fee schedule base period (for supplies, the 12-month period of 1986/1987), deflation factors are applied against current pricing in order to approximate the base period price. The annual deflation factors are specified in 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 Social Security Act for DME.

In determining whether the NTX-100 is comparable to items with existing codes, we undertook a detailed examination of its physical, mechanical, and electrical components along with its function and intended use, in comparison with HCPCS Level II codes E0720 “transcutaneous electrical nerve stimulation (tens) device, two lead, localized stimulation” and E0734 “external upper limb tremor stimulator of the peripheral nerves of the wrist.” We have concluded that while the NTX-100 shares some features with devices described under each code, it is not comparable to either code. For this reason, we have determined that it is most appropriate to determine the Medicare payment amount in accordance with the “gap filling” procedure outlined in 42 CFR 414.238(c).

	<b>NTX-100</b>	<b>E0720</b>	<b>E0734</b>
<b>Physical Components</b>	Therapy control unit  Lower body garment/cuff  Charging accessories  Each unit configured for a single electrode	Therapy control unit  Electric wiring for electrodes  Common configurations provide for attaching two or four leads	Therapy control unit  Wrist garment  Configured for attaching three electrodes

			Base station for charging
<b>Mechanical Components</b>	-	-	Gyroscope and accelerometer
<b>Electrical Components</b>	Battery  Electronics for control mechanism  Delivers 30mA at 4000Hz to electrodes	Battery  Electronics for control mechanism  Delivers pulses at varying frequency and current, typically 50-100Hz	Battery  Electronics for control mechanism  Delivers pulses at 150Hz, alternating between two electrodes through an accelerometer
<b>Function and Intended Use</b>	To treat restless legs syndrome by delivering high current, high frequency electrical stimulation to the peroneal nerve	To treat post-operative acute pain or certain types of chronic pain by delivering low-intensity electric stimulation	To treat hand tremors by delivering electrical stimulation to medial and radial nerves
<b>Additional Aspects and Features</b>	Provides 30-minute stimulation session, turning off upon completion	User controlled therapy length, typically up to 60 minutes	Provides 40-minute stimulation session, turning off upon completion

To develop an appropriate Medicare payment amount in accordance with the “gap filling” procedure, we must identify appropriate commercial pricing for the underlying items. We emphasize that a Manufacturer Suggested Retail Price (MSRP) is not, by itself, an adequate source of commercial pricing. Only verifiable supplier or commercial pricing may be used for gap-filling purposes (84 FR 60648).

We note that while the device is often supplied as a pair of two units, we have proposed to establish a code for a single unit, for the reasons noted above. In accordance with regulations at 42 CFR 414.238I, the median of 2023 prices, as demonstrated by example claims from a variety of third-party payers submitted by the applicant, \$3,562.50, is deflated to the 1986 fee schedule base period using the percentage change in the consumer price index for all urban consumers (CPI-U) from the mid-point of the year the prices are in effect to the mid-point of the fee schedule base period. The price is then updated to the current year using the covered item update factors at section 1834(a)(14) of the Social Security Act. As the price used in calculating the fee schedule amounts is greater than \$150 in the base period, payment would be made on a capped rental basis in accordance with our regulations at 42 CFR 414.229. Our preliminary determination is that the capped rental fee schedule amount would be \$231.88 for months 1 through 3, and \$173.91 for months 4 through 13, resulting in a total capped payment of \$2,434.74 should there be 13 months of continuous use.

Pricing Indicator = 36



**Agenda Item # 11**  
**NTX-100 Tonic Motor Activation Supplies - HCP231231JYTC8**

**Topic/Issue**

Request to establish a new HCPCS Level II code to identify NTX-100 Tonic Motor Activation (NTX-100 ToMAc) supplies.

Applic'nt's suggested language: AXXXX, "Monthly supplies and accessories for external lower extremity nerve stimulator, tonic motor activation for Restless Legs Syndrome, bilateral"

**Summary of Applicant's Submission**

Noctrix Health Inc. submitted a request to establish a new HCPCS Level II code to identify the NTX-100 Tonic Motor Activation (NTX-100 ToMAc) supplies. NTX-100 ToMAc is an accessory for the NTX-100 Tonic Motor Activation (TOMAC) System. The NTX-100 TOMAC System received the Food and Drug Administration's (FDA's) De Novo clearance on April 17, 2023. The NTX-100 TOMAC System delivers electrical stimulation to specific fibers of the peroneal nerve in both legs to relief symptoms for patients with primary drug refractory restless legs syndrome (RLS). RLS is a neurological disorder that causes uncomfortable sensations in the legs and an irresistible urge to move them, mostly in the evening and are most intense at night when resting. RLS can severely disrupt sleep, making it difficult to fall asleep or return to sleep after waking up. Moving the legs or walking typically relieves the discomfort, but the sensations often recur once the movement stops. Chronic sleep deprivation caused by RLS could increase the risk of dementia, heart failure, hypertension, and diabetes mellitus. The typical treatment of RLS consists of medications such as gabapentin, dopamine agonists, and off-label opioids. The use of NTX-100 TOMAC System is recommended when patients have symptoms. The NTX-100 TOMAC System delivers 30-minute stimulation session and automatically turns off. Patients can initiate a second treatment session if the RLS symptoms wake them up from sleep. NTX-100 TOMAC System consists of bilateral therapy delivery units (Therapy Bands), applied to each leg and proprietary charge dispersing interfaces (CDIs), deliver electrical stimulation that is compatible, delivering high current (30 mA) for efficacy at a high frequency (4000 Hz) for comfort during sleep. The CDIs are distinct from standard electrodes, designed and manufactured to spec using a proprietary stack of materials to minimize movement between the stimulation contacts and skin (adhesion), to reduce the impedance across the skin interface, and to distribute current evenly across the target location. The NTX-100 TOMAC System requires the application of one CDI per Therapy Band, and each CDI is replaced approximately every week.

**CMS Preliminary HCPCS Coding Recommendation**

Establish a new HCPCS Level II code AXXXX, "Electrode for external lower extremity nerve stimulator for restless legs syndrome" to describe NTX-100 Tonic Motor Activation supplies.

CMS notes that while the device is often supplied as a pair of two units, we have proposed to establish a code for a single unit, since RLS may affect one limb and at any given time, one unit of the device could need replacement.

## **Preliminary Medicare Benefit Category Determination**

Supplies and Accessories Used with 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.

In order for the NTX-100 Tonic Motor Activation System, which falls within the DME benefit category, to function properly, it requires the use of monthly supplies and accessories. Thus, the NTX-100 supplies and accessories are considered to be supplies and accessories that are used with DME.

## **Preliminary Medicare Payment Determination**

In accordance with regulations at 42 CFR 414.238(c), fee schedule amounts for items and services without a fee schedule pricing history described by new HCPCS Level II 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 purchase price used in calculating the fee schedule amounts is less than \$150 in the base period, payment would be made on a purchase basis, as “inexpensive equipment” (42 CFR 414.220).

If the only available price information is from a period other than the fee schedule base period (for supplies, the 12-month period of 1986/1987), deflation factors are applied against current pricing in order to approximate the base period price. The annual deflation factors are specified in 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 Social Security Act for DME.

In determining whether the NTX-100 Charge-Dispersing Interface (electrode pair) is comparable to items with existing codes, we undertook a detailed examination of its physical, mechanical, and electrical components along with its function and intended use, in comparison with HCPCS Level II codes A4595, “electrical stimulator supplies, 2 lead, per month, (e.g., tens, nmes)” and A4542, “supplies and accessories for external upper limb tremor stimulator of the peripheral nerves of the wrist.” We have concluded that while the NTX-100 CDI shares some features with devices described under each code, it is not comparable to either code. For this reason, we have determined that it is most appropriate to determine the Medicare payment amount in accordance with the “gap filling” procedure outlined in 42 CFR 414.238(c).

	<b>NTX-100 CDI</b>	<b>A4595</b>	<b>A4542</b>
<b>Physical Components</b>	“Charge-Dispersing Interface” consisting of two physically joined electrodes  Connector-free design	Typically, adhesive pads for electrodes  Wide variety of shape, size, and materials	Write-worn cuff  Secures three electrodes, positioned to stimulate medial and radial nerves
<b>Mechanical Components</b>	Dry, metal electrodes  Pure silver conductive layer  Materials designed for one-week of use	Electrodes of varying materials, with widely varying life expectancy depending on specific material and use	Dry, metal electrodes designed for 90-day life expectancy
<b>Electrical Components</b>	Dry, metal electrodes  Pure silver conductive layer  Materials designed for one-week of use	Electrodes of varying materials, with widely varying life expectancy depending on specific material and use  Connected to control with physical wires	Dry, metal electrodes designed for 90-day life expectancy
<b>Function and Intended Use</b>	To treat restless leg syndrome by delivering high current, high frequency electrical stimulation to the peroneal nerve	To treat post-operative acute pain or certain types of chronic pain by delivering low-intensity electric stimulation	To treat hand tremors by delivering electrical stimulation to medial and radial nerves
<b>Additional Aspects and Features</b>	Each “CDI” electrode pair may be removed and stored in separate liner between uses, to maximize life expectancy	Monthly supplies would include any additional supplies needed (e.g., conductive gel)	Electrodes are embedded in the wrist cuff – no separate assembly required for use.

To develop an appropriate Medicare payment amount in accordance with the “gap filling” procedure, we must identify appropriate commercial pricing for the underlying items. We emphasize that a Manufacturer Suggested Retail Price (MSRP) is not, by itself, an adequate source of commercial pricing. Only verifiable supplier or commercial pricing may be used for gap-filling purposes (84 FR 60648).

We note that, for the reasons described above, this code is established for each “charge dispersing interface.” To convert prices for a monthly or a three-month supply of these

electrodes for two units to a single CDI for one unit, we assume that the three-month supply consists of 24 CDIs, and a monthly supply consists of 8 CDIs. In accordance with regulations at 42 CFR 414.238(c), the median of 2023 prices, as demonstrated by example claims from a variety of third-party payers submitted by the applicant, \$9.00, is deflated to the 1986 fee schedule base period using the percentage change in the consumer price index for all urban consumers (CPI-U) from the mid-point of the year the prices are in effect to the mid-point of the fee schedule base period. The price is then updated to the current year using the covered item update factors at section 1834(a)(14) of the Social Security Act. As the price used in calculating the fee schedule amounts is less than \$150 in the base period, payment would be made on a purchase basis in accordance with our regulations at 42 CFR 414.220. Our preliminary determination is that the purchase payment amount would be \$6.07.

Pricing Indicator = 34

**Agenda Item # 12**  
**Portable Neuromodulation Stimulator (PoNS™) Controller - HCP2306299CNLN**

**Topic/Issue**

Request for Medicare payment determination for Portable Neuromodulation Stimulator (PoNS™) Controller.

**Summary of Applicant's Submission**

Helius Medical Inc. submitted a request to establish a new HCPCS Level II code to identify Portable Neuromodulation Stimulator (PoNS™) controller. PoNS™ received the Food and Drug Administration's (FDA's) De Novo clearance on March 25, 2021. PoNS™ is a translingual, non-implantable tongue stimulator. The PoNS™ device provides therapy through two primary components: a controller and a mouthpiece. The controller is a programmable, electronic, durable medical device, when connected to the mouthpiece, orally generates electrical pulses for electrotactile stimulation of the nerves in the tongue. The controller generates and controls the delivery of electrotactile stimulation to the trigeminal and facial nerves through the mouthpiece while the individual is performing prescribed therapeutic exercises to directly activate brainstem areas and trigger neuroplastic changes in the brain (cerebral cortex) over a 14-week therapeutic period. The PoNS™ device is indicated for use as a short-term treatment of gait deficit due to mild to moderate symptoms of multiple sclerosis. The PoNS™ is used as an adjunct to a supervised therapeutic exercise program in patients 22 years of age and over. It is available by prescription only. The PoNS™ device is prescribed by a health care provider, typically a neurologist. The therapeutic exercise regimen is developed by a separate health care provider, typically a physical rehabilitation professional. The controller is packaged separately from the mouthpiece.

**CMS HCPCS Coding Determination**

CMS established a new HCPCS Level II code A4593, "Neuromodulation stimulator system, adjunct to rehabilitation therapy regime, controller" to describe Portable Neuromodulation Stimulator (PoNS™) Controller, effective April 1, 2024.

**Medicare Benefit Category Determination**

CMS determined that the PoNS™ Controller is DME, effective April 1, 2024.

**Preliminary Medicare Payment Determination**

In accordance with regulations at 42 CFR 414.236(b), fee schedule amounts for new HCPCS Level II 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. In determining whether the PoNS™ Controller is comparable to items with existing codes, we undertook a detailed examination of its physical, mechanical, and electrical components, function and intended

use, and any additional aspects and features, in comparison with HCPCS Level II code E0745, “Neuromuscular stimulator, electronic shock unit”.

A neuromuscular stimulator involves the transmission of an electrical impulse to selected muscle groups by way of electrodes. The PoNS™ controller and devices under HCPCS Level II code E0745 are external electrical stimulation devices that utilize electrodes for the delivery of electrical stimulation to affected muscles. Devices under HCPCS Level II code E0745 have a range of electrical forms, treatment times, and can include rechargeable power sources. Additionally, HCPCS Level II code A4593 describes neuromuscular stimulator equipment, and Medicare paid on a reasonable charge basis for neuromuscular stimulator equipment in 1986 using HCPCS Level II code E0745. For this reason, the preliminary payment determination for HCPCS Level II code A4593 is that it is comparable to HCPCS Level II code E0745 and thus the fee schedule amounts from HCPCS Level II code E0745 are mapped to HCPCS Level II code A4593.

We note that on two previous occasions, new codes for NMES devices used for specific indications were added to the HCPCS and fee schedule amounts identical to or similar to the fee schedule amounts for HCPCS Level II code E0745 were established for the new codes. In 2023, HCPCS Level II code E0490 was added for NMES for the treatment of obstructive sleep apnea, and the fee schedule amounts for HCPCS Level II code E0745 were mapped to HCPCS Level II code E0490 for payment purposes. PoNS™ is NMES used for treatment of gait deficit; therefore, we believe it is appropriate and consistent with past precedent to map the fee schedule amounts for HCPCS Level II code E0745 to the new code for the PoNS™ controller device.

	<b>PoNS™ Controller</b>	<b>E0745</b>
<b>Physical Components</b>	External Electrical Stimulator	External Electrical Stimulator
<b>Mechanical Components</b>	NA	NA
<b>Electrical Components</b>	Rechargeable Battery	Stimulator Stimulation delivered via electrodes Can include Rechargeable Batteries
<b>Function and Intended Use</b>	Delivers NMES to the trigeminal and fascial nerves placed through the mouthpiece  Worn on the neck  For Short-term treatment of gait deficit due to mild to moderate symptoms from multiple sclerosis (MS)	Delivers NMES to muscles  Can be used to treat muscle atrophy
<b>Additional Aspects and Features</b>	Intensity of NMES adjusted by the beneficiary	Can use Bluetooth

	<p>It must be reset after weeks of use by a Health Care Professional</p> <p>Connects to the mouthpiece via an electrical cord</p> <p>Three twenty-minute session treatments per day for 14 weeks</p>	
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Per this preliminary determination, the 2024 fee schedule amounts for HCPCS Level II code A4593 would be based on the rental fee schedule amounts for HCPCS Level II code E0745. As the price for the Controller is greater than \$150 in the base period, payment would be made on a capped rental basis in accordance with our regulations at 42 CFR 414.229. Our preliminary determination is that the capped rental fee schedule amount would be approximately \$114.91 on average for months 1 through 3, and approximately \$86.18 on average for months 4 through 13, resulting in a total capped payment of \$1,206.53 should there be 13 months of continuous use.

Pricing Indicator = 36

**Agenda Item # 12**  
**Portable Neuromodulation Stimulator (PoNS™) Mouthpiece - HCP2306294W7HD**

**Topic/Issue**

Request for Medicare payment determination for Portable Neuromodulation Stimulator (PoNS™) mouthpiece.

**Summary of Applicant's Submission**

Helius Medical Inc. submitted a request to establish a new HCPCS Level II code to identify Portable Neuromodulation Stimulator (PoNS™) mouthpiece. PoNS™ received the Food and Drug Administration's (FDA's) De Novo clearance on March 25, 2021. PoNS™ is a translingual, non-implantable tongue stimulator. PoNS™ device is a translingual, non-implantable tongue stimulator. The PoNS™ device provides therapy through two primary components: a mouthpiece and a controller. The mouthpiece is a disposable device that contains an array of 143 gold-plated electrodes through which electro tactile stimulation is applied to the dorsal surface of the patient's tongue and stimulates the trigeminal and facial nerves. The mouthpiece connects to the controller and receives status messages and instructions from the controller. The mouthpiece delivers the stimulation while the individual is performing prescribed therapeutic exercises to activate brainstem areas and trigger neuroplastic changes in the brain (cerebral cortex) over a 14-week therapeutic period. The PoNS™ device is indicated for use as a short-term treatment of gait deficit due to mild to moderate symptoms of multiple sclerosis. The PoNS™ is used as an adjunct to a supervised therapeutic exercise program in patients 22 years of age and over. It is available by prescription only. The PoNS™ device is prescribed by a physician, typically a neurologist. The therapeutic exercise regimen is developed by a separate health care provider, typically a physical rehabilitation professional. The mouthpiece is packaged separately from the controller.

**CMS HCPCS Coding Determination**

CMS established a new HCPCS Level II code A4594, "Neuromodulation stimulator system, adjunct to rehabilitation therapy regime, mouthpiece each" to describe Portable Neuromodulation Stimulator (PoNS™) mouthpiece, effective April 1, 2024.

**Medicare Benefit Category Determination**

CMS determined that the PoNS™ Mouthpiece is DME, effective April 1, 2024.

**Preliminary Medicare Payment Determination**

In accordance with regulations at 42 CFR 414.238(c), fee schedule amounts for items and services without a fee schedule pricing history described by new HCPCS Level II 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 purchase price used in calculating the fee schedule amounts is greater than \$150, then payment would be made on a capped rental basis in accordance with our regulations at 42 CFR 414.229. If the only available price information is from a period other than the fee



schedule base period (for supplies, the 12-month period of 1986/1987), 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 Social Security Act for DME.

In determining whether the PoNS™ Mouthpiece is comparable to items with existing codes, we undertook a detailed examination of its physical, mechanical, and electrical components, function and intended use, and any additional aspects and features, in comparison with HCPCS Level II code E0491, “Oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, used in conjunction with the power source and control electronics unit, controlled by hardware remote, 90-day supply.”

We have concluded that while the PoNS™ Mouthpiece shares some features with the device currently described under HCPCS Level II code E0491, it is not comparable to this code. For this reason, we have determined that it is most appropriate to determine the Medicare payment amount in accordance with the “gap filling” procedure outlined in 42 CFR 414.238(c).

	<b>PoNS™ Mouthpiece</b>	<b>E0491</b>
<b>Physical Components</b>	Paddle-shaped mouthpiece containing nickle, gold, and copper materials with embedded electrodes	Gel pads, cloth, carbon layered, pre-gelled, sealed pouch with built-in electrodes
<b>Mechanical Components</b>	NA	NA
<b>Electrical Components</b>	Electrical Pulse Stimulation	Electrical Pulse Stimulation
<b>Function and Intended Use</b>	Delivers NMES to the trigeminal and fascial nerves placed on the tongue  For Short-term treatment of gait deficit due to mild to moderate symptoms from multiple sclerosis (MS)	Delivers NMES therapy to genioglossus muscle through electrodes placed on the tongue  For the reduction of obstructive sleep apnea
<b>Additional Aspects and Features</b>	Non-implantable  Used as an adjunct to a supervised therapeutic exercise program  Three twenty-minute session treatments per day for 14 weeks	Non-implantable  Can include disposable and reusable parts  Latex free  One twenty-minute session per day for 6 weeks

To develop an appropriate Medicare payment amount in accordance with the “gap filling” procedure, we must identify appropriate commercial pricing for the underlying items. We emphasize that a Manufacturer Suggested Retail Price (MSRP) is not, by itself, an adequate

source of commercial pricing. Only verifiable supplier or commercial pricing may be used for gap-filling purposes (84 FR 60648).

The PoNS™ device can currently be purchased online at the following website:

<https://www.getponstherapy.com/pons-access-information/>. On this website are the “cash pay” prices, which are \$14,500 for the PoNS™ System (includes Controller and Mouthpiece) and \$4,500 for the PoNS™ Mouthpiece. These cash pay prices are also confirmed in a Form 8-K submission from 2023.<sup>3</sup> The applicant has noted that these cash pay prices reflect introductory pricing that has been used for a few customers only and are not representative of the prices that most customers will pay. The Form 8-K<sup>4</sup> also provides list prices for the PoNS™, and the applicant has requested that these list prices be used as the starting point for gap-fill: \$17,800 for the PoNS™ Controller and \$7,900 for the PoNS™ Mouthpiece. However, we have not seen invoices in which these list prices have been paid. We believe these list prices may be an MSRP, and as previously mentioned, an MSRP is not, by itself, an adequate source of commercial pricing. Only verifiable supplier or commercial pricing may be used for gap-filling purposes (84 FR 60648). We consider the cash pay price an internet retail price since it is a price on the internet available for and used by consumers to purchase, and we have used that \$4,500 price for the Mouthpiece as our source for the preliminary payment determination. We welcome the applicant to provide other commercial transactions or claims showing allowable/paid amounts for our consideration.

In accordance with regulations at 42 CFR 414.238(c), \$4,500 is deflated to the 1986 fee schedule base period using the percentage change in the consumer price index for all urban consumers (CPI-U) from the mid-point of the year the prices are in effect to the mid-point of the fee schedule base period. The price is then updated to the current year using the covered item update factors at section 1834(a)(14) of the Social Security Act. As the price used in calculating the fee schedule amounts is greater than \$150 in the base period, payment would be made on a capped rental basis in accordance with our regulations at 42 CFR 414.229. Our preliminary determination is that the monthly capped rental fee schedule amount would be \$292.91 for months 1 through 3, \$219.68 for months 4 through 13, resulting in a total capped payment of \$3,075.53 should there be 13 months of continuous use.

Pricing Indicator = 36

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<sup>3</sup> Exhibit No. 99.2. “Corporate Presentation, dated January 2023.”

<https://www.sec.gov/ix?doc=/Archives/edgar/data/1610853/000155837023000410/hsdt-20230123x8k.htm>

<sup>4</sup> <https://www.sec.gov/ix?doc=/Archives/edgar/data/1610853/000155837023000410/hsdt-20230123x8k.htm>

**Agenda Item # 13**  
**Venowave - HCP220922Q7MR0**

**Topic/Issue**

Request for reconsideration of prior benefit category determination.

**Applicant's Summary**

Venowave Inc. submitted a request to establish a new HCPCS Level II code to identify Venowave VW5. Venowave VW5 received the Food and Drug Administration's (FDA's) 510(k) clearance on March 7, 2008. The Venowave VW5 is a series of compact, battery-operated peristaltic pumps that generate a wave-form motion, and when worn below the knee strapped firmly to the calf, result in compression of the calf and consequently an increased upward volumetric displacement of venous and lymph fluid. According to the applicant, the Venowave VW5 series induces improved vascular and lymphatic flow of the lower limbs. According to the applicant, current existing HCPCS Level II codes are for pneumatic or for non-pneumatic sequential with gradient compression devices and are not appropriate for the Venowave VW5 to be billed. The Venowave VW5 generates a mechanical wave which starts at the lower pivot point and travels to the upper pivot point, a distance of 14 cm (wavelength) traveled for each cycle of the crank. The swept volume or volume of blood or lymph fluid displaced upwards for each cycle is the product of the wavelength (14cm), the width of the wave sheet (7.5 cm) and the depth of the wave (0.95 cm) or approximately 0.1 L/cycle. Operating by way of a single rechargeable 1.5 V NiMh AA battery, this single-patient use device enables the user to receive treatment anywhere, while remaining active. Indications for use as approved by the FDA are the following: management of the symptoms of post thrombotic syndrome (PTS), prevention of deep vein thrombosis (DVT), prevention of primary thrombosis, treatment of lymphedema, diminishing post-operative pain and swelling, treatment of leg swelling due to vascular insufficiency, treatment of varicose veins, treatment of chronic venous insufficiency, enhancing blood circulation, and treatment of intermittent claudication.

**CMS Preliminary HCPCS Coding Recommendation**

On August 23, 2023, CMS assigned existing HCPCS Level II code E0676, "Intermittent limb compression device (includes all accessories), not otherwise specified" to describe Venowave VW5, effective October 1, 2023. However, after reconsideration of the Medicare benefit category determination for Venowave VW5 (as described below), CMS has also decided to revise our prior coding determination. Therefore, we propose to:

Establish a new HCPCS Level II code XXXXX, "Non-pneumatic, non-sequential, peristaltic wave compression pump" to describe Venowave VW5.

**Preliminary Medicare Benefit Category Determination**

**Durable Medical Equipment**

When CMS published a final determination for Venowave on August 23, 2023, we originally stated that Venowave did not fall into a durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) benefit category because it was a single patient use item. 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 five conditions, including that of being able to withstand repeated use. We have reconsidered this determination based on new evidence that the applicant has brought to our attention.

Information later provided by the applicant regarding their refurbishment process, and subsequent clarification that Venowave’s FDA 510(k) label does not specifically state that Venowave is a single-use device, assures that Venowave can withstand repeated use by successive patients. Therefore, Venowave falls in the Durable Medical Equipment benefit category.

**Preliminary Medicare Payment Determination**

In accordance with regulations at 42 CFR 414.238(c), fee schedule amounts for items and services without a fee schedule pricing history described by new HCPCS Level II 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 purchase price used in calculating the fee schedule amounts is greater than \$150, then payment would be made on a capped rental basis in accordance with our regulations at 42 CFR 414.229. If the only available price information is from a period other than the fee schedule base period (for supplies, the 12-month period of 1986/1987), deflation factors are applied against current pricing in order to approximate the base period price. The annual deflation factors are specified in the 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 Social Security Act for DME.

In determining whether Venowave is comparable to items with existing codes, we undertook a detailed examination of its physical, mechanical, and electrical components along with its function and intended use, in comparison with HCPCS Level II codes E0670 (segmental pneumatic appliance for use with pneumatic compressor, integrated, 2 full legs and trunk), E0676 (intermittent limb compression device (includes all accessories), Not Otherwise Specified), and E0681 (non-pneumatic compression controller without calibrated gradient pressure). We have concluded that while Venowave shares some features with devices described under each code, it is not comparable to the codes. For this reason, we have determined that it is most appropriate to determine the Medicare payment amount in accordance with the “gap filling” procedure outlined in 42 CFR 414.238(c).

	<b>Venowave</b>	<b>E0670</b>	<b>E0676</b>	<b>E0681</b>
<b>Physical Components</b>	Peristaltic wave pump  DC Gearmotor  Lower Body Garment/Cuffs	Pumps  Upper or Lower Body Garments/ Cuffs	Pumps  Upper or Lower Body Compression Garments	Controller  Upper or Lower Body Compression Garments
<b>Mechanical Components</b>	Mechanical Plate	-	-	-

	<b>Venowave</b>	<b>E0670</b>	<b>E0676</b>	<b>E0681</b>
<b>Electrical Components</b>	Battery  Mechanical Wave through peristaltic pumping action	Air Chambers	Air chambers  Battery	Sequential Calibrated Gradient Compression Therapy through Lithium-ion battery powered integrated shape memory alloy channels
<b>Function and Intended Use</b>	To prevent accumulation of blood or lymphatic fluid that causes swelling and pain  To treat patients with Post Thrombotic Syndrome (PTS)	To prevent accumulation of blood or lymphatic fluid that causes swelling and pain  To treat patients with Lymphedema and Venous Insufficiency	To prevent accumulation of blood or lymphatic fluid that causes swelling and pain  To treat patients with Deep Vein Thrombosis (DVT)	To prevent accumulation of blood or lymphatic fluid that causes swelling and  To treat patients with Lymphedema, Venous Insufficiency or swelling/ edema following trauma, mastectomy, or post mobilization
<b>Additional Aspects and Features</b>	Weight: 260 g  Adjustable pressure (40-60mmHG)  Portable	Weight: 1.5 Kg  Adjustable pressure(20-80mmHG)  Not Portable  Designed to use by patients with limited mobility	Variable weights  Pressure could be adjustable (not in every device)  Portable	Weight (controller): 3lbs  Adjustable pressure (40-60mmHG)  Portable  Up to 16 independently controlled sections in each arm  To provide mobility for patients.

To develop an appropriate Medicare payment amount in accordance with the “gap filling” procedure, we must identify appropriate commercial pricing for the underlying items. We emphasize that a Manufacturer Suggested Retail Price (MSRP) is not, by itself, an adequate source of commercial pricing. Only verifiable supplier or commercial pricing may be used for

gap-filling purposes (84 FR 60648). To that end, we have identified and are using a commercial price of \$1,199<sup>5</sup> from an official distributor of Venowave in the United States.<sup>6</sup>

As the price used in calculating the fee schedule amounts is greater than \$150, payment would be made on a capped rental basis in accordance with our regulations at 42 CFR 414.229.

In accordance with regulations at 42 CFR 414.238(c), the 2024 price of \$1,199 is deflated to the 1986 fee schedule base period using the percentage change in the consumer price index for all urban consumers (CPI-U) from the mid-point of the year the prices are in effect to the mid-point of the fee schedule base period. The price is then updated to the current year using the covered item update factors at section 1834(a)(14) of the Social Security Act. Our preliminary determination is that the capped rental fee schedule amount would be approximately \$78.05 on average for months 1 through 3, and approximately \$78.05 on average for months 4 through 13, resulting in a total capped payment of \$819.55 should there be 13 months of continuous use.

Pricing Indicator = 36

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<sup>5</sup> <https://herolifecare.com/products/venowave>

<sup>6</sup> <https://www.theglobeandmail.com/investing/markets/stocks/TBRIF/pressreleases/20221870/>

## **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 Level II code falls under. The pricing indicator codes applicable to DMEPOS.

### **Pricing = 00 Service Not Separately Priced**

Items or services described by the HCPCS Level II 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 = 40 Lymphedema Compression Treatment Items

Payment is made on a purchase basis for lymphedema compression treatment items.

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).