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

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

## Second Biannual (B2), 2023 HCPCS Coding Cycle

This document presents a summary of each HCPCS Level II code application and CMS' coding decision for each application processed in CMS' Second Biannual 2023 Non-Drug and Non-Biological Items and Services HCPCS Level II code application review cycle. Each summary includes the Medicare Electronic Application Request Information System™ (MEARIS™) identification number; topic; a summary of the applicant's request as written by the applicant with occasional non-substantive editorial changes made by CMS; CMS' preliminary HCPCS Level II coding recommendation; a summary of public feedback from or following the HCPCS Level II public meeting; CMS' final HCPCS Level II coding decision, as well as CMS' preliminary and final benefit category and payment determination, if applicable.

In accordance with the procedures at 42 CFR §414.240 and §414.114, final Medicare Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) benefit category and payment determinations are listed below, if applicable. These procedures follow HCPCS Level II determinations and payment determinations for new DME under Medicare Part B following public consultation held through public meetings in accordance with section 531(b) of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub L. 106-554). CMS started using these public meetings and procedures for HCPCS Level II code requests for items and services other than DME in 2005. The procedures for making Medicare benefit category and payment determinations for new DMEPOS items and services using the BIPA 531(b) public meeting process were promulgated through regulations. The final rule (86 FR 73860) is available at https://www.federalregister.gov/documents/2021/12/28/2021-27763/medicare-program-durable-medical-equipment-prosthetics-orthotics-and-supplies-dmepos-policy-issues.

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

All new coding actions will be effective April 1, 2024, unless otherwise indicated.

The HCPCS Level II coding decisions below will also be included in the April 2024 HCPCS Quarterly Update, pending publication by CMS in the coming weeks at: https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update. For inquiries regarding coverage, please contact the insurer(s) in whose jurisdiction(s) claim(s) would be filed. Specifically, contact the Medicaid agency in the state in which a Medicaid claim is filed, the individual private insurance entity, the Department of Veterans Affairs, or, for local Medicare coverage determinations, contact the Medicare contractor in the jurisdiction the claim would be filed. For detailed information describing CMS' national coverage determination process, refer to information published at https://www.cms.gov/Medicare/Coverage/DeterminationProcess and https://www.cms.gov/Center/Special-Topic/Medicare-Coverage-Center.

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Final Coding, Benefit Category, and Payment Determinations from the HCPCS Level II Virtual Public Meeting on November 28, 2023 to November 30, 2023.

## KeraStat® Cream - HCP2306273CR3W

### Topic/Issue

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

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

### Summary of Applicant's Submission

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

### CMS Preliminary HCPCS Coding Recommendation

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

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

**Summary of Public Feedback**

KeraNetics, Inc. disagreed with CMS' preliminary HCPCS coding recommendation that the existing HCPCS Level II code A6250, "Skin sealants, protectants, moisturizers, ointments, any type, any size" describes KeraStat® Cream. The speaker noted, unlike KeraStat® Cream, products assigned HCPCS Level II code A6250 are skin sealants, protectants, moisturizers, and ointments and are over the counter. The product KeraStat® Cream is an FDA-cleared 510(k) medical device indicated for radiation dermatitis. It is listed in all major compendia and available to patients under the pharmacy benefit; however, it is not currently available to Medicare beneficiaries. The only product that the speaker could find in A6250 indicated for radiation dermatitis is Biafine. KeraStat® Cream is fundamentally different from these products given that KeraStat® Cream is a prescription product. KeraStat® Cream contains the ingredient keratin, and it has been shown in animal studies to reduce the inflammatory severity score relative to Biafine. Thus, the HCPCS Level II code A6250 is not appropriate for the KeraStat® Cream or other products in development as prescription products for radiation dermatitis. KeraNetics requests that CMS develop a new HCPCS Level II code for products indicated for radiation dermatitis prophylaxis and treatment.

**CMS Final HCPCS Coding Decision**

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

Existing HCPCS Level II code A6250, "Skin sealants, protectants, moisturizers, ointments, any type, any size" describes KeraStat® Cream" to describe KeraStat® Cream.

KeraStat® Cream is designed to create a moist environment conducive for managing wounds, especially those resulting from radiation dermatitis. Despite this distinction, these characteristics still align well with the protectant and moisturizer properties described by HCPCS Level II code A6250. KeraStat® Cream, containing keratin protein, is indicated for radiation dermatitis after radiotherapy as a topical treatment. The reference product for KeraStat® Cream, Biafine, has similar indications of use, and requires a prescription based on indication.

## Restrata® MiniMatrix - HCP230630JLCVQ

### Topic/Issue

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

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

### Summary of Applicant's Submission

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

### CMS Preliminary HCPCS Coding Recommendation

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

CMS has a long-standing convention to assign dose descriptors in the smallest amount that could be billed in multiple units to accommodate a variety of doses and support streamlined billing. This long-standing policy makes coding more robust and facilitates accurate payment and reporting of the exact dose administered, as only 999 units can appear on a claim line for Medicare fee-for-service using the CMS-1500 form. As such, we recommend the dose descriptor of 5 mg based on the largest package size of Restrata® MiniMatrix, which is 2000 mg.

In accordance with HCPCS Level II codes CMS effectuated for similarly situated products in 2022 and the Calendar Year 2022 Physician Fee Schedule Final Rule (86 FR 64996),

Medicare payment for this product will be determined by the Medicare Administrative Contractors.

**Summary of Public Feedback**

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

**CMS Final HCPCS Coding Decision**

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

Establish a new HCPCS Level II code A2026, "Restrata minimatrix, 5 mg" to describe Restrata® MiniMatrix.

CMS has a long-standing convention to assign dose descriptors in the smallest amount that could be billed in multiple units to accommodate a variety of doses and support streamlined billing. This long-standing policy makes coding more robust and facilitates accurate payment and reporting of the exact dose administered, as only 999 units can appear on a claim line for Medicare fee-for-service using the CMS-1500 form. As such, we recommend the dose descriptor of 5 mg based on the largest package size of Restrata® MiniMatrix, which is 2000 mg.

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

## ACEND™ - HCP23070329LQ2

### Topic/Issue

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

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

### Summary of Applicant's Submission

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

### CMS Preliminary HCPCS Coding Recommendation

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

### Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

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

### Preliminary Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

**Summary of Public Feedback**

Trility™ Inc. disagreed with CMS' HCPCS preliminary recommendation to assign ACEND™ to existing HCPCS Level II code A9153, "Multiple vitamins, with or without minerals and trace elements, oral, per dose, not otherwise specified." According to the speaker, patients with HIV/AIDS and cancer do not tolerate enteral nutrition in the same ways that other patients may and their sensitivity to systemic inflammatory responses is unique. The speaker believes ACEND™ addresses the sensitive patient populations directly by providing a polyphenol-rich formulation that is highly convenient for both clinical and home use, and variously flavored to appeal to different taste preferences. These features drastically improve the likelihood of improved compliance and consistent integration into a patient's overall medical care as part of his/her dietary management for chronic infection and cancer. Patients with HIV/AIDS and cancer feature unique inflammatory responses to products in B4155 and B4150, they are medically intolerant of certain ingredients like sugar/sugar substitutes that may cause additional comorbidities. ACEND™ is specially formulated to meet the nutritional needs of patients with HIV/AIDS and cancer. ACEND™'s polyphenolic enteral nutrition formula is exceptionally expensive to develop and produce, but also to distribute. Polyphenolic enteral nutrition meets the recommended definition of "vitamins" as set forth in A9153.

**CMS Final HCPCS Coding Decision**

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

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

The nutritional label for ACEND™ shows ACEND™ is composed of multiple vitamins, which is accurately descried by the existing HCPCS Level II code A9153.

**Final Medicare Benefit Category Determination**

No Medicare DMEPOS benefit category.

**Final Medicare Payment Determination**

No Medicare payment. Pricing Indicator = 00

## Cue COVID-19 Molecular Test Cartridge - HCP2306305R33J

### Topic/Issue

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

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

### Summary of Applicant's Submission

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

### CMS Preliminary HCPCS Coding Recommendation

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

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

### Summary of Public Feedback

Cue Health disagreed with CMS' HCPCS preliminary recommendation to assign the Cue COVID-19 Molecular Test to existing HCPCS Level II code, K1034, "Provision of COVID-19 test, nonprescription self-administered and self-collected use, FDA approved, authorized or cleared, one test count." The speaker stated that they disagreed with the assignment of the cartridge to the existing code due to the fundamental clinical and technical differences between antigen and molecular tests in addition to the impact this would have on patient access. HCPCS Level II code K1034 was established at the onset of the PHE, when only Rapid Antigen Tests (RAT) technology was available and prior to the authorization and approval of the Cue COVID-19 molecular test. At the time, there was little clinical evidence of the performance of RATs and a single antigen test was considered sufficient for conclusive results at the time. Payment for K1034 was established based on RAT technology only. After the PHE, many changes have occurred that require a need for a separate code for a molecular at-home COVID-19 test. Subsequent studies have shown that antigen tests have low accuracy and sensitivity. As a result, FDA made a label change to require serial testing for all at-home COVID-19 rapid antigen tests due to their low accuracy and sensitivity. This means people who receive a negative test result should use multiple tests over a certain period, testing at

least twice over three days if they have symptoms and at least three times over five days if they do not have symptoms. In comparison, the Cue COVID-19 molecular test which, unlike antigen tests, is fully FDA authorized, does not require retesting as the accuracy and sensitivity is similar to a lab PCR test but can be performed at home. If multiple rapid antigen tests need to be run due to their low sensitivity and accuracy, this may result in potentially missing the treatment window to utilize antivirals. For the population with a weakened immune system, timely commencement of these antivirals is critical to reduce the severity of their COVID-19 symptoms and prevent hospitalization or even death. As a result, rapid antigen tests with the K1034 code are not sufficient for this population. This population needs highly accurate and sensitive tests such as the Cue COVID-19 molecular test, but the lack of proper codes and coverage hinders them from getting the necessary access. Advocacy groups such as TRAIPAG (Transplant Recipient and Immunocompromised Patient Advocacy Group) have voiced the critical need to have access to this technology and for it to be coded and covered by insurance. Having access to accurate testing in order to detect COVID-19 and receive treatment early will significantly reduce their chance of progression to hospitalization. Especially with the PHE ending, many of these immunocompromised patients are unable to find rapid turnaround PCR lab tests as these are now offered at very few locations and, if they do venture to get a PCR lab test, they have to travel to urgent care settings where they will be exposed to other sick individuals. An at-home molecular COVID-19 test is the best option for them, but they need the proper codes and coverage in order to gain access to this technology. Lastly, there are many clinical, technological, and patient experience differences between an at-home molecular test and an antigen test as described below. Cue's COVID-19 Molecular test meets the needs of the immunocompromised population as well as having higher accuracy and sensitivity compared to an antigen test with conclusive results within 20 minutes. For these reasons, we feel that a new code is needed for our Cue COVID-19 Molecular Test. Additionally, multiple speakers stated that it is important for people with weakened immune systems to have access to at-home molecular COVID-19 test and requested that a unique code be established.

**CMS Final HCPCS Coding Decision**

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

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

HCPCS Level II code K1034 was established to facilitate claims processing for the Medicare Over-the-Counter COVID-19 Test Demonstration. Following the end of the PHE, Medicare no longer pays for HCPCS Level II code K1034. There is no Medicare Benefit Category for at-home COVID-19 tests. HCPCS is a system for identifying items and services. It is not a methodology or system for making coverage or payment determinations, and the existence of a code does not, of itself, determine coverage or non-coverage for an item or service. Non-Medicare payers still may continue to use and possibly pay post-PHE for at-home COVID-19 tests under HCPCS Level II code K1034. CMS is not aware of any insurers potentially paying differently from HCPCS Level II code K1034 for this type of at-home COVID-19 test. If the Cue Cartridge is used by a registered clinical laboratory, existing HCPCS Level I

Current Procedural Terminology (CPT®) codes can be utilized for claims submission. If information regarding payers who are currently paying for this service differently from HCPCS Level II code K1034 becomes available to describe a claims processing need for a unique HCPCS Level II code, the applicant is welcome to submit a new application.

## POGO Automatic® Test Cartridges - HCP2306306L0YM

### Topic/Issue

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

Applicant's suggested language: XXXXX, “Test Cartridge with Automated Blood Sampling, 50 tests”

### Summary of Applicant's Submission

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

### CMS Preliminary HCPCS Coding Recommendation

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

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

**Preliminary Medicare Benefit Category Determination**

Supply used with Durable Medical Equipment.

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

**Preliminary Medicare Payment Determination**

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

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

Also, the Medicare payment amount for non-mail order diabetic supplies, including test strips, is required under section 1834(a)(1)(H) of the Social Security Act (The Act) to be equal to the single payment amounts established under the national mail order competitive bidding program for diabetic supplies (as established in section 1847 of The Act). We

consider section 1834(a) to be applicable to the POGO Automatic Test Cartridges since they are diabetic supplies used to measure glucose levels.

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

Pricing Indicator = 34

**Summary of Public Feedback**

Intuity Medical, Inc. agreed with the preliminary decision to issue a HCPCS Level II code for POGO Automatic® Test Cartridges, however, Intuity Medical, Inc. disagreed with the preliminary Medicare payment determination of the device. The speakers requested that CMS recognize the PDAC classification of the POGO Automatic® Monitor as E2101. The speakers also disagreed with the preliminary payment decision to crosswalk the POGO Automatic® Cartridge to traditional strips and lancets (A4253 and A4259) because the POGO Automatic® Cartridge is not comparable to traditional strips and lancets. For this reason, the speakers recommended that CMS follow its existing processes to determine the Medicare payment rate for the new HCPCS Level II code assigned to the POGO Automatic® Cartridge based on the established gap-filling methodology.

Written comments encouraged CMS to classify this device under a new unique HCPCS Level II code and described the POGO ABGMS as a device that meets an unmet need of most people with diabetes who have other comorbidities resulting in dexterity impairments. The comments discussed the prevalence of patients with diabetes as well as dexterity concerns and stated that the POGO ABGMS should be made more accessible as an effective alternative for such patients facing difficulties with traditional monitoring methods of monitoring diabetes.

**CMS Final HCPCS Coding Decision**

We appreciate the comments provided in response to CMS' preliminary recommendations. Based on the information provided in the application and after consideration of the comments we received, CMS is revising its preliminary recommendation and finalizing the establishment of two new HCPCS Level II codes:

1. E2104, "Home blood glucose monitor for use with integrated lancing/blood sample testing cartridge"

2. A4271, "Integrated lancing and blood sample testing cartridges for home blood glucose monitor, per month"

After consideration of the comments and information presented in the application, CMS concludes that the POGO Automatic® Blood Glucose Monitoring System (ABGMS) requires the establishment of two new codes to be used in combination. CMS acknowledges the primary difference is that each lancet and test strip must be inserted into the device(s) assigned to E2101 at minimum each day, while the POGO Automatic® requires a testing

cartridge integrating multiple lancets and test strips for multiple tests over more than one day at a time.

**Final Benefit Category Determination**

Supply used with Durable Medical Equipment.

**Final Medicare Payment Determination**

We agree with public consultation that the POGO Automatic® blood glucose monitor and cartridge system fills the gap created by the exit of products that formerly were classified under HCPCS Level II code E2101. In addition, based on our further review of the POGO Automatic® blood glucose monitor and cartridge supplies, we have concluded that the system as a whole is not comparable to the E2101 monitor and A4253 + A4259 supplies primarily because the system design enables it to serve a potentially more specialized patient population (patients with dexterity challenges) and there are material differences from blood glucose monitors and supplies found under E2101, A4253, and A4259 (primarily related to the lancets and strips being embedded in the cartridge and not having to be loaded by the patient into the monitor).

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 only available price information is from a period other than the fee schedule base period (for capped rental items, the last 6 months of 1986), deflation factors are applied against current pricing in order to approximate the base period price. The annual deflation factors are specified in program instructions (Medicare Claims Processing Manual, Chapter 23, Section 60.3) and the deflated amounts are then increased by the update factors specified in section 1834(a)(14) of the Social Security Act for DME. Based on our conclusion that the POGO Automatic® blood glucose monitor and cartridge supplies are not comparable to other items with an existing fee schedule, we are using the gap-fill process to establish the fee schedule amounts for the POGO Automatic® blood glucose monitor and cartridge supplies.

**E2104:** We found several internet retail prices in January 2024 for the POGO Automatic® blood glucose monitor, and the median of these prices is $79.99.[1,2,3,4,5] Using this median price to calculate the fee schedule as well as applicable deflation and update factors, the fee schedule amount for the new HCPCS Level II code E2104, when covered, would be $52.20.

Pricing Indicator = 32

[1] hsastore.com
[2] walmart.com
[3] https://presspogo.com/products/pogo-system-kit
[4] shop.com
[5] fsastore.com

**A4271:** We found several internet retail prices in January 2024 for a monthly supply of 10 POGO Automatic® cartridges and the median of these prices is $10.00 per cartridge.[6,7,8,9,10] Using this median price to calculate the fee schedule as well as applicable deflation and update factors, the fee schedule amount for the new HCPCS Level II code A4271, when covered, would be $6.52 per cartridge, or $65.25 for a monthly supply of ten cartridges.

Pricing Indicator = 34

[6] hsastore.com
[7] walmart.com
[8] https://presspogo.com/products/pogo-automatic-test-cartridges
[9] shop.com
[10] fsastore.com

## Buzzy® Pro Therapeutic Vibrator with Cold Pack - HCP230701T9HT2

### Topic/Issue

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

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

### Summary of Applicant's Submission

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

### CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a program operating need for Medicare or other payers for a new HCPCS Level II code to describe a vibrating motor for focal mechanical stimulation, capable of applying torque perpendicular to the skin surface directly under compression or when attached with a tourniquet.

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

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

We welcome information from the applicant and other insurers who are currently paying for this product to demonstrate a claims processing need for a unique HCPCS Level II code.

**Preliminary Medicare Benefit Category Determination**

No Medicare DMEPOS benefit category.

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

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

**Preliminary Medicare Payment Determination**

No Medicare payment. Pricing Indicator = 00

**Summary of Public Feedback**

Pain Care Labs disagreed with CMS' HCPCS preliminary recommendations. The speaker stated that the mechanism of action for mechanical stimulation (M-Stim) pain relief is neuromodulation. Pacinian mechanoreceptors inhibit nociceptive pain in the dorsal horn of the spinal cord via adenosine release, 2-3 times more effectively than electrical stimulation. Multiple trials demonstrate vibration pain relief is unrelated to distraction but is based on dermatomal surface area neuromodulatory inhibition that can be distant from the pain. In the absence of pain blocking and/or tissue damage Buzzy's 200 Hz M-Stim unit is too low-amplitude, too small, and too intense to be sought for comfort. Using M-stim for needle procedures treating or preventing illness relieves pain from tissue damage (as defined by the International Association for the Study of Pain (IASP)) and is supported by over 80 independent peer-reviewed prospective Randomized Control Trials (RCTs). Unlike massagers which could increase the pain of cannulation or decrease success of a procedure, M-Stim's amplitude activates nerves: it disrupts tissues so little, Buzzy increases success in the delicate procedure of pediatric cannulation. Needle pain is the largest contributor to reduced quality of life in dialysis, to refusal of HPV vaccines (Clark et al), stopping biologics, and failure to get dental and lab draws (Alsbrooks K, 2022). It resulted in 24% of US and 10% of UK citizens not getting COVID vaccines. Finally, novel M-Stim is durable for years, can be disinfected and shared, is primarily used for pain in the home, and thus is not a bundled part of dialysis or home medication injection pain relief.

**CMS Final HCPCS Coding Decision**

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary recommendation. CMS has not identified a program operating need for Medicare or other payers for a new HCPCS Level II code to describe a vibrating motor for focal mechanical stimulation, capable of applying torque perpendicular to the skin surface directly under compression or when attached with a tourniquet. CMS is not aware of any insurers who are currently paying for this product or have a claims processing need for a unique HCPCS Level II code. CMS has not received any comments from any insurers in response to our request for information about the need for a unique HCPCS Level II code.

When Buzzy® Pro is used to control pain associated with needle procedures (e.g., injections, vascular access, cannulation, lab draws, blood donation, dialysis, cosmetic and dental injections), Medicare would typically reflect the costs of it in the payment for the procedure and, as such, it would not be separately payable.

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

**Final Medicare Benefit Category Determination**

No Medicare DMEPOS benefit category.

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

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

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

Medicare program guidance at section 280.1 of chapter 1, part 4 of the Medicare National Coverage Determinations Manual indicates that massage devices are not primarily medical in nature, which means they do not satisfy the definition of DME. Section 280.1 of the Medicare National Coverage Determinations Manual further states that massage devices are personal comfort items excluded from Medicare coverage by section 1862(a)(6) of the Social Security Act.

Also, as discussed in our preliminary recommendation, CMS took into consideration the Calendar Year 2024 ESRD End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) Final Rule (CMS-1782-F) determination that Buzzy® Pro Therapeutic Vibrator will not be paid for using the Transitional Add-on Payment Adjustment for New and Innovative

Equipment and Supplies (TPNIES) per § 413.236(d). In this final rule (88 FR 76415), we said, “Regarding the first TPNIES eligibility criterion in §413.236(b)(1), that the item has been designated by CMS as a renal dialysis service under §413.171, pain management associated with dialysis cannulation is a service that is furnished to individuals for the treatment of ESRD and is essential for the delivery of maintenance dialysis. We consider Buzzy® Pro a renal dialysis service under §413.171.”

In the public meeting the speakers discussed how dialysis patients use the Buzzy Pro® for needle pain relief. We reminded the speakers in the public meeting that dialysis items and services is not one of the DMEPOS benefit categories and that the HCPCS Level II public meetings are only used to make benefit category determinations for DMEPOS items and services.

We are therefore finalizing our preliminary benefit category determination that the Buzzy Pro® does not fall under a DMEPOS benefit category.

**Final Medicare Payment Determination**

No Medicare payment. Pricing Indicator = 00

## Buzzy® Pro Ice Pack Accessory - HCP2307032RY8G

### Topic/Issue

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

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

### Summary of Applicant's Submission

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

### CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a program operating need for Medicare or other payers for a new HCPCS Level II code to describe a reusable cold pack accessory capable of transmitting vibration when frozen, reversible for two temperature options, configured for use with vibrating motor for focal mechanical stimulation.

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

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

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

We welcome information from the applicant and other insurers who are currently paying for this product to demonstrate a claims processing need for a unique HCPCS Level II code.

**Preliminary Medicare Benefit Category Determination**

No Medicare DMEPOS benefit category.

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

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

**Preliminary Medicare Payment Determination**

No Medicare payment. Pricing Indicator = 00

**Summary of Public Feedback**

Pain Care Labs disagreed with CMS' preliminary recommendations. The speaker stated that ice packs are an additional source of conditioned pain modulation via descending noxious inhibitory controls activated in the periaqueductal grey, in addition to slowing nerve conduction of pain at the site. The packs must transmit vibration without losing amplitude or changing frequency. While they are reusable up to 100 times, they are single patient and will eventually dehydrate, thus making typical over the counter ice packs inadequate.

**CMS Final HCPCS Coding Decision**

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary recommendation. CMS has not identified a program operating need for Medicare or other payers for a new HCPCS Level II code to describe a reusable cold pack accessory capable of transmitting vibration when frozen, reversible for two temperature options, configured for use with vibrating motor for focal mechanical stimulation.

CMS is not aware of any insurers who are currently paying for this product or have a claims processing need for a unique HCPCS Level II code. CMS has not received any comments from any insurers in response to our request for information about the need for a unique HCPCS Level II code.

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

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

**Final Medicare Benefit Category Determination**

No Medicare DMEPOS benefit category.

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

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

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

Medicare program guidance at section 280.1 of chapter 1, part 4 of the Medicare National Coverage Determinations Manual indicates that massage devices are not primarily medical in nature, which means they do not satisfy the definition of DME. Section 280.1 of the Medicare National Coverage Determinations Manual further states that massage devices are personal comfort items excluded from Medicare coverage by section 1862(a)(6) of the Social Security Act.

Also, as discussed in our preliminary coding recommendation, CMS took into consideration the Calendar Year 2024 ESRD End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) Final Rule (CMS-1782-F) determination that Buzzy® Pro Therapeutic Vibrator will not be paid for using the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) per § 413.236(d). In this final rule (88 FR 76415), we said, “Regarding the first TPNIES eligibility criterion in §413.236(b)(1), that the item has been designated by CMS as a renal dialysis service under §413.171, pain management associated with dialysis cannulation is a service that is furnished to individuals for the treatment of ESRD and is essential for the delivery of maintenance dialysis. We consider Buzzy® Pro a renal dialysis service under §413.171.”

In the public meeting, the speakers discussed how dialysis patients use the Buzzy Pro® for needle pain relief. We reminded the speakers in the public meeting that dialysis items and services is not one of the DMEPOS benefit categories and that the HCPCS Level II public meetings are only used to make benefit category determinations for DMEPOS items and services.

We are therefore finalizing our preliminary benefit category determination that the Buzzy Pro® does not fall under a DMEPOS benefit category.

**Final Medicare Payment Determination**

No Medicare payment. Pricing Indicator = 00

## VibraCool® Pro - HCP2307036BGBU

### Topic/Issue

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

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

### Summary of Applicant's Submission

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

### CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a program operating need for Medicare or other payers for a new HCPCS Level II code to describe a vibrating motor for focal mechanical stimulation, capable of applying torque perpendicular to the skin surface under compression or indirectly when attached to a rigid brace, with frequency 100-250 Hz.

When VibraCool® Pro is used during the physical therapy to treat myofascial pain caused by trigger points, restricted motion and muscle tension, Medicare would typically reflect the costs of it in the payment for the procedure and, as such, it would not be separately payable. VibraCool® Pro, when used at home, is considered to be a personal comfort item that is not primarily medical in nature, and does not meet the Medicare definition of durable medical equipment and would not be payable by Medicare. We welcome information from the applicant and other insurers who are currently paying for this product to demonstrate a claims processing need for a unique HCPCS Level II code.

**Preliminary Medicare Benefit Category Determination**

No Medicare DMEPOS benefit category.

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

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

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

**Preliminary Medicare Payment Determination**

No Medicare payment. Pricing Indicator = 00

**Summary of Public Feedback**

Pain Care Labs disagreed with CMS’ preliminary recommendations. The speaker stated that the mechanism of action for mechanical stimulation (M-Stim) pain relief is neuromodulation of Pacinian mechanoreceptors to inhibit nociceptive pain in the dorsal horn of the spinal cord, 2-3 times more effectively than electrical stimulation. Multiple trials demonstrate vibration pain relief is unrelated to distraction. In the absence of pain blocking and/or tissue damage VibraCool® Pro's 200 Hz M-Stim units are too low-amplitude, too small, and too intense to be sought for comfort. The location of action is based on dermatomal surface area neuromodulatory inhibition proximal to the pain, whereas massage is placed directly on

soreness. Blocking pain to enhance adherence to physical therapy or after surgical procedures where tissues are damaged, fits the International Association for the Study of Pain (IASP) definition of pain, not comfort. Use of post-op VibraCool® to reduce opioids fulfills a programmatic need: the ubiquity of opioids in circulation after surgery directly leads to new opioid use disorders through misuse, and familiarity increases the risk of fentanyl look-alike overdoses. Unlike massagers which could damage sutures or be ineffective for pain when placed distant from the incision, M-Stim's amplitude is tuned to nerves and doesn't disrupt tissues. Finally, novel M-Stim is durable for years, can be shared, is primarily used for pain in the home, and thus is not a bundled part of post-surgical pain relief.

**CMS Final HCPCS Coding Decision**

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

CMS is not aware of any insurers who are currently paying for this product or has a claims processing need for a unique HCPCS Level II code. CMS has not received any comments from any insurers in response to the need for a unique HCPCS Level II code.

When VibraCool® Pro is used during the physical therapy to treat myofascial pain caused by trigger points, restricted motion and muscle tension, Medicare would typically reflect the costs of it in the payment for the procedure and, as such, it would not be separately payable.

**Final Medicare Benefit Category Determination**

No Medicare DMEPOS benefit category.

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

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

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

Medicare program guidance at section 280.1 of chapter 1, part 4 of the Medicare National Coverage Determinations Manual indicates that massage devices are not primarily medical in nature, which means they do not satisfy the definition of DME. Section 280.1 of the Medicare National Coverage Determinations Manual further states that massage devices are personal

comfort items excluded from Medicare coverage by section 1862(a)(6) of the Social Security Act.

**Final Medicare Payment Determination**

No Medicare payment. Pricing Indicator = 00

## VibraCool® Pro Ice Pack Accessory - HCP230703P85V9

### Topic/Issue

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

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

### Summary of Applicant's Submission

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

### CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a program operating need for Medicare or other payers for a new HCPCS Level II code to describe a reusable ice pack accessory capable of transmitting vibration when frozen, configured for use with a vibrating motor for focal mechanical stimulation.

### Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

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

**Preliminary Medicare Payment Determination**

No Medicare payment. Pricing Indicator = 00

**Summary of Public Feedback**

Pain Care Labs disagreed with CMS' preliminary recommendations. The speaker stated that ice packs are an additional source of conditioned pain modulation via descending noxious inhibitory controls activated in the periaqueductal grey, in addition to slowing nerve conduction of pain at the site. The packs must transmit vibration without losing amplitude or changing frequency. While they are reusable up to 100 times, they are single patient and will eventually dehydrate, thus typical over the counter ice packs are inadequate.

**CMS Final HCPCS Coding Decision**

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary recommendation. CMS has not identified a program operating need for Medicare or other payers for a new HCPCS Level II code to describe a reusable ice pack accessory capable of transmitting vibration when frozen, configured for use with a vibrating motor for focal mechanical stimulation.

CMS is not aware of any insurers who are currently paying for this product or have a claims processing need for a unique HCPCS Level II code. CMS has not received any comments from any insurers in response to the request for information about a need for a unique HCPCS Level II code.

**Final Medicare Benefit Category Determination**

No Medicare DMEPOS benefit category.

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

**Final Medicare Payment Determination**

No Medicare payment. Pricing Indicator = 00

## ZIDA Wearable Neuromodulation System - HCP230703TF2YL

### Topic/Issue

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

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

### Summary of Applicant's Submission

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

**CMS Preliminary HCPCS Coding Recommendation**

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

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

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

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

**Preliminary Medicare Benefit Category Determination**

Durable Medical Equipment.

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

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

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

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

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

**Preliminary Medicare Payment Determination**

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

For the control unit, no determination. In accordance with regulations at 42 CFR § 414.238(c), fee schedule amounts for items and services without a fee schedule pricing history described by new HCPCS 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. Potential appropriate sources for such commercial pricing information can also include payments made by Medicare Advantage plans, as well as verifiable information from supplier invoices and non-Medicare payer data. If the only available price information is from a period other than the fee schedule base period, deflation factors are applied against current pricing in order to approximate the base period price.

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

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

In accordance with regulations at 42 CFR 414.238(c), fee schedule amounts for items and services without a fee schedule pricing history described by new HCPCS 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 only available price information is from a period other than the fee schedule base period (for capped rental items, the last 6 months of 1986), deflation factors are applied against current pricing in order to approximate the base period price. The annual deflation factors are specified in program instructions (Medicare Claims Processing Manual, Chapter 23, Section 60.3) and the deflated amounts are then increased by the update factors specified in section 1834(a)(14) of the Act for DME.

We found several internet prices in August 2023 and the median of these prices is $58.74[11, 12, 13, 14, 15]. As this median price will be used in calculating the fee schedule and the amount is less than $150, payment would be made on an inexpensive or routinely purchased items basis in accordance with our regulations at 42 CFR 414.220. The average 2023 purchased fee schedule amount for EXXXX would be approximately $37.37.

Pricing Indicator = 32

**Summary of Public Feedback**

Zida LLC agreed with CMS' preliminary HCPCS coding recommendation to establish a new HCPCS Level II code to identify the ZIDA Wearable Neuromodulation control unit. However, the speaker disagreed with revising existing HCPCS Level II code E0731, "Form fitting conductive garment for delivery of tens or nmes (with conductive fibers separated from the patient's skin by layers of fabric)" to differentiate the garment based on size. The speaker suggested CMS modify HCPCS Level II code E0731 language based on indication to differentiate between garments used for pain treatment and those used for indications other than pain. The speaker suggested, alternatively, CMS retain the existing HCPCS Level II code E0731 descriptor and reimbursement. The speaker also recommended that if CMS chooses to revise the HCPCS Level II code E0731 descriptor, then CMS should provide clear guidance to payers on the quantitative and qualitative properties of garments with higher and lower reimbursement schedules. The speaker aimed to assist CMS in developing a fee schedule for the ZIDA Wearable Neuromodulation System including the ZIDA Control Device and the ZIDA Control Sock. The ZIDA System utilizes Transcutaneous Tibial Nerve Stimulation for overactive (OAB) treatment, a method with a successful track record in neuromodulation for nearly 40 years.

The presentation at the public meeting compared the Zida System to existing neuromodulation devices reimbursed by CMS. Zida LLC proposed that CMS reference HCPCS Level II codes L8679 and K1018 for pricing input, emphasizing the cost-effectiveness of the ZIDA Control Device and the ZIDA Control Sock. The speaker also suggested that the pricing of the ZIDA Control Sock and other similar targeted nerve stimulation garments should be based on indication rather than size, citing its unique design and superior properties compared to other conductive garments. In conclusion, Zida LLC appreciate the opportunity to advocate for a fee schedule of at least $2,700 for the ZIDA Wearable Neuromodulation System's Control Device and $200 for the Control Sock, emphasizing their cost-effectiveness and potential to significantly impact the lives of patients with OAB, patients with disability, who experience social determinants of health, or reside in rural areas.

A commenter outlined certain concerns identified with respect to apparent limitations of the ZIDA device and inconsistencies with publicly available information. The commenter expressed concern that using the ZIDA as the only predicate to create the HCPCS Level II

[11] $75.00 - https://www.alimed.com/sock-conductive-fabric.html
[12] $89.25 - https://www.alimed.com/conductive-garment-glove.html
[13] $58.74 - https://www.atcmedical.com/Diagnostics/Nerve_Stimulation/FAGAR130/product.aspx
[14] $36.95 - https://www.tenspros.com/conductive-stimulation-sock-GU4025.html
[15] $43.97 - https://www.amazon.com/Silver-Conductive-Socks-Tens-Machine/dp/B07X27JXFT/ref=sr_1_3_sspa?keywords=Conductive%2BTherapy%2BShop&qid=1693502120&sr=8-3-spons&sp_csd=d2lkZ2V0TmFtZT1zcF9hdGY&th=1

codes quoted above could fail to account for these characteristics. First, the technical device and stimulation characteristics of the ZIDA device raise questions of effectiveness and patient safety, especially for a product used unsupervised by a patient in the home setting. Second, questions of clinical efficacy do not appear to be adequately addressed by the available clinical evidence evaluating the ZIDA device, which includes apparent inconsistencies and unexplained data variances in their published manuscript that call into question the true clinical effect of the device. Third, additional public information available from the ZIDA manufacturer (Exodus Innovations) raise concerns with how the device may be provided to Medicare beneficiaries and other patients, including whether fundamental Medicare compliance requirements will be met.

**CMS Final HCPCS Coding Decision**

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

1. Establish a new HCPCS Level II code E0736, "Transcutaneous tibial nerve stimulator" to describe ZIDA Wearable Neuromodulation control unit.

2. Assign existing HCPCS Level II code E0731, "Form fitting conductive garment for delivery of tens or nmes (with conductive fibers separated from the patient's skin by layers of fabric)" to describe ZIDA Wearable Neuromodulation control sock.

CMS agrees with retaining the existing HCPCS Level II code E0731 descriptor. The ZIDA control sock uses nerve stimulation through transcutaneous electrical stimulation of the posterior tibial nerve near the ankle. HCPCS Level II code E0731 is not limited to garments of a specific fabric or textile, garments with embedded electrodes, nor is it limited to garments with electrodes that can be replaced without replacing the garment.

**Final Medicare Benefit Category Determination**

Durable Medical Equipment.

**Final Medicare Payment Determination**

For the control sock, the payment rules and pricing associated with the existing code E0731 apply to this product, if covered. The average 2024 purchase fee schedule amount for E0731 is $194.21.

The average fee schedule amount is the average of the 2024 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 34

We will be deferring our payment determination for the control device. The applicant said in the public meeting that the MSRP for the control device is $2,700. When we asked the

applicant in the public meeting if they have any documentation from any other insurance payors showing that insurance payors are paying the $2,700 amount for the control device, the speaker said the device has not been available for sale yet, so they do not have that information. In our 2019 final rule that set regulations for establishing payment amounts for new DMEPOS items and services, we stated that CMS would not use the MSRP to set the fee schedule rates, and instead, will rely on fees for comparable items and verifiable supplier or commercial prices in an effort to best approximate reasonable charges from the fee schedule base period for the item (84 FR 60739). We therefore will be deferring our payment determination for the control device until we have obtained the information needed to establish the fee schedule amounts for this equipment.

In the interim, until national fee schedule amounts are established in accordance with the procedures at 42 CFR §414.240, local fee schedule amounts for the control device would be established by the DME MACs for any covered claims. If the purchase price used in calculating the fee schedule amounts is greater than $150, then payment would be made on a capped rental basis in accordance with our regulations at 42 CFR 414.229. If the purchase price used in calculating the fee schedule amounts is $150 or less, then payment would be made on a rental or purchase basis in accordance with our regulations at 42 CFR 414.220.

Pricing Indicator = 32

## HDF Assist Module - HCP230111XGWH3

### Topic/Issue

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

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

### Summary of Applicant's Submission

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

### CMS Preliminary HCPCS Coding Recommendation

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

### Summary of Public Feedback

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

### CMS Final HCPCS Coding Decision

Based on the information provided in the application to establish a new HCPCS Level II code and considering that no comments were received, CMS is finalizing its preliminary recommendation. CMS has not identified a program operating need for Medicare or other payers to establish a new Level II code to identify HDF Assist Module. This item is intended for use with a dialysis machine included in the clinical encounter payment, which is typically dialysis treatment for ESRD.

## iNAP One Sleep Therapy System Console - HCP230607VM24W

### Topic/Issue

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

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

### Summary of Applicant's Submission

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

### CMS Preliminary HCPCS Coding Recommendation

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

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

### Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

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

Also, Chapter 15, Section 110.3 of the Medical Benefit Policy Manual (CMS Pub. 100-02) indicates that payment may be made for replacement of essential accessories such as mouthpieces, tubes, etc., for necessary DME, if the patient owns or is purchasing the

equipment. Thus, the existing HCPCS Level II codes for accessories are available for the iNAP One Sleep Therapy System: A7047, "Oral interface used with respiratory suction pump, each"; A7001, "Canister, non-disposable, used with suction pump, each"; A7002, "Tubing, used with suction pump, each"; and E9900, "Miscellaneous DME supply or accessory, not otherwise specified."

**Preliminary Medicare Payment Determination**

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

The average fee schedule amount is the average of the 2023 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 36

**Summary of Public Feedback**

Somnics Inc. disagreed with CMS' published preliminary recommendations. According to the speaker, devices described by HCPCS Level II code E0600 are primarily fluid evacuation pumps used consistently during treatment with no monitoring, data collection, and reporting of adherence capabilities. The iNAP pump uses intermittent suction for positioning the tongue and tissues for airway clearance. Once pressure is achieved the pump stops and iNAP's primary function is maintaining negative pressure in the oral cavity, monitored via sensors, with patient usage and adherence data relayed to the smartphone application. According to the speaker, the device is tunable to patients' needs via the application, by adjusting the target pressure and/or the intensity of suction, the time it takes to achieve target pressure.

**CMS Final HCPCS Coding Decision**

We appreciate the comments provided in response to CMS' published preliminary recommendations. Based on the information provided in the application and after consideration of the comments we received, CMS requires additional time to consider Somnics's request to establish a new HCPCS Level II code to identify iNAP One Sleep Therapy System Console. As a result, CMS is deferring this application to a subsequent biannual coding cycle.

**Final 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.

Following the review of information submitted with the application, additional information was provided by the applicant during the public meeting related to the iNAP One Sleep Therapy System smartphone app. The iNAP System operates with an app on a smartphone owned by the patient or caregiver to turn on, turn off, and activate iNAP One Sleep Therapy System programs. Without use of the smartphone app to operate the device, information and accumulated data on the oral negative pressure of the patient is not available. However, the issue of whether the device incorporates a dedicated component that operates the iNAP One Therapy System is not clarified. Additional information on the smartphone app's purpose, specifically what functions it performs, was not provided. Also, while the applicant clarified that the iNAP One Sleep Therapy System can operate in the absence of a smartphone app, a description of which functions the System can still perform without the app was unclear. This information is important as a smartphone is not DME because it can be useful to an individual in the absence of an illness or injury.

Also, in accordance with 42 CFR 414.202, equipment furnished by a supplier or a home health agency must have an expected life of at least 3 years to be classified as DME. Durability of an item should be tested over the entire system or device and not an individual component. CMS has not yet been presented with evidence that the device itself would last for 3 years when used without a smartphone. For example, the manufacturer can provide standardized test results from an independent testing laboratory demonstrating that the device itself can last and operate for at least 3 years without the smartphone. As a result, the information provided by the applicant does not support a final benefit category determination. We are deferring a benefit category decision until the applicant provides further information and analysis of the components for CMS.

**Final Medicare Payment Determination**

No determination. In the meantime, classification, coverage, and payment for these items will be made on an individual claim-by-claim basis by the Medicare Administrative Contractors (MACs).

## VOCSN VC and VOCSN VC Pro - HCP23063079G6K

### Topic/Issue

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

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

### Summary of Applicant's Submission

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

### CMS Preliminary HCPCS Coding Recommendation

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

### Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

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

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

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

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

The VOCSN VC devices meet these requirements to be classified as DME. Additionally, they fall under the multi-function ventilators definition in 42 CFR §414.222(f)(1).

**Preliminary Medicare Payment Determination**

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

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

Pricing Indicator = 31

**Summary of Public Feedback**

React Health agreed with CMS' preliminary recommendation to establish a new HCPCS Level II code; however, React Health requested CMS review the preliminary Medicare payment determination. They explained that the VOCSN VC Pro configuration contains hardware components to facilitate a high pressure (50 PSI) wall oxygen connection and entrainment as well as a low flow connection for oxygen entrainment, making the VOCSN VC Pro suitable for both hospital and home use. The VOCSN VC configuration only facilitates a low flow, bleed in oxygen connection making this configuration suitable for home use. The speaker clarified that there are physical differences between different models. React Health adds extra hardware components for each model configuration. There are different manufacturing processes for the various configurations. They asked to review the HCPCS Level II code A7020 circuit replacement allowable currently available for the HCPCS Level II code E0482 that does not appear to have been factored into the proposed fee schedule for months 14-60 under the current reimbursement timeframe calculation.

**CMS Final HCPCS Coding Decision**

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

Establish a new HCPCS Level II code E0468, "Home ventilator, dual-function respiratory device, also performs additional function of cough stimulation, includes all accessories, components and supplies for all functions" to describe VOCSN VC and VOCSN VC Pro.

**Final Medicare Benefit Category Determination**

Durable Medical Equipment.

**Final Medicare Payment Determination**

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

Per §414.222(f)(2), the monthly rental fee schedule amount for this multi-function ventilator is equal to the monthly rental fee schedule amount for the ventilator established in paragraph (c) and paragraph (d) of this section plus the monthly cost for the cough stimulating function, which is calculated by dividing the purchase fee for the item by 60. For example, the 2024 monthly rental fee schedule amount for Alabama for the ventilator is $1,107.04 and the purchase fee schedule amount of $5,745.40 for Alabama for the cough stimulator divided by 60 is $95.76. The 2024 monthly rental fee schedule amount for Alabama for this multifunction ventilator would therefore be $1,202.80 ($1,107.04 + $95.76).

Finally, with regard to the applicant's comment about factoring in payment for A7020, E0468 falls under the frequent and substantial servicing payment category, which is described under 1834(a)(3), and this payment category already includes payment for all necessary accessories and supplies. Furthermore, as indicated above, the monthly rental fee schedule amount for E0468 includes payment for E0482 over the 60 months.

Pricing Indicator = 31

## Et Control - HCP230630ETU8C

### Topic/Issue

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

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

### Summary of Applicant's Submission

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

### CMS Preliminary HCPCS Coding Recommendation

EtC is not suitable for coding in the HCPCS Level II code set because it is used in facility settings during procedures reported using a HCPCS Level I Current Procedural Terminology (CPT®) code. We have not identified a specific need for this device to be separately paid, since we believe that a particular payer may elect to pay for the service in which this device is used. For instance, Medicare would typically reflect the costs of the device in the payment for the procedure, if it is used, and as such it would not be separately payable.

### Summary of Public Feedback

GE HealthCare has accepted CMS’ published preliminary recommendation. A comment from the applicant stated they were disappointed with CMS’ decision, however, “we will not contest this decision and have no additional comments.”

**CMS Final HCPCS Coding Decision**

We appreciate the comments provided in response to CMS' published preliminary recommendations. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary recommendation. EtC is not suitable for coding in the HCPCS Level II code set because it is used in facility settings during procedures reported using a HCPCS Level I Current Procedural Terminology (CPT®) code. We have not identified a specific need for this device to be separately paid, since we believe that a particular payer may elect to pay for the service in which this device is used. For instance, Medicare would typically reflect the costs of the device in the payment for the procedure, if it is used, and as such it would not be separately payable.

## TytoHome™ System - HCP230629G0JV5

### Topic/Issue

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

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

### Summary of Applicant's Submission

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

### CMS Preliminary HCPCS Coding Recommendation

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

### Summary of Public Feedback

Tyto Care, Inc. disagreed with CMS’ preliminary recommendation. The speaker stated that TytoHome™ device and software solution is the first all-in-one telemedicine solution, able to perform full-body, remote physical examinations and should be separately payable. They stated, that Elevance Health, formerly Anthem Healthcare, seeks designation of a new HCPCS Level II S code for TytoHome™ to assist Elevance in the expansion of its remote physical examination program. Issuance of an S code would allow Elevance to streamline billing and reimbursement process, improve transparency, and reduce errors and rejections. The speaker stated that the TytoHome™ performs substantially more physiologic measures than occurs with standard audio/visual telehealth encounters. Medicare does not reflect the

cost of robust telemedicine equipment comparable to the TytoHome™ in any HCPCS Level I code. Therefore, the functionality of the TytoHome™ is not included in any existing HCPCS Level II code. The speaker recommended review and comparison of this coding request to the one submitted by Pear Therapeutics for its reSET Device.

In the written comment submitted by the Elevance Health, they disagreed with CMS' HCPCS Level II preliminary recommendation to reflect the cost of TytoHome™ System in the payment for the physician service/procedure and to not be separately payable. They stated that a new HCPCS Level II S code that accurately reflects the TytoHome™ and associated service, is necessary and beneficial for their eligible members to have access to the most up-to-date and effective treatments and procedures. They believe that the use of TytoHome™ will have a significant impact on the quality of care their members receive. They added, that during the last three years, their members have had access to the TytoHome™ and associated service, and more than 17,000 TytoHome™ products have already been distributed to the eligible recipients. The company expects these numbers to significantly increase soon, and therefore a new HCPCS Level II code would help to streamline the billing and reimbursement process, improve transparency, and reduce errors and rejections.

**CMS Final HCPCS Coding Decision**

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, we believe this request should be considered under the Potentially Misvalued Codes Initiative, which examines concerns regarding valuation of existing Current Procedural Terminology (CPT®) codes. At this time, no additional information is needed from the applicant.

## VECTRA™ Drug Delivery Microsponge - HCP23063003PFV

### Topic/Issue

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

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

### Summary of Applicant's Submission

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

### CMS Preliminary HCPCS Coding Recommendation

Our understanding is that the VECTRA™ drug delivery microsponge is not suitable for inclusion in the HCPCS Level II code set because it is used during a procedure and certain items are considered bundled into the facility payment. We have not identified a specific need for this microsponge to be separately paid, since we believe that a particular payer may elect to pay for the service in which this device is used. For instance, Medicare would typically reflect the costs of the device in the payment for the procedure, if it is used, and as such it would not be separately payable.

### Summary of Public Feedback

Hemostasis, LLC disagreed with CMS’ preliminary recommendation. The speaker stated that VECTRA™ was designed to address the significant issues surgeons encounter in treating patients undergoing sinus surgery. Following surgery to remove diseased tissue in the sinuses, the ostia in the frontal, maxillary, and sphenoid sinuses may completely close in about 20 percent of patients, thereby requiring additional surgery to reopen the ostia. Steroid nasal sprays are not effective because the sprays are unable to reach and remain within the surgical area. The PROPEL drug-eluting, resorbable polymeric structure was designed to

address these shortcomings. The PROPEL device is coated with a steroid (mometasome furoate) and placed during surgery to provide localized drug delivery over several days. Subsequently, the VECTRA™ drug delivery microsponge was developed to provide localized drug delivery to the sinus ostia over an extended period of time. They added that VECTRA™ provides several benefits over other options to deliver steroids topically to the site of surgery. First, the VECTRA™ allows the physician to use the steroid of their choice for localized drug delivery. Second, by delivering the steroids topically to the surgical area, the VECTRA™ reduces post-operative scarring and inflammation. Third, the VECTRA™ can be inserted post-operatively in the office if the surgeon feels the targeted steroid delivery to specific areas would be beneficial.

Another speaker stated that there were significant issues in treating patients undergoing sinus surgery, particularly the ostia of the frontal, maxillary and sphenoid sinuses. Steroid nasal sprays were used post-surgery to aid in reducing inflammation and accelerating the healing process in the nasal cavity and sinuses. An advancement in delivering localized drug delivery to the sinuses and ostia came with the introduction of the PROPEL drug eluting stent. The PROPEL device is a resorbable polymeric structure which is coated with a steroid (mometasome furoate). The device is placed in the sinus or ostia after surgery to provide continuous localized drug delivery over a period of time. This provided better outcomes and studies showed revision surgery rates were reduced from 18% to less than 8% for frontal sinus surgery. The VECTRA™ drug delivery microsponge was designed to allow for localized drug delivery to the sinus ostia an extended period of time like the PROPEL device. Typical steroids used are mometasome furoate, triamcinolone, or other steroids used in nasal sprays. Patients obtain similar or better outcomes with the VECTRA™ device over the PROPEL device. The PROPEL device has had reimbursement from commercial payers for many years. PROPEL was assigned a HCPCS Level II code S1091. Commercial payers reimburse for these drug eluting stents when they are used after surgery and in the office. The cost for each PROPEL device is over $1,000. While many commercial payers reimburse for these devices, it is expensive to the health care system and lower cost alternatives are needed. The VECTRA™ device cost is approximately $215 per device which represents a considerable savings. Surgeons and facilities would prefer to use the VECTRA™ device but need to have a HCPCS Level II code for VECTRA™ in order to obtain reimbursement from commercial payers.

**CMS Final HCPCS Coding Decision**

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary recommendation. Our understanding is that the VECTRA™ drug delivery microsponge is not suitable for inclusion in the HCPCS Level II code set because it is used during a procedure and certain items are considered bundled into the facility payment. We have not identified a specific need for this microsponge to be separately paid, since we believe that a particular payer may elect to pay for the service in which this device is used. For instance, Medicare would typically reflect the costs of the device in the payment for the procedure, if it is used, and as such it would not be separately payable.

The information provided by the speakers regarding the usage, cost of VECTRA™, and its comparison to PROPEL, did not change CMS' understanding that VECTRA™ is used during a procedure and certain items are considered bundled into the facility payment as such it is

not suitable for inclusion in the HCPCS Level II. We also note that the PROPEL Contour Sinus Implant received FDA's premarket approval as Class III device. The implant contains mometasone furoate (active ingredient), a synthetic corticosteroid with anti-inflammatory activity. In contrast, VECTRA™ is a Class 1 product and exempt from the FDA review. In 2020, CMS established a new HCPCS Level II code S1091, "Stent, non-coronary, temporary, with delivery system (propel)" and a new HCPCS Level II code J7402, "Mometasone furoate sinus implant, (sinuva), 10 micrograms" to distinguish PROPEL Sinus Implant from Sinuva Sinus Implant that has a New Drug Application (NDA) approval from the FDA.

## Natural Cycles – HCP230626HDWY2

### Topic/Issue

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

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

### Summary of Applicant's Submission

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

### CMS Preliminary HCPCS Coding Recommendation

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

### Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

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

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

5. Is appropriate for use in the home.

All five of these conditions must be met for equipment to be classified as DME. Software applications (apps) are not devices, equipment, or supplies and therefore would not fall under a DMEPOS benefit category. The DME benefit is for equipment such as a wheelchair, hospital bed, ventilator, or oxygen concentrator rented to a patient for use in their home. Standalone software apps do not work unless the patient also has a smartphone, computer or another type of durable device that would enable use of the software. These durable devices are generally useful to individuals in the absence of illness or injury and are therefore not DME. Without the durable device which runs the software app, the software would not work. Therefore, standalone software apps are not DME.

Whether or not the software could fall under some other Medicare benefit category can be considered but would not be addressed under the DMEPOS BCD process.

**Preliminary Medicare Payment Determination**

No Medicare payment. Pricing Indicator = 00

**Summary of Public Feedback**

Natural Cycles USA Corp. agreed with CMS' published preliminary HCPCS coding recommendation to establish a new HCPCS Level II code. However, the speaker recommended revising CMS' proposed code descriptor language to: "Fertility software application for contraception, fda cleared, per course of treatment 12-month duration, includes accessories (e.g., thermometer)." Natural Cycles is a "software application for contraception" cleared by the FDA as a class II medical device under the "contraception" PYT product code and meets the Department of Labor's definition of a covered contraceptive product. Patients, payers, and the FDA make clear distinctions between the use of an app for 'fertility' (i.e., planning a pregnancy), and for 'contraception' (i.e., preventing a pregnancy). The FDA distinguishes between "fertility" and "contraception" by using different risk categories and product codes, unclassified & LHD and class II & PYT respectively. National and regional payers (e.g., Aetna) have published medical policies to pay for software applications for contraception as they are medically necessary per federal preventive care mandates. These policies do not apply to products used for fertility. Finally, the software application is available as an annual subscription (12-month duration plan). The requested clarification of the HCPCS Level II code description to specifically include "for contraception" and "12-month duration" ensures that patients will be able to have their preferred contraceptive method covered without cost-sharing, as required under the Affordable Care Act, and also aligns language with the current FDA classification and revised payer policies.

**CMS Final HCPCS Coding Decision**

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

Establish a new HCPCS Level II code A9293, “Fertility cycle (contraception & conception) tracking software application, fda cleared, per month, includes accessories (e.g., thermometer)”

CMS agreed with the applicant to revise the code language “per course of treatment” and set a certain length of time. We believe that “per month” is the best description of a fertility cycle. A single claim could be submitted for 12 units, if a payer agrees to pay for an extended period of time (e.g., a year). However, CMS disagrees with the applicant regarding the request to remove the word fertility and replace it with contraception. Natural Cycles is approved by the FDA to monitor fertility, which includes the use of preventing or planning a pregnancy. As such, we believe the HCPCS Level II code should describe the whole product. Modifiers may also be assigned by the payer for specific clinical indications, such as contraception rather than conception (planning a pregnancy), and for no-cost sharing if necessary to effectuate cost sharing differences.

**Final Medicare Benefit Category Determination**

No Medicare DMEPOS benefit category.

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

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

All five of these conditions must be met for equipment to be classified as DME. Software applications (apps) are not devices, equipment, or supplies and therefore would not fall under a DMEPOS benefit category. The DME benefit is for equipment such as a wheelchair, hospital bed, ventilator, or oxygen concentrator rented to a patient for use in their home. Standalone software apps do not work unless the patient also has a smartphone, computer or another type of durable device that would enable use of the software. These durable devices are generally useful to individuals in the absence of illness or injury and are therefore not DME. Without the durable device which runs the software app, the software would not work. Therefore, standalone software apps are not DME.

Whether or not the software could fall under some other Medicare benefit category can be considered but would not be addressed under the DMEPOS BCD process.

**Final Medicare Payment Determination**

No Medicare payment. Pricing Indicator = 00

## Leva Pelvic Health System – HCP2306304CXRL

### Topic/Issue

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

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

### Summary of Applicant's Submission

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

### CMS Preliminary HCPCS Coding Recommendation

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

### Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

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

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

All five of these conditions must be met in order for equipment to be classified as DME. The Leva Pelvic Health System does not meet three of these conditions as follows:

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

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

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

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

**Preliminary Medicare Payment Determination**

No Medicare payment. Pricing Indicator = 00

**Summary of Public Feedback**

Axena Health, Inc. agreed with CMS' preliminary recommendations; however, Axena Health, Inc. requested CMS revise the proposed code language. The speaker requested the code language to read "Intra-vaginal motion sensor pelvic floor muscle treatment device", thus substituting "pelvic floor muscle treatment" for "biofeedback". The recommended change is needed so that the descriptor language better aligns with the indications for use of the device and the description in the Food and Drug Administration (FDA) 510(k) clearance summary. The indications of the Leva Pelvic Health System as listed in the 510(k) summary are strengthening of the pelvic floor muscles, rehabilitation and training of weak pelvic floor

muscles for the treatment of stress, mixed and mild to moderate urgency urinary incontinence (including overactive bladder), and rehabilitation and training of weak pelvic floor muscles for the first-line treatment of women with chronic fecal incontinence (>3-month uncontrolled passage of feces). The common thread among these indications is use as a pelvic floor muscle treatment. The Leva Pelvic Health System is a prescription intravaginal device. Importantly, neither the intended uses nor device description from the FDA use the term "biofeedback". Revising the HCPCS Level II code descriptor better aligns to the FDA indications and device description and is essential to assist coders and payers in the submission and processing of claims. When the code descriptor falls short of describing the intended use, it initiates significant internal processes to confirm the claim is legitimate to treat the intended medical condition. When a code descriptor does not meet the intended use, it unfortunately initiates our Special Investigative Unit (SIU) to be involved in every claim, ensuring the appropriate and approved clinical service is indeed being supplied.

CMS received a comment from a payer stating that code descriptors may be broad enough, so they are applicable to a number of proven technologies with the same intended use but narrow enough so that processing claims are not for technologies that are not prescribed by a qualified healthcare providers or for over-the-counter products. In this case, we cannot have products like vibrators and vaginal wall stimulators using this code because they have a sensor and they go in the vagina when the intent of the type of device is to treat the pelvic floor muscles and medical conditions of urinary and fecal incontinence. This will assist us as a payer processing claims for this treatment for women with urinary and fecal incontinence in an appropriate timeframe, meeting the expectations of our members while maintaining appropriate healthcare costs.

The Leva Pelvic Health System addresses significant barriers to access, making it possible to perform the pelvic floor muscle treatment from the privacy of the home and to initiate care within days of prescribing this first-line treatment. Additionally, this small modification will also assist access for patients by streamlining the prescribing process and eliminating the need for prior authorizations. However, the speakers are concerned that the HCPCS Level II code descriptor proposed in the preliminary coding recommendation will lead to confusion regarding when to bill this HCPCS Level II code, given the use of the word, "biofeedback device." For example, there are HCPCS Level I Current Procedural Terminology (CPT®) codes for biofeedback training and the use of the term biofeedback in the code descriptor for this device might lead coders to think that the device should be used in connection with such CPT® codes. However, the device is for home use, whereas the biofeedback training codes are for use with a health care practitioner.

**CMS Final HCPCS Coding Decision**

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

Establish a new HCPCS Level II code S9002, "Intra-vaginal motion sensor system, provides biofeedback for pelvic floor muscle rehabilitation device" to describe Leva Pelvic Health System.

Despite the manufacturer's omission of the term "biofeedback" in their product information, we believe that the described mechanism involves biofeedback. Some private payer policies identify Leva Pelvic Health System as a biofeedback therapy service. We further note that there are multiple indications listed on the FDA 510(k), and we generally do not enumerate the device's indications in the HCPCS Level II code descriptor.

**Final Medicare Benefit Category Determination**

No Medicare DMEPOS benefit category.

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

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

All five of these conditions must be met in order for equipment to be classified as DME. The Leva Pelvic Health System does not meet three of these conditions as follows:

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

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

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

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

**Final Medicare Payment Determination**

No Medicare payment. Pricing Indicator = 00

## Restorex Penile Traction Device - HCP23061702CGD

### Topic/Issue

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

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

### Summary of Applicant's Submission

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

### CMS Preliminary HCPCS Coding Recommendation

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

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

### Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category**.**

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

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

All five of these conditions must be met in order for equipment to be classified as DME. With respect to the first condition, Durable Medical Equipment is a benefit for rental of medical equipment for use in the home and therefore DME items must be able to withstand repeated use by successive patients in accordance with Medicare regulations and as indicated in Medicare program instructions at Chapter 15, Section 110.1 of the Medicare Benefit Policy Manual (CMS Pub. 100-02) and Chapter 1, Part 4, Section 280.1 of the Medicare National Coverage Determinations Manual (CMS Pub. 100-03). The Restorex Penile Device is intended for single patient use and therefore cannot withstand repeated use.

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

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

**Preliminary Medicare Payment Determination**

No Medicare payment. Pricing Indicator = 00

**Summary of Public Feedback**

PathRight Medical disagreed with the preliminary recommendations. The speaker requested CMS to establish an E code, not an S code, and to also establish specific criteria required to meet the code (i.e., “Penile contracture device, manual, >3 lbs traction force”). This would help to differentiate between the first- and second-generation devices. The speaker also stated that this device would also qualify as DME, since it does have a 3-year usable life and could be used by successive patients. The updated Instructions for Use (IFU) indicate that repeated use for sequential patients is viable. Restorex therefore, specifically meets all 5 criteria for DME: repeated use, 3-year life expectancy, primarily used for medical purpose, generally not useful in absence of illness/injury, and, used in home. It is notable to mention that no other traction device meets DME criteria at the present time, and that current 1st generation traction devices are not likely legitimate therapies, in that they do not generate sufficient traction to work (essentially all only generate 1 lb. or less of force). Because of this, the recommendation is to use these devices for 2-9 hours daily, and several studies have shown that patients simply are unable to even do the therapy. Even when patients do achieve this, there are still studies showing no efficacy. Second generation penile traction devices have consistent data demonstrating efficacy with 100 percent of publications at this point demonstrating consistent benefits in multiple disease subtypes. The first randomized, controlled trial demonstrating efficacy validated the need to achieve at least 3 lbs. of traction force to achieve improvements (something which no 1st generation device has accomplished). Additionally, counter-bending was shown to be important in achieving benefits, something which no first-generation device achieves. Typically, there are differentiations when a therapy has distinctive mechanisms and/or distinctive intensity/force applied. Second generation traction meets both of these criteria. Specifically, second generation traction provides 2 distinctive mechanisms for treatment. It provides for the ability

to dynamically lengthen while traction is being applied to an unlimited extent. All first-generation devices are only able to further lengthen a small amount (typically 1-2 cm at most). Restorex is also uniquely able to counter-bend to treat diseased areas. No first-generation device has this ability, which was shown in the first randomized, controlled trial to be important in achieving improvements with Peyronie's disease. Again, second generation traction also applies more intensity/force than first generation devices. All first-generation devices apply ~1 lb. of force, which was shown in the first Restorex randomized, controlled trial to be inadequate to achieve benefits. Greater than (>) 3 lbs. is the minimum requirement needed to achieve benefits, and only second-generation traction achieves this level (applies 3-7 lbs. straight and up to >10 lbs. counter-bent).

**CMS Final HCPCS Coding Decision**

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

Establish a new HCPCS Level II code S4988, "Penile contracture device, manual, greater than 3 lbs traction force" to describe Restorex Penile Traction Device.

**Final Medicare Benefit Category Determination**

No Medicare DMEPOS benefit category.

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

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

All five of these conditions must be met for equipment to be classified as DME. Based on the information in the application and provided during the public meeting process, the applicant discussed recent changes to the device IFU to support repeated use by successive patients and an expected useful life of at least 3 years. However, a text update to the IFU is not sufficient to establish successive repeated use and expected useful life of at least 3 years. We welcome more information demonstrating how Restorex Penile Traction Device meets these classification conditions. Currently, the information for this item has not demonstrated these conditions and thus the device is not considered DME.

**Final Medicare Payment Determination**

No Medicare payment. Pricing Indicator = 00

## ProVate Vaginal Support - HCP230628N8LUJ

### Topic/Issue

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

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

### Summary of Applicant's Submission

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

### CMS Preliminary HCPCS Coding Recommendation

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

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

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

We recommend adding reusable to existing HCPCS Level II code A4561 and A4162 to clearly distinguish it from the newly established HCPCS Level II code AXXXX. Also, we recognize a distinction in the replacement frequency for a disposable pessary device may be up to seven days, whereas one pessary per six months is the Medicare allowable replacement

frequency for a reusable pessary. The distinction in duration of use contributes to revising existing codes A4561 and A4562.

**Preliminary Medicare Benefit Category Determination**

Prosthetic device.

In accordance with Medicare program instructions at Chapter 15, Section 120 of the Medicare Benefit Policy Manual (CMS Pub. 100-02), prosthetic devices (other than dental) are devices which replace all or part of an internal body organ (including contiguous tissue) or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ. Repairs, adjustments, and replacement of medically necessary prosthetic devices are covered. Coverage under this benefit includes pessary items.

**Preliminary Medicare Payment Determination**

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

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

The average fee schedule amount is the average of the 2023 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 38

**Summary of Public Feedback**

ConTIPI Medical agreed with the preliminary decision to issue a HCPCS Level II code for ProVate vaginal support, however, disagreed with the decision regarding the preliminary Medicare payment determination of the device. The speakers did not agree with CMS' preliminary Medicare payment determination to anchor the Medicare payment rate for ProVate to that of a traditional non-rubber pessary. The speakers indicated costs of the ProVate device are greater than other pessaries. The speakers indicated manufacturing of the device requires sophisticated plastic molds, assembly and packaging, strict quality assurance, and shipping delivery to users' homes. The speakers urged CMS to not finalize its preliminary payment determination that would set a payment rate below the manufacturing cost of the device. Instead, CMS should determine that ProVate is not comparable to a non-rubber pessary, and review information from ConTIPI Medical regarding the list price of ProVate. This pricing approach would result in a more equitable reimbursement rate and

ensure access to this treatment for Medicare beneficiaries suffering from pelvic organ prolapse.

**CMS Final HCPCS Coding Decision**

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

1. Establish a new HCPCS Level II code A4564, "Pessary, disposable, any type" to describe ProVate.

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

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

We recommend adding reusable to existing HCPCS Level II code A4561 and A4162 to clearly distinguish it from the newly established HCPCS Level II code A4564. Also, we recognize a distinction in the replacement frequency for a disposable pessary device may be up to an average of seven days, whereas one pessary per six months is the Medicare allowable replacement frequency for a reusable pessary. The distinction in duration of use contributes to revising existing codes A4561 and A4562.

**Final Medicare Benefit Category Determination**

Prosthetic device.

**Final Medicare Payment Determination**

No determination. More time is needed to evaluate additional information provided recently by the manufacturer to determine how these items and services can be priced under Medicare Part B. In the meantime, payment for any covered items will be made on an individual claim-by-claim basis by the MACs.

Pricing Indicator = 46

## MyoPro® – 18.118

### Topic/Issue

Request for Medicare payment determination for MyoPro®.

### Applicant's Summary

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

The MyoPro® Motion G is an elbow-wrist-hand-finger device that has two degrees of freedom and a multi-articulating wrist joint. Common components are upper-arm shell, harness attachment, upper-arm sensor cuff, upper arm closure, battery compartment, forearm closure, forearm bar, forearm shell, control panel, elbow motor, wrist joint, hand motor and hand support shell. The wrist and hand shells are attached by a rigid wrist extension and is at a fixed angle. The entire device for utilizes a single rigid metal upright linking all components to the joints into a single device. Straps and padding are used to anchor the device to the patient's upper extremity. This device has two replaceable batteries with charging stand, circuit board, and a motor mounted at the elbow joint, permitting microprocessor mediated, volitionally controlled, elbow flexion and extension. Patients can also use a laptop with software-based, settings-control interface accessed through wireless connectivity to adjust the input settings/sensitivity in real-time when needed. Patients use their muscle signals to control movements of a paretic or weakened limb. When the patient

tries to bend their arm, or open and close their hand, precision sensors in the brace detect the weak muscle signals which activate motors to move the hand and arm in the desired directions. The surface EMG sensors continuously monitors and senses, but does not stimulate, the patient's muscles. The MyoPro® filters and processes the EMG signal and translates this information into motor movement. The power assist moves the motor with speed proportional to patient's exertion. The direction of motion is determined by which set of sensors are triggered. A microprocessor amplifies the acquired signal to power electric motors to initiate and complete desired movement in the elbow and fingers. The primary purpose of the MyoPro® is to assist upper extremity joint motion in a weakened body member to improve the beneficiary's functional activities of daily living.

**CMS HCPCS Coding**

CMS established HCPCS Level II code L8701, "Powered upper extremity range of motion assist device, elbow, wrist, hand with single or double upright(s), includes microprocessor, sensors, all components and accessories, custom fabricated" to describe MyoPro® Motion E and Motion W and 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" to describe MyoPro® Motion G, effective January 1, 2019.

**Medicare Benefit Category Determination**

CMS determined through rulemaking that MyoPro® is an arm brace (CMS-1780-F).

**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 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(h)(4) of the Social Security Act for prosthetic devices and orthotics and prosthetics.

In determining whether the devices described by L8701 and L8702 are comparable to items with existing codes and fee schedule amounts, we undertook a detailed examination of the physical, mechanical, and electrical components along with the function and intended use. Although we believe that portions of the devices could be comparable to a combination of products described by existing codes, we believe that the overall form and function of these upper extremity exoskeletons incorporate revolutionary features (such as self-powered responses to myoelectric inputs) and cannot be compared to any other devices. 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).

In order to develop an appropriate Medicare payment amount in accordance with this procedure, we must identify appropriate commercial pricing for the underlying items. We would 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).

For L8701, the most recent commercial pricing we have found is that which was submitted as part of the original application in 2018. This application demonstrated an average price of $40,148 for the two models described by L8701. The annual deflation factors are specified in program instructions and the deflated amounts are then increased by the update factors specified in section 1834(h)(4) of the Act. The average 2023 purchase fee schedule amount for L8701 would be approximately $31,745.42.

For L8702, the most recent commercial pricing we have found is from 2023, with an average price of $95,281 for the model described by L8702. The annual deflation factors are specified in program instructions and the deflated amounts are then increased by the update factors specified in section 1834(h)(4) of the Act. The average 2023 purchase fee schedule amount for L8702 would be approximately $62,457.28.

Pricing indicator = 38

**Summary of Public Feedback**

Myomo Inc. agreed in writing with CMS's published preliminary recommendation.

**Final Medicare Payment Determination**

The fee schedule amounts will be established as discussed in the preliminary determination. For L8701, the average 2024 purchase fee schedule amount will be $33,480.90. For L8702, the average 2024 purchase fee schedule amount will be $65,871.74.

Pricing indicator = 38

## ReWalk Personal Prosthetic Exoskeleton System – 20.085

### Topic/Issue

Request for Medicare payment determination for ReWalk.

### Applicant's Summary

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

### CMS HCPCS Coding

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

### Medicare Benefit Category Determination

CMS determined through rulemaking that ReWalk is a leg brace (CMS-1780-F).

### 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 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(h)(4) of the Social Security Act for prosthetic devices and orthotics and prosthetics.

In determining whether the devices described by this code are comparable to items with existing codes and fee schedule amounts, we undertook a detailed examination of the physical, mechanical, and electrical components along with the function and intended use. Although we believe that portions of the devices could be comparable to a combination of existing products described by existing codes, we believe that the overall form and function of these lower extremity exoskeletons incorporate revolutionary features (such as self-powered responses to inputs) and cannot be described by any existing codes. For this reason, we have determined it is most appropriate to determine the Medicare payment amount in accordance with the "gap filling" procedure outlined in 42 CFR 414.238(c).

We understand that since the original application, ReWalk has increased the MSRP for their device described by this code. We would note that for gap filling purposes, we can only use verifiable supplier or commercial pricing – that is, there must be evidence of genuine market transactions at a certain price. We have verifiable commercial pricing from the original application; the average of the prices of these 2020 market transactions was $125,500. We note that ReWalk is not the only device on the market described by K1007. We welcome any information from other makers of bilateral, lower limb exoskeletons to ensure that the Medicare payment amount for this code accurately reflects the full market of devices that would be classified in this code.

The annual deflation factors are specified in program instructions and the deflated amounts are then increased by the update factors specified in section 1834(h)(4) of the Act. Based on available, verifiable commercial pricing, the average 2023 purchase fee schedule amount for K1007 would be approximately $94,616.95.

Pricing Indicator = 38

**Summary of Public Feedback**

Lifeward LTD, rebranded from ReWalk Robotics, disagreed with the preliminary payment determination. They expressed concern that CMS had used 2020 pricing information for a ReWalk model that is no longer commercially available. In March 2023, Lifeward received FDA 510(k) clearance for a new version. When asked to describe the differences between the old and new versions in more detail, the speaker explained that the new version has improved functionality for ambulation over curbs and on stairs, with strengthened components to reflect this additional functionality. In support of the current (2023) pricing, the company submitted examples of verifiable transactions with the Veterans Administration (VA) at the Federal Supply Schedule contracted price of $101,437.69, and two commercial sales at different prices that the company argued do not represent "widespread" pricing for the current ReWalk device. In addition, the company provided a number of Medicare claims citing total charges of $186,000, which they believe most accurately reflect "widespread" current prices and believe would be the most appropriate price to use for gap-fill purposes.

In addition to the primary speaker for Lifeward, representatives from several other manufacturers of exoskeletons provided public comment. A representative of Trexo Robotics spoke about their pediatric exoskeleton, used to improve mobility for children with ambulatory impairments. In addition, a representative of Ekso Bionics introduced their Indego personal exoskeleton, currently in the process of PDAC code verification. Both speakers expressed their appreciation for the determination that exoskeletons can be categorized as braces.

**Final Medicare Payment Determination**[16]

We agree with the comments provided by Lifeward that the preliminary payment determination was calculated based on prices for an older version of the ReWalk device and that pricing for the current version of the ReWalk device should be used in establishing the fee schedule amounts for code K1007. Comments were also provided at the public meeting by Ekso, manufacturer of the Indego® Personal exoskeleton, identifying another product falling under code K1007. The final payment determination for code K1007 is to establish the fee schedule amounts based on pricing for the exoskeleton devices that would be classified under code K1007. We were aware of pricing from multiple manufacturers, and we averaged the average price[17] of each manufacturer's current prices paid by commercial payers and the Department of Veterans Affairs to establish a current price of $125,951.75 for K1007. Consistent with our regulations, the Medicare fee schedule amount is calculated by deflating current prices for items described by code K1007 to the fee schedule base period, and then applying the update factors as specified in section 1834(h)(4) of the Social Security Act. The average of the deflated and updated prices for the devices that would be classified under code K1007 results in a 2024 Medicare purchase fee schedule amount of $91,031.93.

Pricing Indicator = 38

[16] Revised on April 11, 2024 to reflect an updated payment determination.

[17] An illustrative example of "the average of averages" cited above:
Step 1: (Manufacturer A VA + Manufacturer A private payer + Manufacturer A private payer#2)/3 = W
Step 2: (Manufacturer B VA + Manufacturer B private payer)/2 = X
Step 3: (Manufacturer C VA + Manufacturer C private payer + Manufacturer C private payer#2)/3 = Y
Step 4: (W+X+Y)/3 = Z
Certain aspects of the information are considered commercial confidential.

## External Chest Compressor - HCP230628J67H1

### Topic/Issue

Request to establish a new HCPCS Level II code to identify external chest compressor.

Applicant's suggested language: XXXXX, “External chest compressor, anterior and posterior sagittal control, produces intracavitary pressure, anterior extends from 3 inches superior to pectus prominence to 3 inches inferior to pectus prominence, rigid circumferential frame with rigid pads, anteriorly and posteriorly, custom fabricated”

### Summary of Applicant's Submission

Children’s Healthcare of Atlanta submitted a request to establish a new HCPCS Level II code to identify custom pectus carinatum orthosis for non-surgical treatment of pectus carinatum. While there is some variation in a pectus carinatum deformity, the most frequent type consists of anterior displacement of the mid and lower sternum and the attached costal cartilage (the cartilage that connects the sternum and the ends of the ribs; its elasticity allows the chest to move when breathing). There is an overgrowth of cartilage that causes the cartilage to buckle and push the sternum forward. During puberty, the chest wall is compliant, making non-surgical treatment an effective option. Non-surgical treatment involves a compressive pectus carinatum orthosis that is worn for most of the day and night. The orthosis applies pressure over the apex of the deformity. The most used method, the Calgary protocol, recommends wearing the brace 23 hours a day until a 48-hour out of brace correction is maintained. At that time the patients are transitioned to wearing the orthosis 8 hours a day until skeletal maturity is achieved. The compliance with custom orthoses yields deformity correction, minimal reoccurrence, quality of life improvement, and self-esteem improvement. Orthotic treatment has been shown to be successful in peer reviewed literature, and avoids the substantial risk and cost associated with major chest wall surgery.

### CMS Preliminary HCPCS Coding Recommendation

Establish a new HCPCS Level II code LXXXX, “Thoracic, pectus carinatum orthosis, sternal compression, rigid circumferential frame with anterior and posterior rigid pads, custom fabricated.”

The new HCPCS Level II code, LXXXX, describes all features of the external chest compressor for non-surgical treatment of pectus carinatum.

### Preliminary Medicare Benefit Category Determination

Back Brace (Orthotic).

The application supports a preliminary benefit category determination that the Custom Pectus Carinatum Orthosis is used as a brace. Section 130 of Chapter 15 of the Medicare Benefit Policy Manual (CMS Pub. 100-02) defines a brace as a rigid or semi-rigid device used for the

purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body. The Custom Pectus Carinatum Orthosis is a rigid device that is used to treat and correct pectus carinatum.

**Preliminary Medicare Payment Determination**

No determination.

As a code representing custom products without a claims history, no payment basis exists on which to develop an appropriate fee schedule amount for LXXXX. We invite the applicant to provide any documentation or claims examples that would demonstrate current commercial pricing for this item.

At this time, the DME fee schedule amounts for this item would be established by the DME MACs pending a payment determination established in accordance with the procedures at 42 CFR §414.240. 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. In particular, 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. If there are no items with existing fee schedule amounts that are comparable to the items and services under the new code, then we establish the fee schedule using supplier or commercial price lists. If the purchase price used in calculating the fee schedule amounts is greater than $150, then payment would be made on a capped rental basis in accordance with our regulations at 42 CFR 414.229. If the purchase price used in calculating the fee schedule amounts is $150 or less, then payment would be made on a rental or purchase basis in accordance with our regulations at 42 CFR 414.220.

Pricing Indicator = 46

**Summary of Public Feedback**

Children's Healthcare of Atlanta agreed with CMS' preliminary recommendation to issue a HCPCS Level II code for a custom pectus carinatum orthosis. However, the applicant disagreed with the decision regarding payment of the device. The speaker stated that the pricing information was provided, noting fee schedules from various orthotic and prosthetic providers ranging from $2,500 to $4,434, and supplier invoices ranging from $1,095 to $3,579.

**CMS Final HCPCS Coding Decision**

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

Establish a new HCPCS Level II code L1320, “Thoracic, pectus carinatum orthosis, sternal compression, rigid circumferential frame with anterior and posterior rigid pads, custom fabricated” to describe a custom pectus carinatum orthosis.

**Final Medicare Benefit Category Determination**

Back Brace (Orthotic).

**Final Medicare Payment Determination**

No determination.

During the public meeting, the speaker provided a general range of current pricing for the chest compressor. However, the prices discussed during the presentation demonstrate the highly customized nature of this device, ranging from hundreds to thousands of dollars. As such, we do not believe it would be appropriate to establish a national fee schedule amount for L1320 at this time. We are finalizing our preliminary determination in which at this time, local fee schedule amounts for this item would be established by the DME MACs in accordance with the procedures at 42 CFR §414.238.

Pricing Indicator = 46

## Sure Stance Knee - HCP2306308HLHL

### Topic/Issue

Request to establish a new HCPCS Level II code to identify Sure Stance Knee.

Applicant's suggested language: XXXXX, “Addition, endoskeletal knee/shin system, 4-bar linkage or multiaxial, pneumatic swing phase control with mechanical stance-phase lock”

### Summary of Applicant's Submission

DAW Industries submitted a request to establish a new HCPCS Level II code to identify Sure Stance Knee. The Sure Stance Knee is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The Sure Stance Knee has completely unique swing and stance phase features. The Sure Stance Knee is a non-microprocessor-controlled, 4-bar pneumatic swing-phase control knee with a mechanical stance-phase control lock. The weight activated stance feature activates up to 35-degree knee flexion, drastically reducing the instances of the patient falling and injuring themselves during a common stumble or misstep. HCPCS Level II code L5840, “4-bar pneumatic swing-phase control” serves as the Sure Stance Knee's "base" code, however, L5840 alone, does not fully describe the Sure Stance Knee’s safety features, particularly in the stance phase. A standard 4-bar pneumatic knee, as described by HCPCS Level II code L5840, does not provide any stability past a few degrees of flexion. If a patient bears weight on a basic 4-bar pneumatic knee during flexion (for example, if the patient stubs their toe on the ground) that knee will buckle under the patient, resulting in a fall. Knee buckling like this is a common cause of injury amongst individuals with above knee amputation(s). Code L5816, “Polycentric, mechanical stance-phase lock” is the code that most closely describes the Sure Stance Knee's weight-activated stance control safety feature but does not make any mention of a function for swing-phase control and therefore, cannot describe the variable cadence swing-phase control provided by the Sure Stance Knee’s pneumatics. Together, codes L5840 and L5816 could be used to describe the swing and stance phase features of the Sure Stance Knee, however CMS has already declared the use of these two codes together as “incorrect coding,” citing Policy Article A52496. In this article, it states that codes L5840 and L5816 are both classified as a “base knee code” which can “fully describe a complete knee-shin system,” and therefore the use of these two codes on the same claim is considered “incorrect coding (unbundling),” again per Policy Article A52496, paragraph 3 of the section entitled "KNEES." CMS’ Medical Administrative Contractors (MACs) will authorize the use of HCPCS Level II code L5840 but will not authorize L5816 to be bundled with it. Due to the classification of L5816 as a “knee base code,” in the policy article referenced above, that code cannot be included with L5840 as used to describe the Sure Stance Knee’s stance-phase control safety feature.

### CMS Preliminary HCPCS Coding Recommendation

Establish a new HCPCS Level II code LXXXX, “Addition, endoskeletal knee-shin system, polycentric, pneumatic swing, and stance phase control”

We agree with the applicant that the device contains features that are not described by any single existing code. There are enough unique features with this product that a new HCPCS Level II code is warranted, because the existing HCPCS Level II codes only describe the base prosthetic knees, and not the combination of features of the Sure Stance Knee. As explained

in more detail under the payment determination below, use of multiple codes would not be appropriate, as this would duplicate payment for certain knee system base characteristics.

**Preliminary Medicare Benefit Category Determination**

Artificial Leg (Prosthetic).

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

**Preliminary Medicare Payment Determination**

In accordance with 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.

As described in the application, the Sure Stance Knee is an addition for an endoskeletal knee-shin system containing three key, price-determining features: polycentric linkage, weight-activated stance control locking (safety knee), and pneumatic swing control. All of these features are present in devices covered by existing codes, so we are developing a payment amount by combining appropriate codes in order to cover these key features without duplicating payment for base characteristics.

While the application suggested combining L5840, “addition, endoskeletal knee/shin system, 4-bar linkage or multiaxial, pneumatic swing phase control” and L5816, “addition, endoskeletal knee-shin system, polycentric, mechanical stance phase lock” to account for these features, adding the payment amount for these codes would duplicate payment for base characteristics, namely, those described by L5810, “addition, endoskeletal knee-shin system, single axis, manual lock.” These codes would also duplicate payment for the 4-bar polycentric linkage feature, while failing to account for the weight-activated control locking mechanism.

The base characteristics for all devices in the L5810-L5840 range are described by L5810. Therefore, we are subtracting the fee schedule amount for L5810 from the payment amount for L5812, “addition, endoskeletal knee-shin system, single axis, friction swing and stance phase control (safety knee)” and L5830, “addition, endoskeletal knee-shin system, single axis, pneumatic/ swing phase control” in order to determine an appropriate payment amount for the weight-activated stance control locking (safety knee) and pneumatic swing-control features, respectively. These amounts have been added to the payment amount for L5816, “addition, endoskeletal knee-shin system, polycentric, mechanical stance phase lock” in order to represent the complete system and features of the Sure Stance Knee.

| | Sure Stance Knee | L5810 | L5812 | L5830 | L5816 |
|---|---|---|---|---|---|
| **Physical Components** | | | | | |
| Single axis | | X | X | X | |
| 4-Bar Polycentric Linkage | X | | | | X |
| **Mechanical Components** | | | | | |
| Pneumatic swing control | X | | | X | |
| Stance phase control: Manual Lock | | X | | | X |
| Stance phase control: Geometric Lock | X | | | X | |
| Stance Phase Control: Weight-activated control locking mechanism | X | | X | | |
| **Electrical Components** | n/a | n/a | n/a | n/a | n/a |
| **Function and Intended Use** | | | | | |
| Transfemoral and hip disarticulation level | X | X | X | X | X |
| Lower extremity device/component | X | X | X | X | X |
| **Additional Aspects and Features** | n/a | n/a | n/a | n/a | n/a |

**Example of pricing using 2023 Medicare Fee Schedule Amounts for Alabama**

| Code and Description | 2023 Alabama Fee Schedule Amount | Implied Payment for Feature Alone |
|---|---|---|
| L5810, "Addition, endoskeletal knee-shin system, single axis, manual lock" | $556.19 | N/A |
| L5812, "Addition, endoskeletal knee-shin system, single axis, friction swing and stance phase control (safety knee)" | $645.80 | **$89.61** (safety knee feature) |
| L5830, "Addition, endoskeletal knee-shin system, | $2,167.76 | **$1,611.57** (pneumatic swing phase control feature) |

| | | |
|---|---|---|
| single axis, pneumatic/ swing phase control" | | |
| L5816, "Addition, endoskeletal knee-shin system, polycentric, mechanical stance phase lock" | **$977.42** (polycentric knee-shin system) | N/A |
| **Preliminary Payment Determination (e.g., Alabama)** | | |
| LXXXX, "Addition, endoskeletal knee-shin system, polycentric, pneumatic swing, and stance phase control" | **$2,678.60** | |

Therefore, the preliminary payment determination is that the fee schedule amounts for HCPCS Level II code LXXXX will be established using the fee schedule amounts for HCPCS Level II code L5816 plus payment for the safety knee feature (the fee schedule amounts for HCPCS Level II code L5812 minus the fee schedule amounts for HCPCS Level II code L5810) and payment for the pneumatic swing phase control feature (the fee schedule amounts for HCPCS Level II code L5830 minus the fee schedule amounts for HCPCS Level II code L5810).

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

Pricing Indicator = 38

**Summary of Public Feedback**

DAW Industries agreed with CMS' preliminary decision to issue a HCPCS Level II code for Sure Stance Knee, however, disagreed with the decision regarding the preliminary Medicare payment determination of the device. The speaker stated that the existing code that most closely resembles the Sure Stance Knee code is K1014. The Sure Stance Knee provides three key price-determining features: 4-Bar Linkage, Stance Phase Control & Pneumatic Swing. The CMS preliminary determination for the payment amount produced the following code formula L5816 + (L5812 – L5810) + L5830. The speaker recommended removing L5816 & L5830 and replacing these two codes with L5840. The resulting formula would be L5840 + (L5812 – L5810). L5840 serves as a more accurate "base knee code" than L5816 because it most closely describes the true basic nature of the knee, which is a 4-Bar pneumatic knee, with the additional safety feature of Stance Control. There is an enormous technological difference between a single-axis stance control mechanism (L5812 – L5810) and a 4-Bar stance control mechanism. The inexpensive stance control mechanism of a single-axis knee, if retrofit to a 4-Bar knee, cannot provide a functional weight-activated safety feature due to the inadequate sensitivity of the mechanism. Manufacturing a weight-activated stance control mechanism that can operate reliably on a 4-Bar knee was only achievable using highly specialized equipment and the highest-grade materials, including aerospace alloys. The descriptions for these two codes differ only in that one is hydraulic, and the other is pneumatic. Regarding the list of appropriate codes for determining payment, replacing code L5613 with L5840 "4-Bar, Pneumatic Swing," was recommended by the speaker. The resulting code formula would accurately describe the features of the Sure Stance Knee.

## CMS Final HCPCS Coding Decision

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

Establish a new HCPCS Level II code L5841, "Addition, endoskeletal knee-shin system, polycentric, pneumatic swing, and stance phase control" to describe Sure Stance Knee.

## Final Medicare Benefit Category Determination

Artificial Leg (Prosthetic).

## Final Medicare Payment Determination

While the application[18] suggested that CMS determine the fee schedule amount by combining L5840 and L5816, neither the oral nor written comments addressed the concern we identified in the preliminary determination: these codes would also duplicate payment for the 4-bar polycentric linkage feature, while failing to account for the weight-activated control locking mechanism. Furthermore, although the speaker requested that CMS multiply the amounts for the safety knee feature (L5812 minus L5810) by "no less than a factor of 27," there was no specific evidence presented to substantiate this adjustment beyond the general assertion that fabrication costs were higher to integrate weight-activated stance control into the Sure Stance knee as compared with the devices described by L5812. We note that the speaker also proposed an alternative method of comparing the Sure Stance knee with K1014, highlighting that the only apparent difference is that K1014 describes fluid swing control as opposed to pneumatic. The fluid control mechanism is when the knee joints are responsive to variable cadence as the resistance around the knee joint increases with speed during the stance or swing phases. Fluid control comes in two forms: hydraulic (controlled by liquid) and pneumatic (controlled by air or gas). Pneumatic (air) resistance differs from hydraulic because, due to low density and viscosity of air, it requires greater accuracy in the passage control, and has a "bouncier" fashion due to the compressibility of the air. In pneumatic knees, due to the compressibility of air, the patient experiences a springier sensation while walking at different speeds. K1014 is specifically intended for *hydraulic* fluid swing and stance phase control, not the pneumatic fluid mechanism used in Sure Stance; due to the significant differences in terms of components and pricing, it would be inappropriate to compare a pneumatic device to a code used for hydraulic devices. For these reasons, we are finalizing the payment determination as proposed in the preliminary determination.

The fee schedule amounts for HCPCS Level II code L5841 will be established using the fee schedule amounts for HCPCS Level II code L5816 plus payment for the safety knee feature (the fee schedule amounts for HCPCS Level II code L5812 minus the fee schedule amounts for HCPCS Level II code L5810) and payment for the pneumatic swing phase control feature (the fee schedule amounts for HCPCS Level II code L5830 minus the fee schedule amounts for HCPCS Level II code L5810), as discussed in the preliminary determination.

[18] Revised on April 11, 2024 to correct that this information was from the application and not speaker.

Following the example in the preliminary determination, the 2024 average fee schedule amount for Alabama will be $2,748.22.
The average fee schedule amount will be determined for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 38

## RevoFit® - HCP2306296NDGX

### Topic/Issue

Request to establish a new HCPCS Level II code to describe RevoFit®.

Applicant's suggested language: LXXXX, “Addition to lower limb prosthesis, user adjustable, integrated, mechanical, residual limb volume management system”

### Summary of Applicant's Submission

Click Medical submitted a request to establish a new HCPCS Level II code to identify RevoFit®. RevoFit® is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The RevoFit® is a system to be used in an addition to current lower extremity base socket and socket replacement codes. The RevoFit® volume management system is a kit of components that a prosthetist adds to a custom-fabricated socket which allows the beneficiary to adjust their socket volume throughout the day. RevoFit® enables the user to increase/decrease the volume of their socket as they experience limb volume changes. Users report decreased limb pain and secondary complications, and an increase in device usage and activities of daily living (ADLs) when managing socket volume at home. The RevoFit® volume management system is available to prosthetists and applied in accordance with established prosthetic principles. The prosthetist determines areas of adjustability and adds the system (kit) to the base or replacement socket during custom fabrication. Once delivered, the beneficiary can tighten their device to reduce socket volume or loosen their device to increase socket volume. The interface between the socket and a residual limb is often considered to be the most important factor in the success or failure of a prosthesis. Traditional sockets cannot be compressed or expanded by the user and instead require a combination of fitting socks, pads, or intervention from a prosthetist to adjust socket volume. By contrast, the addition of the RevoFit® system allows the patient to instantly control socket volume without having to remove their prosthesis or interrupt their ADLs. Traditional socket HCPCS Level II codes were established more than twenty years ago. These codes have been complemented with “addition-to” codes to describe innovations that did not exist when the base socket codes, replacement socket codes, and fee schedules were originally established. The RevoFit® volume management system, introduced eight years ago, provides distinct therapeutic benefits through a unique functional and operational approach. Accordingly, this technology should be considered for a new “addition-to” code and fee schedule.

### CMS Preliminary HCPCS Coding Recommendation

Establish a new HCPCS Level II code LXXXX, “Addition to lower extremity, user adjustable, mechanical, residual limb volume management system”

RevoFit® is one form of a volume management system that has custom sockets with adjustable elements. These fully laminated sockets are fit to a model of a patient’s limb with one or more adjustable elements added in or fabricated with. This device includes added adjustable features such as the tensioning cable with floating panel or ratchet straps, which apply or release pressure to a cut-out a flexible portion of the socket. Additionally, the RevoFit® features an existing socket that requires alterations in socket fabrication or disruption to traditional physical structure of sockets. RevoFit® is not intended to replace

conventional methods, but rather to serve as an adjunctive option for patients with an unmet need. It aims to reduce the frequency of socket replacements and adjustment visits for patients. Furthermore, this RevoFit® system is not intended to integrate with body tissues or with one's nervous system, like bionic limbs usually do. For these reasons, the applicant's above suggested long descriptor language/word "integrated," does not correctly describe the features provided with this RevoFit® volume management system, for use with this product's intended patient population.

**Preliminary Medicare Benefit Category Determination**

Artificial Leg (Prosthetic).

The application supports a preliminary benefit category determination that the RevoFit® Volume Management System is used in addition to a lower extremity prosthesis and would fall under the Medicare benefit for artificial legs (prosthetics).

**Preliminary Medicare Payment Determination**

In accordance with regulations at 42 CFR 414.238(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 only available price information is from a period other than the fee schedule base period, deflation factors are applied against current pricing in order to approximate the base period price. 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(h)(4) of the Social Security Act for orthotics and prosthetics.

We have found that while the cost for the RevoFit® kit itself is approximately $270, this does not account for the substantial time required for the Prosthetist/Orthotist to integrate the RevoFit® into a socket. This fabrication time would normally be accounted for in the price of a custom socket, such as one that has been modified to incorporate the RevoFit®. Based on pricing support documents available on the manufacturer's website, we have found that the current price typically charged for the integration of RevoFit® into a socket is approximately $4,495. The annual deflation factors are specified in program instructions and the deflated amounts are then increased by the update factors specified in section 1834(h)(4) of the Act.

The average 2023 purchase fee schedule amount for LXXXX would be approximately $2,946.49.

Pricing Indicator = 38

**Summary of Public Feedback**

Click Medical agreed with CMS' preliminary recommendations to issue a HCPCS Level II code, benefit category and payment determination for RevoFit®.

**CMS Final HCPCS Coding Decision**

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

Establish a new HCPCS Level II code L5783, "Addition to lower extremity, user adjustable, mechanical, residual limb volume management system" to describe RevoFit®.

**Final Medicare Benefit Category Determination**

Artificial Leg (Prosthetic).

**Final Medicare Payment Determination**

The fee schedule amounts for HCPCS L5783 will be established using the current price of $4,495 as discussed in the preliminary determination. Deflating this price and increasing by the update factors specified in section 1834(h)(4) results in an average 2024 purchase fee schedule amount of $3,015.92.

Pricing Indicator = 38

## Xtend Foot - HCP230629CERGA

### Topic/Issue

Request to establish a new HCPCS Level II code to identify Xtend Foot.

The applicant did not submit any suggested language.

### Summary of Applicant's Submission

Lindhe Xtend submitted a request to establish a new HCPCS Level II code to identify Xtend Foot. Xtend Foot is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The Medicare Contractor for Pricing, Data Analysis and Coding of HCPCS Level II DMEPOS Codes (PDAC) determined the increased coronal plane motion provided by Xtend Foot flexible adhesive component is a dynamic feature intrinsic of the keel design, for which this prosthetic foot system is described in HCPCS Level II code L5981 (“All lower extremity prostheses, flex-walk system or equal”) and cannot be used to fully describe an additional feature of the L5981 prosthetic foot system. Code L5986 states that the coronal function cannot solely come from the split toe keel design. PDAC commented that there is no numeric value assigned to the function and that it is more dependent by how the motion is accomplished, i.e., a separate, integrated component. Xtend Foot is not a true split-keel, the top strut is a split design, and the base is a solid construction footplate. This construction allows the flexible urethane adhesive to provide motion. Lindhe Xtend evaluated Dynastar by Proteor, currently coded under L5986, “All lower extremity prostheses, multi-axial rotation unit ('mcp' or equal)” and L5981, and believes Dynastar strongly resembles the Xtend Foot in construction.

### CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code L5981, “All lower extremity prostheses, flex-walk system or equal” describes Xtend Foot.

The Xtend Foot provides the multiaxial motion achieved from the inherent flexibility of the prosthetic keel or a split keel/heel prosthetic foot design. Existing HCPCS Level II code L5986, “All lower extremity prostheses, multi-axial rotation unit ('mcp' or equal),” describes a product that is used as an ‘addition to’ L code foot system for lower limb prosthesis construction. The Xtend Foot has a flexible adhesive component in the keel which binds the carbon fiber lower keel to glass fiber upper keel. This component is included in the prosthetic foot system described by existing HCPCS Level II code L5981, “All lower extremity prostheses, flex-walk system or equal.”

### Preliminary Medicare Benefit Category Determination

Artificial Leg (Prosthetic).

The application supports a preliminary benefit category determination that the Xtend Foot replaces a missing foot through the ankle joint and would fall under the Medicare benefit for artificial legs (prosthetics).

**Preliminary Medicare Payment Determination**

The payment rules and pricing associated with the existing code L5981 will apply to this product, if covered. The current average 2023 fee schedule amount for L5981 is $3,666.92.

The average fee schedule amount is the average of the 2023 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 38

**Summary of Public Feedback**

No verbal or written comments were provided in response to CMS' published preliminary recommendations.

**CMS Final HCPCS Coding Decision**

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

Existing HCPCS Level II code L5981, "All lower extremity prostheses, flex-walk system or equal" to describe Xtend Foot.

**Final Medicare Benefit Category Determination**

Artificial Leg (Prosthetic).

**Final Medicare Payment Determination**

The payment rules and pricing associated with the existing code L5981 will apply to this product, if covered. The current average 2024 fee schedule amount for L5981 is $3,762.26. The average fee schedule amount is the average of the 2024 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 38

## Dynasplint, Dynamic Adjustable Elbow Extension/Flexion Device - HCP230630HDBV8

### Topic/Issue

Request to establish two new modifiers to be used with existing HCPCS Level II code E1800, "Dynamic adjustable elbow extension/flexion device, includes soft interface material"

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

### Summary of Applicant's Submission

Dynasplint Systems, Inc. submitted a request to establish two new HCPCS modifiers to be used with E1800, "Dynamic adjustable elbow extension/flexion device, includes soft interface material." Dynasplint dynamic adjustable elbow extension/flexion device is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The elbow is a hinge joint which is a type of synovial joint. Hinge joints can only allow for one plane of motion (i.e., either extension or flexion, but not both). The E1800 code is an inadequate and confusing description. The short and long E1800 descriptions create the assumption that one E1800 device can work both extension and flexion for a hinge joint, which is not always the case. The proposed two modifiers are as follows: XT = Extension, and FL = Flexion. Current CMS billing guidelines allow for the payment of two of the same HCPCS Level II codes for the same patient on the same date of service. For example, E1800 can be billed with the modifiers RT and LT to indicate the right elbow and left elbow respectively (E1800RRRT & E1800RRLT). However, when billing for a flexion device at the same time as an extension device, it creates a denial for the second device because it is seen as a duplicate (E1800 and E1800). A modifier such as XT and FL will allow CMS to recognize two distinct devices and pay for two of the same HCPCS Level II codes for the same patient on the same date of service. For example, E1800RRRTXT (right elbow extension) and E1800RRRTFL (right elbow flexion).

### CMS Preliminary HCPCS Coding Recommendation

CMS does not recognize a need to create a modifier to identify "extension" and a modifier to identify "flexion." The current code descriptors for HCPCS Level II codes E1800, E1805, E1810, E1815, E1825, and E1830 identify devices that provide extension and/or flexion of the applicable anatomical joint, and the current code set provides a description to treat either flexion and/or extension when clinically necessary. To clarify, CMS' intention in these code descriptors was to identify devices that provide extension and/or flexion. Further, CMS is unaware of clinical scenarios where patients require two devices to concurrently perform different functions (i.e., one for flexion, and one for extension) and are being denied for the number of device units that they need. Therefore, CMS maintains that there is no operating need for the creation of new modifiers to represent flexion and extension. If the applicant is receiving claims denials, they should contact their Durable Medical Equipment Medicare Administrative Contractor for guidance.

### Summary of Public Feedback

Dynasplint Systems, Inc. disagreed with CMS' preliminary recommendation. The speaker stated that clinical indications require both extension and flexion devices for patients. Patients need both concurrently or the patient outcomes can suffer. There is no dynamic low load prolonged stretching device that can provide extension and flexion stretching in one device. It

is not mechanically feasible or biomechanically correct to use one device to stretch both directions. When extension and flexion devices are submitted together on a health insurance claim, the claim is denied because it appears it is the same device twice. The applicant submitted 4 claim denial examples. The first two denials show claims for patients who received both an extension and flexion device. Each of those claims was denied as a duplicate because the same HCPCS Level II code and the same modifiers were used. The next two claim denials are similar except that they contain the "GY" modifier, which is used to indicate that the second device is a non-covered claim. Use of the “GY” modifier also indicates that Dynasplint Systems, Inc. has already obtained an Advance Beneficiary Notice of Noncoverage (ABN) form. The use of the ABN form allows the applicant to charge the patient directly for the second device since it is not paid by Medicare. The applicant further stated that they have approximately 600 denials from this year alone that would illustrate this claims issue. However, as noted below, many more patients decline the second device because of the cost and thus the second device is never provided/billed. Medicare beneficiaries are not receiving the devices ordered by the prescribing doctor. Since 2021, nearly 10,000 beneficiaries have been prescribed both an extension and flexion device by their doctor. However, only 46% of patients received both devices because the beneficiaries must pay for the second device when extension and flexion are billed at the same time, because Medicare will not reimburse for both devices. Adding the requested modifiers will allow Medicare to differentiate two devices billed on the same date of service and allow Medicare beneficiaries to receive the devices that are prescribed by their physicians without having to pay for the second device. Again, when Medicare patients are asked to pay for a device that is not reimbursable, the patient is more likely to decline to pay. Thus, the patient's rehabilitation from surgery/injury is delayed and the patient will take longer to recover to full range of motion, if ever.

**CMS Final HCPCS Coding Decision**

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

1. Revise existing HCPCS Level II code E1800, “Dynamic adjustable elbow extension/flexion device, includes soft interface material” to instead read “Dynamic adjustable elbow extension and flexion device, includes soft interface material”

2. Establish a new HCPCS Level II code E1803, “Dynamic adjustable elbow extension only device, includes soft interface material”

3. Establish a new HCPCS Level II code E1804, “Dynamic adjustable elbow flexion only device, includes soft interface material”

These three coding actions will be effective January 1, 2025. We believe this delay will allow time for any payers that currently list these codes in their written policies or contracts to make any necessary updates.

**Final Medicare Benefit Category Determination**

Durable Medical Equipment.

**Preliminary Medicare Payment Determination**

No determination. CMS did not previously issue a preliminary payment determination for this device in this cycle. A preliminary payment determination is stated below, and interested parties will have an opportunity to provide comment to CMS during the first biannual 2024 HCPCS coding cycle later this year. For claims payment on an interim basis, payment for the Dynasplint dynamic adjustable elbow flexion/extension device will be made at the discretion of the DME MACs pending a payment determination established in accordance with the procedures at 42 CFR §414.240.

For E1800, the payment rules and pricing associated with the existing code apply to this product, if covered. The 2024 average capped rental fee schedule amount for E1800 would be approximately $156.04 for months 1 through 3 and approximately $117.03 for months 4 through 13, for a total of $1,638.42 after 13 months of continuous use.

For codes E1803 and E1804, in accordance with regulations at 42 CFR 414.236(a) if a new HCPCS Level II code is added for a DMEPOS item, CMS and/or DME MACs make efforts to determine whether the item has a pricing history. If there is a pricing history, the previous payment amounts for the previous code(s) are mapped to the new code(s) to ensure continuity of pricing. In this case, new codes E1803 and E1804 have a pricing history based on E1800. When there is a single code that describes two or more distinct complete items (with E1800, that would be flexion and extension), and separate codes are subsequently established for each item (E1804 for flexion and E1803 for extension), the payment amounts that applied to the single code are applied to and divided between each of the items described by the new codes. Thus, the preliminary payment determination for new codes E1803 and E1804 is to establish the fee schedule amount by halving the existing fee schedule amount for the related item described by HCPCS Level II code E1800.

Based on this preliminary determination pricing for both E1803 and E1804 is represented by the following formula: E1800*.5. Therefore the 2024 average capped rental fee schedule amount for both E1803 and E1804 would be approximately $78.02 for months 1 through 3 and approximately $58.52 for months 4 through 13, for a total of $819.21 after 13 months of continuous use.

The average fee schedule amount is the average of the 2024 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 36

## Dynasplint, Dynamic Adjustable Wrist Extension/Flexion Device - HCP2306303YX0F

### Topic/Issue

Request to establish two new modifiers to be used with existing HCPCS Level II code E1805, "Dynamic adjustable wrist extension / flexion device, includes soft interface material"

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

### Summary of Applicant's Submission

Dynasplint Systems, Inc. submitted a request to establish two new HCPCS modifiers to be used with E1805, "Dynamic adjustable wrist extension / flexion device, includes soft interface material." Dynasplint dynamic adjustable wrist extension/flexion device is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The wrist is a hinge joint which is a type of synovial joint. Hinge joints can only allow for one plane of motion (i.e., either extension or flexion, but not both). The E1805 code is an inadequate and confusing description. The short and long E1805 descriptions create the assumption that one E1805 device can work both extension and flexion for a hinge joint, which is not always the case. The proposed two modifiers are as follows: XT = Extension, and FL = Flexion. Current CMS billing guidelines allow for the payment of two of the same HCPCS Level II codes for the same patient on the same date of service. For example, E1805 can be billed with the modifiers RT and LT to indicate the right wrist and left wrist respectively (E1805RRRT & E1805RRLT). However, when billing for a flexion device at the same time as an extension device, it creates a denial for the second device because it is seen as a duplicate (E1805 and E1805). A modifier such as XT and FL will allow CMS to recognize two distinct devices and pay for two of the same HCPCS Level II codes for the same patient on the same date of service. For example, E1805RRRTXT (right wrist extension) and E1805RRRTFL (right wrist flexion).

### CMS Preliminary HCPCS Coding Recommendation

CMS does not recognize a need to create a modifier to identify "extension" and a modifier to identify "flexion." The current code descriptors for HCPCS Level II codes E1800, E1805, E1810, E1815, E1825, and E1830 identify devices that provide extension and/or flexion of the applicable anatomical joint, and the current code set provides a description to treat either flexion and/or extension when clinically necessary. To clarify, CMS' intention in these code descriptors was to identify devices that provide extension and/or flexion. Further, CMS is unaware of clinical scenarios where patients require two devices to concurrently perform different functions (i.e., one for flexion, and one for extension) and are being denied for the number of device units that they need. Therefore, CMS maintains that there is no operating need for the creation of new modifiers to represent flexion and extension. If the applicant is receiving claims denials, they should contact their Durable Medical Equipment Medicare Administrative Contractor for guidance.

### Summary of Public Feedback

Dynasplint Systems, Inc. disagreed with CMS' preliminary recommendation. The speaker stated that clinical indications require both extension and flexion devices for patients. Patients need both concurrently or the patient outcomes can suffer. There is no dynamic low load prolonged stretching device that can provide extension and flexion stretching in one device. It

is not mechanically feasible or biomechanically correct to use one device to stretch both directions. When extension and flexion devices are submitted together on a health insurance claim, the claim is denied because it appears it is the same device twice. The applicant submitted 4 claim denial examples. The first two denials show claims for patients who received both an extension and flexion device. Each of those claims was denied as a duplicate because the same HCPCS Level II code and the same modifiers were used. The next two claim denials are similar except that they contain the "GY" modifier, which is used to indicate that the second device is a non-covered claim. Use of the “GY” modifier also indicates that Dynasplint Systems, Inc. has already obtained an Advance Beneficiary Notice of Noncoverage (ABN) form. The use of the ABN form allows the applicant to charge the patient directly for the second device since it is not paid by Medicare. The applicant further stated that they have approximately 600 denials from this year alone that would illustrate this claims issue. However, as noted below, many more patients decline the second device because of the cost and thus the second device is never provided/billed. Medicare beneficiaries are not receiving the devices ordered by the prescribing doctor. Since 2021, nearly 10,000 beneficiaries have been prescribed both an extension and flexion device by their doctor. However, only 46% of patients received both devices because the beneficiaries must pay for the second device when extension and flexion are billed at the same time, because Medicare will not reimburse for both devices. Adding the requested modifiers will allow Medicare to differentiate two devices billed on the same date of service and allow Medicare beneficiaries to receive the devices that are prescribed by their physicians without having to pay for the second device. Again, when Medicare patients are asked to pay for a device that is not reimbursable, the patient is more likely to decline to pay. Thus, the patient's rehabilitation from surgery/injury is delayed and the patient will take longer to recover to full range of motion, if ever.

**CMS Final HCPCS Coding Decision**

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

1. Revise existing HCPCS Level II code E1805, “Dynamic adjustable wrist extension / flexion device, includes soft interface material” to instead read “Dynamic adjustable wrist extension and flexion device, includes soft interface material”

2. Establish a new HCPCS Level II code E1807, “Dynamic adjustable wrist extension only device, includes soft interface material”

3. Establish a new HCPCS Level II code E1808, “Dynamic adjustable wrist flexion only device, includes soft interface material”

These three coding actions will be effective January 1, 2025. We believe this delay will allow time for any payers that currently list these codes in their written policies or contracts to make any necessary updates.

**Final Medicare Benefit Category Determination**

Durable Medical Equipment.

**Preliminary Medicare Payment Determination**

No determination. CMS did not previously issue a preliminary payment determination for this device in this cycle. A preliminary payment determination is stated below, and interested parties will have an opportunity to provide comment to CMS during the first biannual 2024 HCPCS coding cycle later this year. For claims payment on an interim basis, payment for the Dynasplint dynamic adjustable wrist extension/flexion device will be made at the discretion of the DME MACs pending a payment determination established in accordance with the procedures at 42 CFR §414.240.

For E1805, the payment rules and pricing associated with the existing code apply to this product, if covered. The 2024 average capped rental fee schedule amount for E1805 would be approximately $163.08 for months 1 through 3 and approximately $122.31 for months 4 through 13, for a total of $1,712.34 after 13 months of continuous use.

For codes E1807 and E1808, in accordance with regulations at 42 CFR 414.236(a) if a new HCPCS Level II code is added for a DMEPOS item, CMS and/or DME MACs make efforts to determine whether the item has a pricing history. If there is a pricing history, the previous payment amounts for the previous code(s) are mapped to the new code(s) to ensure continuity of pricing. In this case, new codes E1807 and E1808 have a pricing history based on E1805. When there is a single code that describes two or more distinct complete items (with E1805, that would be flexion and extension), and separate codes are subsequently established for each item (E1808 for flexion and E1807 for extension), the payment amounts that applied to the single code applied to and divided between each of the items described by the new codes. Thus, the preliminary payment determination for new codes E1807 and E1808 is to establish the fee schedule amount by halving the existing fee schedule amount for the related item described by HCPCS Level II code E1805.

Based on this preliminary determination pricing for both E1807 and E1808 is represented by the following formula: E1805*.5. Therefore the 2024 average capped rental fee schedule amount for both E1807 and E1808 would be approximately $81.54 for months 1 through 3 and approximately $61.16 for months 4 through 13, for a total of $856.17 after 13 months of continuous use.

The average fee schedule amount is the average of the 2024 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 36

## Dynasplint, Dynamic Adjustable Knee Extension/Flexion Device - HCP230630T4NRE

### Topic/Issue

Request to establish two new modifiers to be used with existing HCPCS Level II code E1810, "Dynamic adjustable knee extension / flexion device, includes soft interface material"

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

### Summary of Applicant's Submission

Dynasplint Systems, Inc. submitted a request to establish two new HCPCS modifiers to be used with E1810, "Dynamic adjustable knee extension / flexion device, includes soft interface material." Dynasplint dynamic adjustable knee extension/flexion device is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The knee is a hinge joint which is a type of synovial joint. Hinge joints can only allow for one plane of motion (i.e., either extension or flexion, but not both). The E1810 code is an inadequate and confusing description. The short and long E1810 descriptions create the assumption that one E1810 device can work both extension and flexion for a hinge joint, which is not always the case. The proposed two modifiers are as follows: XT = Extension and FL = Flexion. Current CMS billing guidelines allow for the payment of two of the same HCPCS Level II codes for the same patient on the same date of service. For example, E1810 can be billed with the modifiers RT and LT to indicate the right knee and left knee respectively (E1810RRRT & E1810RRLT). However, when billing for a flexion device at the same time as an extension device, it creates a denial for the second device because it is seen as a duplicate (E1810 and E1810). A modifier such as XT and FL will allow CMS to recognize two distinct devices and pay for two of the same HCPCS Level II codes for the same patient on the same date of service. For example, E1810RRRTXT (right knee extension) and E1810RRRTFL (right knee flexion).

### CMS Preliminary HCPCS Coding Recommendation

CMS does not recognize a need to create a modifier to identify "extension" and a modifier to identify "flexion." The current code descriptors for HCPCS Level II codes E1800, E1805, E1810, E1815, E1825, and E1830 identify devices that provide extension and/or flexion of the applicable anatomical joint, and the current code set provides a description to treat either flexion and/or extension when clinically necessary. To clarify, CMS' intention in these code descriptors was to identify devices that provide extension and/or flexion. Further, CMS is unaware of clinical scenarios where patients require two devices to concurrently perform different functions (i.e., one for flexion, and one for extension) and are being denied for the number of device units that they need. Therefore, CMS maintains that there is no operating need for the creation of new modifiers to represent flexion and extension. If the applicant is receiving claims denials, they should contact their Durable Medical Equipment Medicare Administrative Contractor for guidance.

### Summary of Public Feedback

Dynasplint Systems, Inc. disagreed with CMS' preliminary recommendation. The speaker stated that clinical indications require both extension and flexion devices for patients. Patients need both concurrently or the patient outcomes can suffer. There is no dynamic low load

prolonged stretching device that can provide extension and flexion stretching in one device. It is not mechanically feasible or biomechanically correct to use one device to stretch both directions. When extension and flexion devices are submitted together on a health insurance claim, the claim is denied because it appears it is the same device twice. The applicant submitted 4 claim denial examples. The first two denials show claims for patients who received both an extension and flexion device. Each of those claims was denied as a duplicate because the same HCPCS Level II code and the same modifiers were used. The next two claim denials are similar except that they contain the "GY" modifier, which is used to indicate that the second device is a non-covered claim. Use of the “GY” modifier also indicates that Dynasplint Systems, Inc. has already obtained an Advance Beneficiary Notice of Noncoverage (ABN) form. The use of the ABN form allows the applicant to charge the patient directly for the second device since it is not paid by Medicare. The applicant further stated that they have approximately 600 denials from this year alone that would illustrate this claims issue. However, as noted below, many more patients decline the second device because of the cost and thus the second device is never provided/billed. Medicare beneficiaries are not receiving the devices ordered by the prescribing doctor. Since 2021, nearly 10,000 beneficiaries have been prescribed both an extension and flexion device by their doctor. However, only 46% of patients received both devices because the beneficiaries must pay for the second device when extension and flexion are billed at the same time, because Medicare will not reimburse for both devices. Adding the requested modifiers will allow Medicare to differentiate two devices billed on the same date of service and allow Medicare beneficiaries to receive the devices that are prescribed by their physicians without having to pay for the second device. Again, when Medicare patients are asked to pay for a device that is not reimbursable, the patient is more likely to decline to pay. Thus, the patient's rehabilitation from surgery/injury is delayed and the patient will take longer to recover to full range of motion, if ever.

**CMS Final HCPCS Coding Decision**

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

1. Revise existing HCPCS Level II code E1810, “Dynamic adjustable knee extension / flexion device, includes soft interface material” to instead read “Dynamic adjustable knee extension and flexion device, includes soft interface material”

2. Establish a new HCPCS Level II code E1813, “Dynamic adjustable knee extension only device, includes soft interface material”

3. Establish a new HCPCS Level II code E1814, “Dynamic adjustable knee flexion only device, includes soft interface material”

These three coding actions will be effective January 1, 2025. We believe this delay will allow time for any payers that currently list these codes in their written policies or contracts to make any necessary updates.

**Final Medicare Benefit Category Determination**

Durable Medical Equipment.

**Preliminary Medicare Payment Determination**

No determination. CMS did not previously issue a preliminary payment determination for this device in this cycle. A preliminary payment determination is stated below, and interested parties will have an opportunity to provide comment to CMS during the first biannual 2024 HCPCS coding cycle later this year. For claims payment on an interim basis, payment for the Dynasplint dynamic adjustable knee extension/flexion device will be made at the discretion of the DME MACs pending a payment determination established in accordance with the procedures at 42 CFR §414.240.

For E1810, the payment rules and pricing associated with the existing code apply to this product, if covered. The 2024 average capped rental fee schedule amount for E1810 would be approximately $160.35 for months 1 through 3 and approximately $120.26 for months 4 through 13, for a total of $1,683.65 after 13 months of continuous use.

For codes E1813 and E1814, in accordance with regulations at 42 CFR 414.236(a) if a new HCPCS Level II code is added for a DMEPOS item, CMS and/or DME MACs make efforts to determine whether the item has a pricing history. If there is a pricing history, the previous payment amounts for the previous code(s) are mapped to the new code(s) to ensure continuity of pricing. In this case, new codes E1813 and E1814 have a pricing history based on E1810. When there is a single code that describes two or more distinct complete items (with E1810, that would be flexion and extension), and separate codes are subsequently established for each item (E1814 for flexion and E1813 for extension), the payment amounts that applied to the single code applied to and divided between each of the items described by the new codes. Thus, the preliminary payment determination for new codes E1813 and E1814 is to establish the fee schedule amount by halving the existing fee schedule amount for the related item described by HCPCS Level II code E1810.

Based on this preliminary determination pricing for both E1813 and E1814 is represented by the following formula: E1810*.5. Therefore the 2024 average capped rental fee schedule amount for both E1813 and E1814 would be approximately $80.18 for months 1 through 3 and approximately $60.13 for months 4 through 13, for a total of $841.83 after 13 months of continuous use.

The average fee schedule amount is the average of the 2024 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 36

## Dynasplint, Dynamic Adjustable Ankle Extension/Flexion Device - HCP23063066K8A

### Topic/Issue

Request to establish two new modifiers to be used with existing HCPCS Level II code E1815, "Dynamic adjustable ankle extension/flexion device, includes soft interface material"

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

### Summary of Applicant's Submission

Dynasplint Systems, Inc. submitted a request to establish two new HCPCS modifiers to be used with E1815, "Dynamic adjustable ankle extension/flexion device, includes soft interface material." Dynasplint dynamic adjustable ankle extension/flexion device is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The ankle is a hinge joint which is a type of synovial joint. Hinge joints can only allow for one plane of motion (i.e., either extension or flexion, but not both). The E1815 code is an inadequate and confusing description. The short and long E1815 descriptions create the assumption that one E1815 device can work both extension and flexion for a hinge joint, which is not always the case. The proposed two modifiers are as follows: XT = Extension and FL = Flexion. Current CMS billing guidelines allow for the payment of two of the same HCPCS Level II codes for the same patient on the same date of service. For example, E1815 can be billed with the modifiers RT and LT to indicate the right ankle and left ankle respectively (E1815RRRT & E1815RRLT). However, when billing for a flexion device at the same time as an extension device, it creates a denial for the second device because it is seen as a duplicate (E1815 and E1815). A modifier such as XT and FL will allow CMS to recognize two distinct devices and pay for two of the same HCPCS Level II codes for the same patient on the same date of service. For example, E1815RRRTXT (right ankle extension) and E1815RRRTFL (right ankle flexion).

### CMS Preliminary HCPCS Coding Recommendation

CMS does not recognize a need to create a modifier to identify "extension" and a modifier to identify "flexion." The current code descriptors for HCPCS Level II codes E1800, E1805, E1810, E1815, E1825, and E1830 identify devices that provide extension and/or flexion of the applicable anatomical joint, and the current code set provides a description to treat either flexion and/or extension when clinically necessary. To clarify, CMS' intention in these code descriptors was to identify devices that provide extension and/or flexion. Further, CMS is unaware of clinical scenarios where patients require two devices to concurrently perform different functions (i.e., one for flexion, and one for extension) and are being denied for the number of device units that they need. Therefore, CMS maintains that there is no operating need for the creation of new modifiers to represent flexion and extension. If the applicant is receiving claims denials, they should contact their Durable Medical Equipment Medicare Administrative Contractor for guidance.

### Summary of Public Feedback

Dynasplint Systems, Inc. disagreed with CMS' preliminary recommendation. The speaker stated that clinical indications require both extension and flexion devices for patients. Patients need both concurrently or the patient outcomes can suffer. There is no dynamic low load

prolonged stretching device that can provide extension and flexion stretching in one device. It is not mechanically feasible or biomechanically correct to use one device to stretch both directions. When extension and flexion devices are submitted together on a health insurance claim, the claim is denied because it appears it is the same device twice. The applicant submitted 4 claim denial examples. The first two denials show claims for patients who received both an extension and flexion device. Each of those claims was denied as a duplicate because the same HCPCS Level II code and the same modifiers were used. The next two claim denials are similar except that they contain the "GY" modifier, which is used to indicate that the second device is a non-covered claim. Use of the “GY” modifier also indicates that Dynasplint Systems, Inc. has already obtained an Advance Beneficiary Notice of Noncoverage (ABN) form. The use of the ABN form allows the applicant to charge the patient directly for the second device since it is not paid by Medicare. The applicant further stated that they have approximately 600 denials from this year alone that would illustrate this claims issue. However, as noted below, many more patients decline the second device because of the cost and thus the second device is never provided/billed. Medicare beneficiaries are not receiving the devices ordered by the prescribing doctor. Since 2021, nearly 10,000 beneficiaries have been prescribed both an extension and flexion device by their doctor. However, only 46% of patients received both devices because the beneficiaries must pay for the second device when extension and flexion are billed at the same time, because Medicare will not reimburse for both devices. Adding the requested modifiers will allow Medicare to differentiate two devices billed on the same date of service and allow Medicare beneficiaries to receive the devices that are prescribed by their physicians without having to pay for the second device. Again, when Medicare patients are asked to pay for a device that is not reimbursable, the patient is more likely to decline to pay. Thus, the patient's rehabilitation from surgery/injury is delayed and the patient will take longer to recover to full range of motion, if ever.

**CMS Final HCPCS Coding Decision**

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

1. Revise existing HCPCS Level II code E1815, “Dynamic adjustable ankle extension/flexion device, includes soft interface material” to instead read “Dynamic adjustable ankle extension and flexion device, includes soft interface material”

2. Establish a new HCPCS Level II code E1822, “Dynamic adjustable ankle extension only device, includes soft interface material”

3. Establish a new HCPCS Level II code E1823, “Dynamic adjustable ankle flexion only device, includes soft interface material”

These three coding actions will be effective January 1, 2025. We believe this delay will allow time for any payers that currently list these codes in their written policies or contracts to make any necessary updates.

**Final Medicare Benefit Category Determination**

Durable Medical Equipment.

**Preliminary Medicare Payment Determination**

No determination. CMS did not previously issue a preliminary payment determination for this device in this cycle. A preliminary payment determination is stated below, and interested parties will have an opportunity to provide comment to CMS during the first biannual 2024 HCPCS coding cycle later this year. For claims payment on an interim basis, payment for the Dynasplint dynamic adjustable ankle extension/flexion device will be made at the discretion of the DME MACs pending a payment determination established in accordance with the procedures at 42 CFR §414.240.

For E1815, the payment rules and pricing associated with the existing code apply to this product, if covered. The 2024 average capped rental fee schedule amount for E1815 would be approximately $163.59 for months 1 through 3 and approximately $122.69 for months 4 through 13, for a total of $1,717.67 after 13 months of continuous use.

For codes E1822 and E1823, in accordance with regulations at 42 CFR 414.236(a) if a new HCPCS Level II code is added for a DMEPOS item, CMS and/or DME MACs make efforts to determine whether the item has a pricing history. If there is a pricing history, the previous payment amounts for the previous code(s) are mapped to the new code(s) to ensure continuity of pricing. In this case, new codes E1822 and E1823 have a pricing history based on E1815. When there is a single code that describes two or more distinct complete items (with E1815, that would be flexion and extension), and separate codes are subsequently established for each item (E1823 for flexion and E1822 for extension), the payment amounts that applied to the single code are applied to and divided between each of the items described by the new codes. Thus, the preliminary payment determination for new codes E1822 and E1823 is to establish the fee schedule amount by halving the existing fee schedule amount for the related item described by HCPCS Level II code E1815.

Based on this preliminary determination pricing for both E1822 and E1823 is represented by the following formula: E1815*.5. Therefore the 2024 average capped rental fee schedule amount for both E1822 and E1823 would be approximately $81.80 for months 1 through 3 and approximately $61.35 for months 4 through 13, for a total of $858.84 after 13 months of continuous use.

The average fee schedule amount is the average of the 2024 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 36

## Dynasplint, Dynamic Adjustable Finger Extension/Flexion Device - HCP230630U7JWP

### Topic/Issue

Request to establish two new modifiers to be used with existing HCPCS Level II code E1825, "Dynamic adjustable finger extension/flexion device, includes soft interface material"

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

### Summary of Applicant's Submission

Dynasplint Systems, Inc. submitted a request to establish two new HCPCS modifiers to be used with E1825, "Dynamic adjustable finger extension/flexion device, includes soft interface material." Dynasplint dynamic adjustable finger extension/flexion device is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The finger is a hinge joint which is a type of synovial joint. Hinge joints can only allow for one plane of motion (i.e., either extension or flexion, but not both). The E1825 code is an inadequate and confusing description. The short and long E1825 descriptions create the assumption that one E1825 device can work both extension and flexion for a hinge joint, which is not always the case. The proposed two modifiers are as follows: XT = Extension and FL = Flexion. Current CMS billing guidelines allow for the payment of 2 of the same HCPCS Level II codes for the same patient on the same date of service. For example, E1825 can be billed with the modifiers RT and LT to indicate the right finger and left finger respectively (E1825RRRT & E1825RRLT). However, when billing for a flexion device at the same time as an extension device, it creates a denial for the second device because it is seen as a duplicate (E1825 and E1825). A modifier such as XT and FL will allow CMS to recognize two distinct devices and pay for two of the same HCPCS Level II codes for the same patient on the same date of service. For example, E1825RRRTXT (right finger extension) and E1825RRRTFL (right finger flexion).

### CMS Preliminary HCPCS Coding Recommendation

CMS does not recognize a need to create a modifier to identify "extension" and a modifier to identify "flexion." The current code descriptors for HCPCS Level II codes E1800, E1805, E1810, E1815, E1825, and E1830 identify devices that provide extension and/or flexion of the applicable anatomical joint, and the current code set provides a description to treat either flexion and/or extension when clinically necessary. To clarify, CMS' intention in these code descriptors was to identify devices that provide extension and/or flexion. Further, CMS is unaware of clinical scenarios where patients require two devices to concurrently perform different functions (i.e., one for flexion, and one for extension) and are being denied for the number of device units that they need. Therefore, CMS maintains that there is no operating need for the creation of new modifiers to represent flexion and extension. If the applicant is receiving claims denials, they should contact their Durable Medical Equipment Medicare Administrative Contractor for guidance.

### Summary of Public Feedback

Dynasplint Systems, Inc. disagreed with CMS' preliminary recommendation. The speaker stated that clinical indications require both extension and flexion devices for patients. Patients need both concurrently or the patient outcomes can suffer. There is no dynamic low load

prolonged stretching device that can provide extension and flexion stretching in one device. It is not mechanically feasible or biomechanically correct to use one device to stretch both directions. When extension and flexion devices are submitted together on a health insurance claim, the claim is denied because it appears it is the same device twice. The applicant submitted 4 claim denial examples. The first two denials show claims for patients who received both an extension and flexion device. Each of those claims was denied as a duplicate because the same HCPCS Level II code and the same modifiers were used. The next two claim denials are similar except that they contain the "GY" modifier, which is used to indicate that the second device is a non-covered claim. Use of the “GY” modifier also indicates that Dynasplint Systems, Inc. has already obtained an Advance Beneficiary Notice of Noncoverage (ABN) form. The use of the ABN form allows the applicant to charge the patient directly for the second device since it is not paid by Medicare. The applicant further stated that they have approximately 600 denials from this year alone that would illustrate this claims issue. However, as noted below, many more patients decline the second device because of the cost and thus the second device is never provided/billed. Medicare beneficiaries are not receiving the devices ordered by the prescribing doctor. Since 2021, nearly 10,000 beneficiaries have been prescribed both an extension and flexion device by their doctor. However, only 46% of patients received both devices because the beneficiaries must pay for the second device when extension and flexion are billed at the same time, because Medicare will not reimburse for both devices. Adding the requested modifiers will allow Medicare to differentiate two devices billed on the same date of service and allow Medicare beneficiaries to receive the devices that are prescribed by their physicians without having to pay for the second device. Again, when Medicare patients are asked to pay for a device that is not reimbursable, the patient is more likely to decline to pay. Thus, the patient's rehabilitation from surgery/injury is delayed and the patient will take longer to recover to full range of motion, if ever.

**CMS Final HCPCS Coding Decision**

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

1. Revise existing HCPCS Level II code E1825, “Dynamic adjustable finger extension/flexion device, includes soft interface material” to instead read “Dynamic adjustable finger extension and flexion device, includes soft interface material”

2. Establish a new HCPCS Level II code E1826, “Dynamic adjustable finger extension only device, includes soft interface material”

3. Establish a new HCPCS Level II code E1827, “Dynamic adjustable finger flexion only device, includes soft interface material”

These three coding actions will be effective January 1, 2025. We believe this delay will allow time for any payers that currently list these codes in their written policies or contracts to make any necessary updates.

**Final Medicare Benefit Category Determination**

Durable Medical Equipment.

**Preliminary Medicare Payment Determination**

No determination. CMS did not previously issue a preliminary payment determination for this device in this cycle. A preliminary payment determination is stated below, and interested parties will have an opportunity to provide comment to CMS during the first biannual 2024 HCPCS coding cycle later this year. For claims payment on an interim basis, payment for the Dynasplint dynamic adjustable finger extension/flexion device will be made at the discretion of the DME MACs pending a payment determination established in accordance with the procedures at 42 CFR §414.240.

For E1825, the payment rules and pricing associated with the existing code apply to this product, if covered. The 2024 average capped rental fee schedule amount for E1825 would be approximately $163.08 for months 1 through 3 and approximately $122.31 for months 4 through 13, for a total of $1,712.34 after 13 months of continuous use.

For codes E1826 and E1827, in accordance with regulations at 42 CFR 414.236(a) if a new HCPCS Level II code is added for a DMEPOS item, CMS and/or DME MACs make efforts to determine whether the item has a pricing history. If there is a pricing history, the previous payment amounts for the previous code(s) are mapped to the new code(s) to ensure continuity of pricing. In this case, new codes E1826 and E1827 have a pricing history based on E1825. When there is a single code that describes two or more distinct complete items (with E1825, that would be flexion and extension), and separate codes are subsequently established for each item (E1827 for flexion and E1826 for extension), the payment amounts that applied to the single code are applied to and divided between each of the items described by the new codes. Thus, the preliminary payment determination for new codes E1826 and E1827 is to establish the fee schedule amount by halving the existing fee schedule amount for the related item described by HCPCS Level II code E1825.

Based on this preliminary determination pricing for both E1826 and E1827 is represented by the following formula: E1825*.5. Therefore the 2024 average capped rental fee schedule amount for both E1826 and E1827 would be approximately $81.54 for months 1 through 3 and approximately $61.16 for months 4 through 13, for a total of $856.17 after 13 months of continuous use.

The average fee schedule amount is the average of the 2024 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 36

## Dynasplint, Dynamic Adjustable Toe Extension/Flexion Device - HCP230630UCV21

### Topic/Issue

Request to establish two new modifiers to be used with existing HCPCS Level II code E1830, "Dynamic adjustable toe extension/flexion device, includes soft interface material"

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

### Summary of Applicant's Submission

Dynasplint Systems, Inc. submitted a request to establish two new HCPCS modifiers to be used with E1830, "Dynamic adjustable toe extension/flexion device, includes soft interface material." Dynasplint dynamic adjustable toe extension/flexion device is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The toe is a hinge joint which is a type of synovial joint. Hinge joints can only allow for one plane of motion (i.e., either extension or flexion, but not both). The E1830 code is an inadequate and confusing description. The short and long E1830 descriptions create the assumption that one E1830 device can work both extension and flexion for a hinge joint, which is not always the case. The proposed two modifiers are as follows: XT = Extension and FL = Flexion. Current CMS billing guidelines allow for the payment of two of the same HCPCS Level II codes for the same patient on the same date of service. For example, E1830 can be billed with the modifiers RT and LT to indicate the right toe and left toe respectively (E1830RRRT & E1830RRLT). However, when billing for a flexion device at the same time as an extension device, it creates a denial for the second device because it is seen as a duplicate (E1830 and E1830). A modifier such as XT and FL will allow CMS to recognize two distinct devices and pay for two of the same HCPCS Level II codes for the same patient on the same date of service. For example, E1830RRRTXT (right toe extension) and E1830RRRTFL (right toe flexion).

### CMS Preliminary HCPCS Coding Recommendation

CMS does not recognize a need to create a modifier to identify "extension" and a modifier to identify "flexion." The current code descriptors for HCPCS Level II codes E1800, E1805, E1810, E1815, E1825, and E1830 identify devices that provide extension and/or flexion of the applicable anatomical joint, and the current code set provides a description to treat either flexion and/or extension when clinically necessary. To clarify, CMS' intention in these code descriptors was to identify devices that provide extension and/or flexion. Further, CMS is unaware of clinical scenarios where patients require two devices to concurrently perform different functions (i.e., one for flexion, and one for extension) and are being denied for the number of device units that they need. Therefore, CMS maintains that there is no operating need for the creation of new modifiers to represent flexion and extension. If the applicant is receiving claims denials, they should contact their Durable Medical Equipment Medicare Administrative Contractor for guidance.

### Summary of Public Feedback

Dynasplint Systems, Inc. disagreed with CMS' preliminary recommendation. The speaker stated that clinical indications require both extension and flexion devices for patients. Patients need both concurrently or the patient outcomes can suffer. There is no dynamic low load

prolonged stretching device that can provide extension and flexion stretching in one device. It is not mechanically feasible or biomechanically correct to use one device to stretch both directions. When extension and flexion devices are submitted together on a health insurance claim, the claim is denied because it appears it is the same device twice. The applicant submitted 4 claim denial examples. The first two denials show claims for patients who received both an extension and flexion device. Each of those claims was denied as a duplicate because the same HCPCS Level II code and the same modifiers were used. The next two claim denials are similar except that they contain the "GY" modifier, which is used to indicate that the second device is a non-covered claim. Use of the “GY” modifier also indicates that Dynasplint Systems, Inc. has already obtained an Advance Beneficiary Notice of Noncoverage (ABN) form. The use of the ABN form allows the applicant to charge the patient directly for the second device since it is not paid by Medicare. The applicant further stated that they have approximately 600 denials from this year alone that would illustrate this claims issue. However, as noted below, many more patients decline the second device because of the cost and thus the second device is never provided/billed. Medicare beneficiaries are not receiving the devices ordered by the prescribing doctor. Since 2021, nearly 10,000 beneficiaries have been prescribed both an extension and flexion device by their doctor. However, only 46% of patients received both devices because the beneficiaries must pay for the second device when extension and flexion are billed at the same time, because Medicare will not reimburse for both devices. Adding the requested modifiers will allow Medicare to differentiate two devices billed on the same date of service and allow Medicare beneficiaries to receive the devices that are prescribed by their physicians without having to pay for the second device. Again, when Medicare patients are asked to pay for a device that is not reimbursable, the patient is more likely to decline to pay. Thus, the patient's rehabilitation from surgery/injury is delayed and the patient will take longer to recover to full range of motion, if ever.

**CMS Final HCPCS Coding Decision**

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

1. Revise existing HCPCS Level II code E1830, “Dynamic adjustable toe extension/flexion device, includes soft interface material” to instead read “Dynamic adjustable toe extension and flexion device, includes soft interface material”

2. Establish a new HCPCS Level II code E1828, “Dynamic adjustable toe extension only device, includes soft interface material”

3. Establish a new HCPCS Level II code E1829, “Dynamic adjustable toe flexion only device, includes soft interface material”

These three coding actions will be effective January 1, 2025. We believe this delay will allow time for any payers that currently list these codes in their written policies or contracts to make any necessary updates.

**Final Medicare Benefit Category Determination**

Durable Medical Equipment.

**Preliminary Medicare Payment Determination**

No determination. CMS did not previously issue a preliminary payment determination for this device in this cycle. A preliminary payment determination is stated below, and interested parties will have an opportunity to provide comment to CMS during the first biannual 2024 HCPCS coding cycle later this year. For claims payment on an interim basis, payment for the Dynasplint dynamic adjustable toe extension/flexion device will be made at the discretion of the DME MACs pending a payment determination established in accordance with the procedures at 42 CFR §414.240.

For E1830, the payment rules and pricing associated with the existing code apply to this product, if covered. The 2024 average capped rental fee schedule amount for E1830 would be approximately $163.08 for months 1 through 3 and approximately $122.31 for months 4 through 13, for a total of $1,712.34 after 13 months of continuous use.

For codes E1828 and E1829, in accordance with regulations at 42 CFR 414.236(a) if a new HCPCS Level II code is added for a DMEPOS item, CMS and/or DME MACs make efforts to determine whether the item has a pricing history. If there is a pricing history, the previous payment amounts for the previous code(s) are mapped to the new code(s) to ensure continuity of pricing. In this case, new codes E1828 and E1829 have a pricing history based on E1830. When there is a single code that describes two or more distinct complete items (with E1830, that would be flexion and extension), and separate codes are subsequently established for each item (E1829 for flexion and E1828 for extension), the payment amounts that applied to the single code are applied to and divided between each of the items described by the new codes. Thus, the preliminary payment determination for new codes E1828 and E1829 is to establish the fee schedule amount by halving the existing fee schedule amount for the related item described by HCPCS Level II code E1830.

Based on this preliminary determination pricing for both E1828 and E1829 is represented by the following formula: E1830*.5. Therefore the 2024 average capped rental fee schedule amount for both E1828 and E1829 would be approximately $81.54 for months 1 through 3 and approximately $61.16 for months 4 through 13, for a total of $856.17 after 13 months of continuous use.

The average fee schedule amount is the average of the 2024 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 36

## Ankle Foot Orthosis - HCP230522KHLFG

### Topic/Issue

Request to revise an existing HCPCS Level II code L1971, "Ankle foot orthosis, plastic or other material with ankle joint, prefabricated, includes fitting and adjustment" to expand use of L1971 to patients who do not ambulate.

The applicant did not submit any suggested language.

### Summary of Applicant's Submission

Restorative Medical submitted a request to revise an existing HCPCS Level II code L1971, "Ankle foot orthosis, plastic or other material with ankle joint, prefabricated, includes fitting and adjustment" for it to be covered for individuals who do not ambulate. The current Policy Article, A52457, and Local Coverage Determination (LCD), L33686, state that HCPCS Level II code L1971 is covered for beneficiaries who can ambulate. Many neurologically involved patients need this orthosis and cannot ambulate. Patients with neurological conditions that have diagnosis of inversion or eversion require ankle foot orthosis that are coded using HCPCS Level II code L1971 to bring their foot into a neutral position. While this ankle foot orthosis holds a patient's foot in a neutral position, they can simultaneously work to improve their dorsiflexion. Improving dorsiflexion is not possible if a patient has inversion or eversion that is not being accommodated. This is all done to improve a patient's functional independence and reduce existing range of motion limitations.

### CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code L1971, "Ankle foot orthosis, plastic or other material with ankle joint, prefabricated, includes fitting and adjustment" describes the Ankle Foot Orthosis by Restorative Medical. The description of L1971 does not distinguish between patients who do or do not ambulate. As such, CMS has not identified a program operating need for Medicare or other payers to revise existing HCPCS Level II code L1971. Inquiries regarding the current Policy Article, A52457, and LCD, L33686, should be directed to the Medicare Administrative Contractor (MAC).

### Preliminary Medicare Benefit Category Determination

Leg brace (Orthotic).

The application supports a preliminary benefit category determination that the Ankle Foot Orthosis by Restorative Medical is used as a lower extremity brace and would fall under the Medicare benefit for Leg brace (Orthotic). Section 130 of Chapter 15 of the Medicare Benefit Policy Manual (CMS Pub. 100-02) defines a brace as a rigid or semi-rigid device used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body. A review of the information submitted by the applicant supports the preliminary benefit category determination of leg brace which requires the item to be used to support a weak or deformed lower extremity.

**Preliminary Medicare Payment Determination**

The payment rules and pricing associated with the existing code L1971 apply to this product, if covered. The current average 2023 fee schedule amount for L1971 is $534.86.

The average fee schedule amount is the average of the 2023 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 38

**Summary of Public Feedback**

No verbal or written comments were provided in response to CMS' published preliminary recommendations.

**CMS Final HCPCS Coding Decision**

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

Our understanding is that the existing HCPCS Level II code L1971, "Ankle foot orthosis, plastic or other material with ankle joint, prefabricated, includes fitting and adjustment" describes the Ankle Foot Orthosis by Restorative Medical. The description of HCPCS Level II code L1971 does not distinguish between patients who do or do not ambulate. As such, CMS has not identified a program operating need for Medicare or other payers to revise existing HCPCS Level II code L1971. Inquiries regarding the current Policy Article, A52457, and LCD, L33686, should be directed to the Medicare Administrative Contractor (MAC).

**Final Medicare Benefit Category Determination**

Leg brace (Orthotic).

**Final Medicare Payment Determination**

The payment rules and pricing associated with the existing code L1971 apply to this product, if covered. The current average 2024 fee schedule amount for L1971 is $548.77.

The average fee schedule amount is the average of the 2024 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 38

## Portable Neuromodulation Stimulator (PoNS™) Controller - HCP2306299CNLN

### Topic/Issue

Request to establish a new HCPCS Level II code to identify Portable Neuromodulation Stimulator (PoNS™) Controller.

Applicant's suggested language: EXXXX, "Non-implanted neuromodulation tongue stimulator, 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 Preliminary HCPCS Coding Recommendation

CMS is seeking additional detailed information to further inform our decision. Please provide responses to the following questions:

1. When using the PoNS™ device, what specific physical activity is the patient performing in the home and in the physical therapist's clinical setting? How long are the sessions (minutes and/or hours) in the home and in the clinical setting? And how many sessions are required per week?
2. Does the patient need any specific equipment to use with the PoNS™ device in the home?
3. May the PoNS™ device be used 100% of the time without a physical therapist's clinical involvement?
4. During the 14-week period of use, how many times does the patient need to see or consult with a physical therapist?
5. After the initial 14-week period, will the patient need to use the device again in the future?

**Preliminary Medicare Benefit Category Determination**

The preliminary Medicare benefit category determination is deferred, pending response to the questions posed in the CMS Preliminary HCPCS Coding Recommendation.

**Preliminary Medicare Payment Determination**

The preliminary Medicare payment determination is deferred, pending response to the questions posed in the CMS Preliminary HCPCS Coding Recommendation.

**Summary of Public Feedback**

Helius Medical, Inc. addressed specific questions about the PoNS™ Controller and PoNS™ Mouthpiece and its use by patients. The speaker stated the PoNS™ System (PoNS™ Controller and the PoNS™ Mouthpiece) qualifies as durable medical equipment (DME) such that Medicare benefit category determinations and Medicare payment determinations should be made in the final decision and take effect on April 1, 2024.

When using the PoNS™ device, there is no difference in the physical activities the patient performs in the home compared to those done during the initial clinical visits. When a patient starts PoNS™ Therapy, the rehabilitation therapist establishes a set of gait, balance, movement control exercises, and breathing and awareness training, based on the initial assessment of the patient's needs and ability to perform the program. The patient is instructed to perform, at home and autonomously, the same physical exercises performed in the clinic with the therapist. The specific activities a patient performs while using the PoNS™ System differs from patient to patient, based on the regimen determined for each patient by their rehabilitation specialist. No special equipment is required for the patient to perform the rehabilitation program with the PoNS™ System in the home. While patients may utilize equipment they already have at their home (e.g., a treadmill), most activities do not require the use of specific equipment.

Physical exercise sessions while using the PoNS™ System, whether at home or in clinic, are 20 minutes. In a given day, a patient is typically recommended to perform 5 sessions: this consists of one 40-minute exercise routine (consisting of two 20-minute sessions, one each for balance and gait exercises) and one 60-minute exercise routine (balance and gait sessions, with an added 20-min BAT session in the evening). There is no difference in the length of the sessions performed in the clinical setting during the two-week training period and the sessions performed in the home. Altogether, the patient is recommended to complete 100 minutes of PoNS™ Therapy using the PoNS™ device each day, for 5 to 6 days a week. There is no specific requirement as to the number of sessions per week using the PoNS™ System. Rather, the patient's rehabilitation specialist develops a regimen for the patient that includes a recommended number of sessions per week.

The device may be used 100% of the time without the need for the rehabilitation specialist to assist with its utilization with the exception of the time, at start of therapy, when the specialist, during the initial in-clinic evaluation/therapy sessions over the first two weeks of the 14-week period of use, activates the device and establishes the exercise program. Further, during the initial two weeks, at least half of the time the patient is using the device, they are doing so at home. Over a recommended 14-week period of use, the PoNS™ System is used in 432 sessions and 393 of those sessions are performed in the home and only 39 sessions

(9.3%) are performed in the clinical setting. There is no mandatory number of in-clinic visits over the 14-week treatment period. Whether a particular patient will use the device again after the completion of the initial 14- week period is a determination made by the patient's healthcare provider. That likely would be based on the individual progression of the patient's medical condition and/or decline in their functional gait/balance ability.

Under CMS' multi-component device policy, the controller, which has a 3-year useful life, performs the medically necessary function of driving the electrotactile stimulation to the trigeminal and facial nerves by controlling the delivery and stimulation level of the energy. The other DME requirements are such that the controller is an item of DME and the Mouthpiece is a supply necessary for the effective use of an item of DME. Regarding Medicare payment, both devices are new, with no pricing history and no comparable items such that payment for each should be determined using the gap-filling methodology.

**CMS Final HCPCS Coding Decision**[19]

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

Establish a new HCPCS Level II code A4593, "Neuromodulation stimulator system, adjunct to rehabilitation therapy regime, controller" to describe Portable Neuromodulation Stimulator (PoNS™) Controller.

**Final Medicare Benefit Category Determination**

Durable Medical Equipment.

CMS did not provide a preliminary determination previously, because additional information was needed to determine the benefit category for the PoNS™ controller. Instead, we provided a list of questions to help us determine whether the PoNS™ device is used by a patient with or without a clinician's service. After reviewing the applicant's responses to our questions and the applicant's public meeting presentation, we determined that the PoNS™ controller is DME.

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

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

All five of these conditions must be met for equipment to be classified as DME. The information submitted by the applicant was reviewed along with input received during the

[19] Revised on March 14, 2024, to update the long descriptor for HCPCS Level II code A4593 to include "controller."

public meeting and written information received after the meeting, and the PoNS™ controller was determined to meet the requirements to be classified as DME. We believe this device is primarily and customarily used for the short-term treatment of gait deficit due to mild to moderate symptoms of multiple sclerosis and generally is not useful to an individual in the absence of an illness or injury.

Note that although the application stated that the PoNS™ controller could be used by successive patients, a public meeting presenter stated that the PoNS™ controller cannot be used by successive patients (cannot withstand repeated use) because the applicant had not developed a refurbishment program to restore the controllers for continuous use. After the public meeting, the applicant stated in writing that the information provided during the meeting was incorrect. The applicant clarified in writing that the PoNS™ controller has been used by successive patients in clinical trials, and the process used to refurbish and restore the controllers in those clinical trials is the same process that can be used for the controllers on the commercial market. Thus, we have concluded that the PoNS™ controller can be used by successive patients.

**Final Medicare Payment Determination**

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

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

Pricing Indicator = 46

## Portable Neuromodulation Stimulator (PoNS™) Mouthpiece - HCP2306294W7HD

### Topic/Issue

Request to establish a new HCPCS Level II code to identify Portable Neuromodulation Stimulator (PoNS™).

Applicant's suggested language: AXXXX, "Non-implanted neuromodulation tongue stimulator, 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 electrotactile 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 Preliminary HCPCS Coding Recommendation

CMS is seeking additional detailed information to further inform our decision. Please provide responses to the following questions:

1. When using the PoNS™ device, what specific physical activity is the patient performing in the home and in the physical therapist's clinical setting? How long are the sessions (minutes and/or hours) in the home and in the clinical setting? And how many sessions are required per week?
2. Does the patient need any specific equipment to use with the PoNS™ device in the home?
3. May the PoNS™ device be used 100% of the time without a physical therapist's clinical involvement?
4. During the 14-week period of use, how many times does the patient need to see or consult with a physical therapist?

5. After the initial 14-week period, will the patient need to use the device again in the future?

**Preliminary Medicare Benefit Category Determination**

The preliminary Medicare benefit category determination is deferred, pending response to the questions posed in the CMS Preliminary HCPCS Coding Recommendation.

**Preliminary Medicare Payment Determination**

The preliminary Medicare payment determination is deferred, pending response to the questions posed in the CMS Preliminary HCPCS Coding Recommendation.

**Summary of Public Feedback**

Helius Medical, Inc. addressed specific questions about the PoNS™ Controller and PoNS™ Mouthpiece and its use by patients. The speaker stated the PoNS™ System (PoNS™ Controller and the PoNS™ Mouthpiece) qualifies as durable medical equipment (DME) such that Medicare benefit category determinations and Medicare payment determinations should be made in the final decision and take effect on April 1, 2024.

When using the PoNS™ device, there is no difference in the physical activities the patient performs in the home compared to those done during the initial clinical visits. When a patient starts PoNS™ Therapy, the rehabilitation therapist establishes a set of gait, balance, movement control exercises, and breathing and awareness training, based on the initial assessment of the patient's needs and ability to perform the program. The patient is instructed to perform, at home and autonomously, the same physical exercises performed in the clinic with the therapist. The specific activities a patient performs while using the PoNS™ System differs from patient to patient, based on the regimen determined for each patient by their rehabilitation specialist. No special equipment is required for the patient to perform the rehabilitation program with the PoNS™ System in the home. While patients may utilize equipment they already have at their home (e.g., a treadmill), most activities do not require the use of specific equipment.

Physical exercise sessions while using the PoNS™ System, whether at home or in clinic, are 20 minutes. In a given day, a patient is typically recommended to perform 5 sessions: this consists of one 40-minute exercise routine (consisting of two 20-minute sessions, one each for balance and gait exercises) and one 60-minute exercise routine (balance and gait sessions, with an added 20-min BAT session in the evening). There is no difference in the length of the sessions performed in the clinical setting during the two-week training period and the sessions performed in the home. Altogether, the patient is recommended to complete 100 minutes of PoNS™ Therapy using the PoNS™ device each day, for 5 to 6 days a week. There is no specific requirement as to the number of sessions per week using the PoNS™ System. Rather, the patient's rehabilitation specialist develops a regimen for the patient that includes a recommended number of sessions per week.

The device may be used 100% of the time without the need for the rehabilitation specialist to assist with its utilization with the exception of the time, at start of therapy, when the specialist, during the initial in-clinic evaluation/therapy sessions over the first two weeks of the 14-week period of use, activates the device and establishes the exercise program. Further,

during the initial two weeks, at least half of the time the patient is using the device, they are doing so at home. Over a recommended 14-week period of use, the PoNS™ System is used in 432 sessions and 393 of those sessions are performed in the home and only 39 sessions (9.3%) are performed in the clinical setting. There is no mandatory number of in-clinic visits over the 14-week treatment period. Whether a particular patient will use the device again after the completion of the initial 14- week period is a determination made by the patient's healthcare provider. That likely would be based on the individual progression of the patient's medical condition and/or decline in their functional gait/balance ability.

Under CMS' multi-component device policy, the controller, which has a 3-year useful life, performs the medically necessary function of driving the electrotactile stimulation to the trigeminal and facial nerves by controlling the delivery and stimulation level of the energy. The other DME requirements are such that the controller is an item of DME and the Mouthpiece is a supply necessary for the effective use of an item of DME. Regarding Medicare payment, both devices are new, with no pricing history and no comparable items such that payment for each should be determined using the gap-filling methodology.

**CMS Final HCPCS Coding Decision**

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

Establish a new HCPCS Level II code A4594, "Neuromodulation stimulator system, adjunct to rehabilitation therapy regime, mouthpiece each" to describe Portable Neuromodulation Stimulator (PoNS™) mouthpiece.

**Final Medicare Benefit Category Determination**

Durable Medical Equipment.

The PoNS™ mouthpiece serves as a DME accessory to the PoNS™ device that has been modified to meet the definition of DME. The mouthpiece is an integral part of the PoNS™'s multi-component system that provides treatment of gait deficit due to mild to moderate symptoms of multiple sclerosis. Section 110.3 of the Medical Benefit Policy Manual (CMS Pub. 100-03) indicates that payment may be made for supplies that are necessary for the effective use of durable medical equipment. Because the PoNS™ mouthpiece is an accessory for a code that is DME (A4593), the mouthpiece falls under the DME benefit category.

**Final Medicare Payment Determination**

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

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

price used in calculating the fee schedule amounts is $150 or less, then payment would be made on a rental or purchase basis in accordance with our regulations at 42 CFR 414.220.

Pricing Indicator = 46

## IpsiHand™ Upper Extremity Rehabilitation System - HCP230701PDW27

### Topic/Issue

Request to establish a new HCPCS Level II code to identify Neurolutions IpsiHand™ Upper Extremity Rehabilitation System.

Applicant's suggested language: XXXXX, “Brain-computer interface (BCI) controlled therapy device including noninvasive EEG headset, powered motion assist device, includes microprocessor, all components and accessories”

### Summary of Applicant's Submission

Neurolutions Inc. submitted a request to establish a new HCPCS Level II code to identify Neurolutions IpsiHand™ Upper Extremity Rehabilitation System (IpsiHand™). IpsiHand™ received the Food and Drug Administration’s (FDA’s) De Novo clearance on April 23, 2021. Neurolutions 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 Preliminary HCPCS Coding Recommendation

CMS is interested in understanding how other payers treat therapy devices used by a patient at home for maintaining or restoring some degree of function. Would the use of IpsiHand™ at home be considered providing medical therapy relative to when using an exercise

equipment? Who writes the order and who develops and oversees a plan of care involving IpsiHand™?

**Preliminary Medicare Benefit Category Determination**

The preliminary Medicare benefit category determination is deferred, pending response to the questions posed in the CMS Preliminary HCPCS Coding Recommendation.

**Preliminary Medicare Payment Determination**

The preliminary Medicare payment determination is deferred, pending response to the questions posed in the CMS Preliminary HCPCS Coding Recommendation.

**Summary of Public Feedback**

Neurolutions Inc. neither agreed nor disagreed with CMS' preliminary recommendations because there was no specific recommendation. The speaker extrapolated a series of distinctions between 'medical therapy' and 'exercise equipment' respectively to establish that IpsiHand™ is a medical therapy and not exercise equipment. Medical therapy in general will require a prescription from a healthcare provider, is not useful in the absence of an illness or injury, is primarily medical in nature, intended to treat an illness or injury and will ideally have an FDA authorization for a specific indication. Conversely, exercise equipment will typically not require a prescription, may be useful in the absence of an injury and is not primarily medical in nature. IpsiHand™ meets the definition of being a medical therapy as it is exclusively available with a prescription, is useless in the absence of an injury of the brain, is ordered by a healthcare provider, has been shown in published clinical studies to rebuild or remodel neuronal pathways in the brain and it is both De Novo cleared & Breakthrough designated by FDA for a specific indication. The plan of care is overseen by the prescribing healthcare provider. Neurolutions' staff will work with the patient and the prescribing healthcare provider to facilitate delivery, training, and patient support throughout usage of the device. A patient's IpsiHand™ usage data is uploaded to a Health Insurance Portability and Accountability Act compliant online application which is accessible to the prescribing physician. Neurolutions staff will periodically complete an Upper Extremity Fugl-Meyer assessment and input the data into the portal so the healthcare provider can track both usage and outcomes.

Based on preliminary research, one product was identified that met the conditions of the request for being therapeutic, used at-home, and having an ability to restore some degree of function: Vivistim, an implantable vagus nerve stimulator (VNS) by Microtransponder. They looked at a multitude of payer's medical policies on VNS devices including UHC, Aetna, Cigna, and Anthem and VNS technology was consistently classified as medically necessary for refractory epilepsy but as investigational and not medically necessary for most other applications.

**CMS Final HCPCS Coding Decision**

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

Establish a new 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.

**Final Medicare Benefit Category Determination**

Durable Medical Equipment

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

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

All five of these conditions must be met in order for equipment to be classified as DME. The information submitted by the applicant was reviewed along with input received during the public meeting and the IpsiHand™ Upper Extremity Rehabilitation System was determined to meet the requirements to be classified as DME. We believe this device is primarily and customarily used for the treatment of stroke and generally is not useful to an individual in the absence of an illness or injury.

**Final Medicare Payment Determination**

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

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

Pricing Indicator = 46

## Motus Hand and Motus Foot - HCP230314K8EQG

### Topic/Issue

Request to establish a new HCPCS Level II Code to identify the Motus Hand and the Motus Foot.

The applicant did not submit any suggested language.

### 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 survivors of stroke to use at home or in the clinic; they guide patients through therapeutic activities, provide intuitive robotic assistance to augment weakness 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 HCPCS Coding Recommendation

CMS is interested in understanding how payers treat therapy devices used by patients at home for maintaining or restoring some degree of function. Would the use of the Motus Hand and Foot devices at home be considered providing medical therapy relative to when using exercise equipment?

### Preliminary Medicare Benefit Category Determination

The preliminary Medicare benefit category determination is deferred, pending response to the questions posed in the CMS Preliminary HCPCS Coding Recommendation.

### Preliminary Medicare Payment Determination

The preliminary Medicare payment determination is deferred, pending response to the questions posed in the CMS Preliminary HCPCS Coding Recommendation.

### Summary of Public Feedback

Motus Nova neither agreed nor disagreed with CMS' preliminary recommendations because there was no specific recommendation. According to the speaker, the HCPCS Level II code A9300, "Exercise equipment," does not describe the Motus Hand and Motus Foot and neither device meets the definition of biofeedback in the National Coverage Determination 30.1 "Biofeedback Therapy." The speaker stated both devices provide medical therapy to neuro patients in their homes through active assistance, audio/visual and pneumatic biofeedback, without the need for a provider to be present. The speaker suggested code language for the Motus Hand and Foot respectively: EXXXX, "Upper extremity powered, active-assisted kinetic and kinematic computer interface-controlled biofeedback therapy device, includes

microprocessor, all components and accessories" and EXXXX, "Lower extremity powered, active-assisted kinetic and kinematic computer interface-controlled biofeedback therapy device, includes microprocessor, all components and accessories." Commenters stated that creating new HCPCS Level II codes to describe the Motus Hand and Foot technology was essential to providing effective neuro rehabilitative therapy to patients in their homes.

**CMS Final HCPCS Coding Decision**

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

Establish 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.

**Final Medicare Benefit Category Determination**

Durable Medical Equipment

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

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

All five of these conditions must be met in order for equipment to be classified as DME. The information submitted by the applicant was reviewed along with input received during the public meeting and the Motus Hand and Foot was determined to meet the requirements to be classified as DME. We believe this device is primarily and customarily used for the treatment of stroke and generally is not useful to an individual in the absence of an illness or injury. Additionally, we do not find these devices to be subject to the National Coverage Decision 30.1.

**Final Medicare Payment Determination**

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

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

price used in calculating the fee schedule amounts is $150 or less, then payment would be made on a rental or purchase basis in accordance with our regulations at 42 CFR 414.220.

Pricing Indicator = 46

## Nalu™ Adhesive Clip - HCP230630M0GF7

### Topic/Issue

Request to establish a new HCPCS Level II code to identify Nalu™ Adhesive Clip.

Applicant's suggested language: AXXXX, “Adhesive clip applied to the skin to secure relief therapy disc, each”

### Summary of Applicant's Submission

Nalu Medical, Inc. submitted a request to establish a new HCPCS Level II code to identify the Nalu™ Adhesive Clip. The Nalu™ Adhesive Clip received the Food and Drug Administration’s (FDA’s) 510(k) clearance on March 29, 2019. The Nalu™ Neurostimulation System includes features that are different from all other systems requiring adhesives. The Nalu™ Neurostimulation System comes with an adhesive wearable clip that is a medical supply furnished by the durable medical equipment carrier for beneficiaries outside and separate from the cost and reimbursement of the Nalu™ Neurostimulation System. The adhesive clip assembly includes usability features making it easy for users of the Nalu™ Neurostimulation System to precisely position, align and secure their external therapy disc over their implantable neurostimulator to ensure robust bidirectional wireless communication throughout the day. The physical clip also has retention features that balance convenient therapy disc insertion and removal by users (patients may swap therapy discs multiple times per wear period) while reliably retaining the therapy disc throughout days of normal use activities such as walking, working, exercising, sleeping, showering which can be further monitored by an accelerometer onboard the therapy disc.

### CMS Preliminary HCPCS Coding Recommendation

Establish a new HCPCS Level II code AXXXX, “Adhesive clip applied to the skin to secure external electrical nerve stimulator controller, each”

### Preliminary Medicare Benefit Category Determination

Supply used with Prosthetic Device.

In order for the Nalu™ Neurostimulation System (electrical nerve stimulator) to function properly, the system requires the use of the Nalu™ Adhesive Clip. The system includes an implantable pulse generator and an external therapy disc that includes a controller and a battery. However, the system depends upon the adhesive clip to assist the patient in precisely positioning, aligning, and securing the external therapy disc over the implantable neurostimulator to ensure bidirectional wireless communication. Therefore, the Nalu™ Adhesive Clip is a supply to the electrical nerve stimulator which is a prosthetic device.

### Preliminary Medicare Payment Determination

In accordance with regulations at 42 CFR § 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. The preliminary payment determination for code AXXXX, for this item, is to establish the fee schedule amounts using existing fee schedule amounts for comparable items described by HCPCS Level II code A5126, “Adhesive or non-adhesive; disk or foam pad.”

We note that as an ostomy supply, A5126 uses a different fee schedule base period than prosthetics, and so the payment amount for AXXXX has been adjusted accordingly. Based on this preliminary determination, the 2023 fee schedule amounts for AXXXX would be approximately $1.93 on average.

The average fee schedule amount is the average of the 2023 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 38

**Summary of Public Feedback**

No verbal or written comments were provided in response to CMS’ published preliminary recommendations.

**CMS Final HCPCS Coding Decision**

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

Establish a new HCPCS Level II code A4438, “Adhesive clip applied to the skin to secure external electrical nerve stimulator controller, each” to describe Nalu™ Adhesive Clip.

**Final Medicare Benefit Category Determination**

Supply used with Prosthetic Device.

**Final Medicare Payment Determination**

The fee schedule amount for A4438 will be established based on the payment amount for A5126, as discussed in the preliminary determination. We note that as an ostomy supply, A5126 uses a different fee schedule base period and annual update factors than prosthetics, and so the payment amount for A4438 has been adjusted accordingly. The 2024 fee schedule amount will be approximately $2.09 on average.

Pricing Indicator = 38

## mRNA and mmRNA - HCP230630CKHA7

### Topic/Issue

Request to establish a new HCPCS Level II code to identify mandibular Repositioning Nighttime Appliance (mRNA) and modified mandibular Repositioning Nighttime Appliance (mmRNA).

Applicant's suggested language: XXXXX, “Oral device/appliance, custom fabricated, removable, mandibular advancement and non-surgical jaw expansion, with or without a fixed mechanical hinge”

### Summary of Applicant's Submission

Vivos® Therapeutics Inc. submitted a request to establish a new HCPCS level II code to identify mRNA and mmRNA. mRNA and mmRNA received the Food and Drug Administration’s (FDA’s) 510(k) clearance on August 19, 2021. Both the mRNA and mmRNA are indicated for the adult treatment of mild and moderate Obstructive Sleep Apnea. Both devices (mRNA and mmRNA) represent a significant increase in complexity of design and cost of fabrication versus the mandibular advancement only oral appliances described by the current code set (E0486 or K1027).

### CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code K1027, “Oral device/appliance used to reduce upper airway collapsibility, without fixed mechanical hinge, custom fabricated, includes fitting and adjustment” describes mRNA.

Existing HCPCS Level II code E0486, “Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, custom fabricated, includes fitting and adjustment” describes mmRNA.

CMS welcomes more information from the applicant on how the existing codes do not meet the features and functions of their products and how the existing codes do not represent the significant increase in complexity.

### Preliminary Medicare Benefit Category Determination

No determination.

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

### Preliminary Medicare Payment Determination

No determination.

**Summary of Public Feedback**

Vivos® Therapeutics Inc. disagreed with CMS' preliminary recommendation to assign mandibular Repositioning Nighttime Appliance (mRNA) and modified mandibular Repositioning Nighttime Appliance (mmRNA) to an existing HCPCS Level II codes, K1027 and E0486. Obstructive sleep apnea (OSA) is a prevalent malady typically managed, but not treated, with positive airway pressure (PAP) therapies. PAP therapy is considered the medical gold standard in the management of OSA in adults. Mandibular advancement devices (MAD) are an effective alternative therapy in the medical management of OSA; however, like PAP, MADs only manage the disorder. Alternative surgical interventions to increase upper airway (pharyngeal) space not only effectively decrease Apnea hypopnea index (AHI) but maxillomandibular advancement surgery is curative (AHI <5) in a significant percentage of treated patients (~43%). The speaker stated that the procedure code selection for these new appliances (E0486 and K1027) is problematic with the current code set. Available codes specific for oral device/appliance, custom fabricated, removable used to treat Obstructive Sleep Apnea were promulgated for MADs that have an upper and lower dental arch component and have the singular capability of advancing the mandible with or without a fixed hinge mechanism. These codes are inadequate to address the single arch nature of the DNA, jaw expansion capability of all three devices (DNA, mRNA and mmRNA), and combination MAD/jaw expansion capabilities of the mRNA and mmRNA appliances. The jaw expansion mechanism(s) of these devices significantly increase the dental laboratory manufacturing cost of these appliances versus typical MADs. To prevent an insurmountable financial obstacle to access to treatment of this type, final benefit determination needs to consider the current production cost of these appliances is ~5-8 times the cost of producing a typical MAD. Of note, the increase in benefit cost should be balanced not only by the generally higher compliance rate of oral appliance vs. PAP (less unmanaged or poorly managed OSA patients) but also the cost savings derived from the effective cure rate of the treatment (no additional therapy/supplies needed).

**CMS Final HCPCS Coding Decision**

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

1. Existing HCPCS Level II code K1027, "Oral device/appliance used to reduce upper airway collapsibility, without fixed mechanical hinge, custom fabricated, includes fitting and adjustment" to describe mRNA.

2. Existing HCPCS Level II code E0486, "Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, custom fabricated, includes fitting and adjustment" to describe mmRNA.

mRNA and mmRNA are custom fabricated oral appliances that may adjust the position, alignment, size, and/or shape of the jaw to increase the pharyngeal airway. Vivos® Therapeutics refers to this as non-surgical jaw expansion. We have not identified a program need to separately identify the non-surgical jaw expansion feature associated with this device. CMS recognizes the importance of coding precision for the appropriate categorization of medical devices. Therefore, while the applicant has made a case for the uniqueness of jaw

expansion, it is incumbent upon them to provide compelling evidence that this feature is not already encompassed within the existing codes (K1027 and E0486) and that it offers a significant therapeutic advantage in the treatment of OSA. Until such evidence is presented and verified, existing HCPCS Level II codes K1027 and E0486 describes mRNA and mmRNA, respectively. Inquiries regarding the current policy for HCPCS Level II code E0486 related to adjustment period should be directed to the Medicare Administrative Contractor (MAC).

**Final Medicare Benefit Category Determination**

No determination.

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

**Final Medicare Payment Determination**

No determination. As stated in the Final Medicare Benefit Category Determination, in the meantime, classification, coverage, and payment for these items will be made on an individual claim-by-claim basis by the MACs.

## Daytime Nighttime Appliance (DNA) - HCP2306308TG88

### Topic/Issue

Request to establish a new HCPCS Level II code to identify Daytime Nighttime Appliance (DNA).

Applicant's suggested language: XXXXX, "Oral device/appliance, custom fabricated, removable used to treat mild or moderate obstructive sleep apnea by non-surgical jaw expansion"

### Summary of Applicant's Submission

Vivos® Therapeutics Inc. submitted a request to establish a new HCPCS Level II code to identify DNA. DNA received the Food and Drug Administration's (FDA's) 510(k) clearance on December 30, 2022. DNA is indicated in the adult treatment of mild and moderate obstructive sleep apnea. DNA is a custom fabricated, removable, oral device/appliance for the treatment of obstructive sleep apnea by non-surgical jaw expansion.

### CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code K1027, "Oral device/appliance used to reduce upper airway collapsibility, without fixed mechanical hinge, custom fabricated, includes fitting and adjustment" describes DNA.

### Preliminary Medicare Benefit Category Determination

No determination.

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

### Preliminary Medicare Payment Determination

No determination.

### Summary of Public Feedback

Vivos® Therapeutics Inc. disagreed with CMS' HCPCS preliminary recommendation to assign Daytime Nighttime Appliance to an existing HCPCS Level II code K1027. The commenters stated that obstructive sleep apnea (OSA) is a prevalent malady typically managed, but not treated, with positive airway pressure (PAP) therapies. PAP therapy is considered the medical gold standard in the management of OSA in adults. Mandibular advancement devices (MAD) are an effective alternative therapy in the medical management of OSA; however, like PAP, MADs only manage the disorder. Alternative surgical interventions to increase upper airway (pharyngeal) space not only effectively decrease Apnea hypopnea index (AHI) but maxillomandibular advancement surgery is curative (AHI <5) in a significant percentage of treated patients (~43%). The speaker stated that the

procedure code selection for these new appliances (E0486 and K1027) is problematic with the current code set. Available codes specific for oral device/appliance, custom fabricated, removable used to treat OSA were promulgated for MADs that have an upper and lower dental arch component and have the singular capability of advancing the mandible with or without a fixed hinge mechanism. These codes are inadequate to address the single arch nature of the DNA, jaw expansion capability of all three devices (DNA, mRNA and mmRNA), and combination MAD/jaw expansion capabilities of the mRNA and mmRNA appliances. The jaw expansion mechanism(s) of these devices significantly increase the dental laboratory manufacturing cost of these appliances versus typical MADs. To prevent an insurmountable financial obstacle to access to treatment of this type, final benefit determination needs to consider the current production cost of these appliances is ~5-8 times the cost of producing a typical MAD. Of note, the increase in benefit cost should be balanced not only by the generally higher compliance rate of oral appliance vs. PAP (less unmanaged or poorly managed OSA patients) but also the cost savings derived from the effective cure rate of the treatment (no additional therapy/supplies needed).

**CMS Final HCPCS Coding Decision**

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

Existing HCPCS Level II code K1027, "Oral device/appliance used to reduce upper airway collapsibility, without fixed mechanical hinge, custom fabricated, includes fitting and adjustment" to describe DNA.

DNA is a custom fabricated oral appliance that may adjust the position, alignment, size, and/or shape of the jaw to increase the pharyngeal airway. Vivos® Therapeutics refers to this as non-surgical jaw expansion. We have not identified a program need to separately identify the non-surgical jaw expansion feature associated with this device. CMS recognizes the importance of coding precision for the appropriate categorization of medical devices. Therefore, while the applicant has made a case for the uniqueness of jaw expansion, it is incumbent upon them to provide compelling evidence that this feature is not already encompassed within the existing code, K1027, and that it offers a significant therapeutic advantage in the treatment of OSA. Until such evidence is presented and verified, existing HCPCS Level II code K1027 describes DNA. Inquiries regarding the current policy for HCPCS Level II code E0486 related to adjustment period should be directed to the Medicare Administrative Contractor (MAC).

**Final Medicare Benefit Category Determination**

No determination.

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

**Final Medicare Payment Determination**

No determination. As stated in the Final Medicare Benefit Category Determination, in the meantime, classification, coverage, and payment for these items will be made on an individual claim-by-claim basis by the MACs.

## The Slide®- HCP230703WJE8T

### Topic/Issue

Request to revise an existing HCPCS Level II code E0486, "Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, custom fabricated, includes fitting and adjustment" to identify The Slide®.

The applicant did not submit any suggested language.

### Summary of Applicant's Submission

LeBlanc Dental Products submitted a request to revise existing HCPCS Level II code E0486, "Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, custom fabricated, includes fitting and adjustment" to identify The Slide®. The Slide® received the Food and Drug Administration's (FDA's) 510(k) clearance on July 20, 2021. The Slide® is a prescribed intraoral device worn while sleeping to reduce nighttime snoring and mild to moderate obstructive sleep apnea. The fixed hinge is defined as a mechanical joint, containing an inseparable pivot point. Interlocking flanges, tongue and groove mechanisms, hook and loop or hook and eye clasps, elastic straps or bands, mono-block articulation, traction-based articulation, compression-based articulation, etc. (not all-inclusive) do not meet this requirement of CMS' Policy Article A52512 published at https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=52512.

### CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code K1027, "Oral device/appliance used to reduce upper airway collapsibility, without fixed mechanical hinge, custom fabricated, includes fitting and adjustment" describes The Slide®.

### Preliminary Medicare Benefit Category Determination

No determination.

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

### Preliminary Medicare Payment Determination

No determination.

### Summary of Public Feedback

LeBlanc Dental Products disagreed with CMS' preliminary recommendation to assign The Slide® to existing HCPCS Level II code K1027. The speaker requested the policy related to existing HCPCS Level II code E0486 should be updated. The speaker noted some products that received existing HCPCS Level II code E0486 that their hinge is not called out as excluded in the existing policy. The Slide® has a locking rail design, which is not called out

in the policy and as such should be coded under E0486. The Slide® locking rail design and patient comfort key to achieving compliance. The speaker requested existing HCPCS Level II code E0486 as there is established practices and reimbursements. The speaker commented that The Slide® was assigned K1027 by the Pricing, Data Analysis and Coding, which the code language accurately describes the product, however the code does not allow for proper reimbursement cost. According to the comments, time has brought advancements, yet patient access is being limited to an original policy article written 8 years ago.

**CMS Final HCPCS Coding Decision**

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

Existing HCPCS Level II code K1027, "Oral device/appliance used to reduce upper airway collapsibility, without fixed mechanical hinge, custom fabricated, includes fitting and adjustment" to describe The Slide®.

The locking rail design of The Slide® is not considered a fixed hinge. As such, existing HCPCS Level II code K1027 best describes The Slide®. Inquiries regarding the current policy related to E0486 should be directed to the Medicare Administrative Contractor (MAC).

**Final Medicare Benefit Category Determination**

No determination.

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

**Final Medicare Payment Determination**

No determination. As stated in the Final Medicare Benefit Category Determination, in the meantime, classification, coverage, and payment for these items will be made on an individual claim-by-claim basis by the MACs.

## EVO® Sleep and Snore Device - HCP230703YHFLY

### Topic/Issue

Request to establish a new HCPCS Level II code to identify EVO® Sleep and Snore Device.

Applicant's suggested language: KXXXX, “Oral device used to reduce upper airway collapsibility, that is iteratively adjustable with interlocking lateral flanges, custom fabricated from US Pharmacopeia Class VI qualified material with a forward engineered and wholly embedded patient monitoring sensor technology”

### Summary of Applicant's Submission

ProSomnus® Sleep Technologies submitted a request to establish a new HCPCS Level II code to identify EVO® Sleep and Snore Device. EVO® Sleep and Snore Device received the Food and Drug Administration’s (FDA’s) 510(k) clearance on November 20, 2020. EVO® Sleep and Snore Device is a custom oral device to reduce upper airway collapsibility and to monitor medically important physiologic patient data. Physiologic data medically relevant to upper airway collapsibility include temperature, blood pressure, pulse rate, heart rate, and oxygen. The available coding for oral devices to reduce upper airway collapsibility, specifically E0486 and K1027, does not provide for patient monitoring. The available coding for patient monitoring devices, including K0554 and E2102, are specific to glucose monitoring. It should be noted that there are similar concepts in the existing codes about glucose monitoring: K0554, “receiver (monitor), dedicated, for use with therapeutic continuous glucose monitor system.” Also, E2103, “non-adjunctive, non-implanted continuous glucose monitor or receiver” as maintained by CMS falls under miscellaneous pumps and monitors and E2102, “adjunctive continuous glucose monitor or receiver.” Both codes are specific to glucose monitoring and are therefore not applicable to EVO® Sleep and Snore Device’s technology for reducing upper airway collapsibility. EVO® Sleep and Snore Device’s technology will measure physiological metrics relevant to upper airway collapsibility and their effects on the patient including temperature, oxygen levels, blood pressure, heart rate, and/or pulse rate.

### CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code K1027, “Oral device/appliance used to reduce upper airway collapsibility, without fixed mechanical hinge, custom fabricated, includes fitting and adjustment” describes EVO Sleep and Snore Device.

We have not identified a program need to separately identify the monitoring feature associated with this device. We note that items used in the patient’s home that provide monitoring and measurements for the physician/practitioner to evaluate the patient’s condition and course of treatment do not fall under the Medicare benefit for DME used in the home. CMS welcomes more information from the applicant on how the existing codes do not meet the features and functions of their products.

### Preliminary Medicare Benefit Category Determination

No determination.

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

**Preliminary Medicare Payment Determination**

No determination.

**Summary of Public Feedback**

ProSomnus® Sleep Technologies partially disagreed with CMS' preliminary recommendation to assign EVO® Sleep and Snore Device to existing HCPCS Level II code K1027. The speaker stated that mandibular advancement devices (MAD) therapy with ProSomnus® EVO is a first line of therapy that showed high efficacy, and high adherence in patients with moderate and severe obstructive sleep apnea. In a conducted study, 40 percent of participants preferred CPAP therapy versus MAD. This can potentially overcome some of the barriers for sleep physicians to prescribe custom made MAD devices for moderate to severe OSA. As suggested, HCPCS Level II code K1027, likely describes ProSomnus® EVO. However, EVO embodies device features and functions that are neither specified in E0486 nor K1027 coding. The speaker indicated that the clinical studies associated with better performance for beneficiaries warrant coding that is more specific to these features and functions. The speaker mentioned the monitoring features associated with the device will provide monitoring and measurements for the physician/practitioner to evaluate the patient condition and compliance.

**CMS Final HCPCS Coding Decision**

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

Existing HCPCS Level II code K1027, "Oral device/appliance used to reduce upper airway collapsibility, without fixed mechanical hinge, custom fabricated, includes fitting and adjustment" to describe EVO Sleep and Snore Device.

We have not identified a program need to separately identify the monitoring feature associated with this device. We note that items used in the patient's home that provide monitoring and measurements for the physician/practitioner to evaluate the patient's condition and course of treatment do not fall under the Medicare benefit for DME used in the home.

**Final Medicare Benefit Category Determination**

No determination.

More time is needed to evaluate this complex issue to determine how these items and services can be classified under Medicare Part B. In the meantime, classification, coverage, and

payment for these items will be made on an individual claim-by-claim basis by the Medicare Administrative Contractors (MACs).

**Final Medicare Payment Determination**

No determination. As stated in the Final Medicare Benefit Category Determination, in the meantime, classification, coverage, and payment for these items will be made on an individual claim-by-claim basis by the MACs.

## Docking Station/Power Supply for an Oral Device/Appliance - HCP230703C4XWT

### Topic/Issue

Request to establish a new HCPCS Level II code to identify a docking station/power supply for an oral device/appliance.

Applicant's suggested language: KXXXX, “Docking station encompasses power supply, and one or more of feature; transmission data, cleaning, or protection for an oral device/appliance used to reduce upper airway collapsibility with a completely embedded remote patient monitoring sensor/chip component”

### Summary of Applicant's Submission

ProSomnus® Sleep Technologies submitted a request to establish a new HCPCS Level II code to identify a docking station/power supply for an oral device/appliance. The purpose of this request is to assign a new HCPCS Level II coding that supports a docking station/power supply for an oral device/appliance used to reduce upper airway collapsibility with a completely embedded remote patient monitoring sensor/chip component. The available coding for oral devices/appliances to reduce upper airway collapsibility, specifically E0486 and K1027, do not provide for remote patient monitoring docking stations/power supply. The docking station may include but is not limited to power supply, transmission data, cleaning, or protection of the device.

### CMS Preliminary HCPCS Coding Recommendation

Establish a new HCPCS Level II code KXXXX, “Docking station for use with oral device/appliance used to reduce upper airway collapsibility”

### Preliminary Medicare Benefit Category Determination

No determination.

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

### Preliminary Medicare Payment Determination

No determination.

### Summary of Public Feedback

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

**CMS Final HCPCS Coding Decision**

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

Establish a new HCPCS Level II code K1037, "Docking station for use with oral device/appliance used to reduce upper airway collapsibility" to describe a docking station/power supply for an oral device/appliance.

**Final Medicare Benefit Category Determination**

No determination.

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

**Final Medicare Payment Determination**

No determination. As stated in the Final Medicare Benefit Category Determination, in the meantime, classification, coverage, and payment for these items will be made on an individual claim-by-claim basis by the MACs.

**Power Seat Elevation for Complex Rehab Power Wheelchair Bases - HCP2307031B3DD**

**Topic/Issue**

Request to delete existing HCPCS Level II code E2300, “Wheelchair accessory, power seat elevation system, any type” and establish two new HCPCS Level II codes to identify complex rehab technology power seat elevation system.

Applicant's suggested language:

1. EXXXX, “Wheelchair Accessory, Power Seating System, Complex Rehab Seat Elevation, Standard Weight Capacity (Up to and including 300 pounds)”

2. EXXXX, “Wheelchair Accessory, Power Seating System, Complex Rehab Seat Elevation, Heavy Duty Weight Capacity, (301 pounds up to and including 450 pounds)”

**Summary of Applicant's Submission**

The National Coalition for Assistive and Rehab Technology (NCART), on behalf of its member manufacturers of power seat elevation systems, submitted a request to establish two new HCPCS Level II codes to identify complex rehab technology (CRT) power seat elevation system and the deletion of E2300, “Wheelchair accessory, power seat elevation system, any type.” In decision memo CAG-00461N, National Coverage Determination for Power Seat Elevation Equipment on Power Wheelchairs, the Centers for Medicare & Medicaid Services confirmed “power seat elevation equipment is a wheelchair accessory that is added to a power wheelchair” and found that power seat elevation equipment on Medicare-covered power wheelchairs (PWCs) falls within the benefit category for durable medical equipment (DME). To implement this decision, HCPCS Level II codes and code characteristics and requirements must be established that accurately reflect CRT seat elevation. Moreover, it is important to distinguish CRT seat elevation from the seat elevation incorporated into Group 2 Seat Elevation Power Wheelchairs K0830 and K0831. The recommended code characteristic requirements for both of the requested new CRT power seat elevation codes are clinically relevant, supported by evidence, and include: (1) elevation of at least 10 inches, (2) capable of elevating/descending while the power wheelchair moves, (3) capable of moving on a horizontal surface while fully elevated, (4) compatible with other power seating options (i.e., tilt and/or recline). A unique HCPCS Level II code is needed to represent patient weight capacity and accurately reflect the additional complexity associated with elevating a patient weight of 301-450 lbs. To provide the durability, strength, and stability of a CRT heavy duty (HD) seat elevation system for use on CRT HD power wheelchairs, the HD systems require robust components to safely lift the full weight of the patient and any additional power seating systems necessary and other components. These systems must pass different test requirements due to the additional weight capacity. They must be able to maintain stability with a frequently changing center of gravity as the individual shifts to reach and to perform mobility-related activities of daily living.

**CMS Preliminary HCPCS Coding Recommendation**

Discontinue existing HCPCS Level II code E2300, “Wheelchair accessory, power seat elevation system, any type” and establish two new HCPCS Level II codes:

1. EXXXX, “Complex rehabilitative power wheelchair accessory, power seat elevation system, any type”

2. EXXXX, “Power wheelchair accessory, power seat elevation system, any type”

While the applicant requested different codes for seat elevation equipment on CRT power wheelchairs based on patient weight, our research did not show a significant price difference between power seat elevation systems based on weight class for complex rehabilitative power wheelchairs. Instead, the price differences based on weight class exist between the base CRT power wheelchairs themselves. Thus, we do not believe there is a programmatic need for two new HCPCS Level II codes and only one code for CRT wheelchair power seat elevation systems is being established. We welcome comments on this finding.

The second code listed here, “Power wheelchair accessory, power seat elevation system, any type” describes only the seat elevation system and thus could be billed for use with a non-complex rehabilitative Group 2 power wheelchair base. CMS believes the establishment of this new accessory code may obviate the need for existing non-complex rehabilitative Group 2 codes that describe an integrated seat elevation system and a Group 2 power wheelchair base. As such, CMS also recommends the discontinuation of the following Group 2 power wheelchair codes:

1. K0830, “Power wheelchair, group 2 standard, seat elevator, sling/solid seat/back, patient weight capacity up to and including 300 pounds”

2. K0831, “Power wheelchair, group 2 standard, seat elevator, captains chair, patient weight capacity up to and including 300 pounds”

**Medicare Benefit Category Determination**

Durable Medical Equipment.

CMS issued a final Benefit Category Determination (BCD) and National Coverage Determination (NCD) for NCD 280.16 for power seat elevation equipment on certain power wheelchairs on May 16, 2023. This determination finds that power seat elevation equipment on Medicare-covered power wheelchairs falls within the benefit category for durable medical equipment. For more information on NCD 280.16, please refer to the information published at https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=376&ncdver=1&keyword=seat%20elevation&keywordType=starts&areaId=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1.

**Preliminary Medicare Payment Determination**

With respect to the proposed code, EXXXX, “Complex rehabilitative power wheelchair accessory, power seat elevation system, any type:”

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 only available price information is from a period other than the fee schedule base period (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.

We note that the applicant suggested that power seat elevation for a complex rehabilitative power wheelchair should be considered comparable to power seat tilt for a complex rehabilitative power wheelchair. We do not believe this to be an appropriate comparison. Different mechanical components are used to effect seat elevation from seat tilt (for example, seat elevation may use a telescoping seat post or scissor-lift component, while tilt would use a hinged mechanism with a geared connection to the motor), and while seat tilt must accommodate an expected shift in the center of gravity from front-to-back, seat elevation only impacts the center of gravity in the vertical axis. For these reasons, we find that seat elevation is not comparable to any item with an existing fee schedule amount, and so the gap-fill approach is the most appropriate method for making a payment determination.

To ensure an appropriate universe of commercial pricing for seat elevation systems that would be classified in this code, we compiled a list of all complex rehabilitative wheelchairs with power seat elevation options available on the Product Classification List for the relevant base wheelchair codes. We verified the comprehensive nature of this list by comparing against manufacturer websites and websites of wheelchair suppliers. We further ensured that this list included all of the seat elevation options specifically mentioned by the applicants. In total, we identified seat elevation equipment for twenty power wheelchair models (listed in the below table). We then searched for the best pricing available online for each of these seat elevation options. We excluded any supplier that did not advertise a full manufacturer's warrantee or being an "authorized" supplier. We further excluded discounts that appeared to represent a time-limited or unique offer (e.g., "10% off orders received before" a specified date, "10% off your first order"). Finally, we excluded prices for suppliers that did not offer standard customizations, for example, suppliers offering refurbished units or with limited build options (e.g., only pre-build models that could not be further customized to reflect beneficiary needs).

| **Complex Rehabilitative Wheelchairs with Power Seat Elevation** | |
|---|---|
| Alltrack M3 | Alltrack M3 HD |
| Alltrack R3 | Alltrack R3 HD |
| Alltrack P3 | F3 Corpus |
| F3 Corpus HD | Frontier V6 |
| TDX SP2<br>Aviva FX | Aviva Storm Rx<br>Quantum Rehab Q6 |
| Rovi X3 | Rovi X3 mini |
| Quantum Rival 3 | Quantum 4Front 2 |
| Quickie Q300 | Quickie Q500 |
| Quickie Q700 Std | Quickie Q700 HD |

The average price across the seat elevation systems we found would be classified in this code was $3,450.60. 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. Based on these adjustments, the purchase price would be approximately $2,261.89. Under the capped rental rules for complex rehabilitative power wheelchairs, the rental price would be approximately $339.28 for months 1-3 and $135.71 for months 4-13 for a total of $2,374.94 for 13 months of continuous use.

Pricing Indicator = 36

With respect to the proposed code, EXXXX, "Power wheelchair accessory, power seat elevation system, any type:"

No determination.

As an extensive review of evidence to determine the coverage criteria for power seat elevation equipment for non-complex rehabilitative power wheelchairs is not complete, we are unable to determine the appropriate universe of seat elevation equipment that may be covered as a Medicare benefit under this code and, for this reason, we are unable to develop an appropriate payment amount at this time. Given the substantial price difference between seat elevation equipment for various models of non-complex rehabilitative power wheelchairs – ranging from around $600 to over $2,000 – it is critical to have a better understanding of the needs of the users for whom seat elevation equipment on this type of wheelchair would be covered, so as to ensure that the payment amount accurately reflects the type of equipment provided. We welcome additional input so that a payment determination for this item can be addressed at a subsequent HCPCS public meeting.

In the meantime, the DME fee schedule amounts for this item would be established by the DME MACs pending a payment determination established in accordance with the procedures at 42 CFR §414.240. 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. In particular, 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. If there are no items with existing fee schedule amounts that are comparable to the items and services under the new code, then we establish the fee schedule using supplier or commercial price lists. If the purchase price used in calculating the fee schedule amounts is greater than $150, then payment would be made on a capped rental basis in accordance with our regulations at 42 CFR 414.229. If the purchase price used in calculating the fee schedule amounts is $150 or less, then payment would be made on a rental or purchase basis in accordance with our regulations at 42 CFR 414.220.

Pricing Indicator = 46

**Summary of Public Feedback**

The National Coalition for Assistive and Rehab Technology (NCART) partially agreed with CMS' published preliminary recommendations and appreciates CMS' efforts to establish coding, coverage, and payment for CRT power seat elevation (PSE). The speaker stated they agreed with the preliminary decision to discontinue code E2300; however, they asked that CMS adopt the suggested code language in the application for the new codes and ensure that

any product that meets the description of CRT PSE possess the minimum performance characteristics outlined in the application. In addition, the speaker asked CMS to reconsider the need for a separate code for HD CRT PSE, stating there could be access issues involved for Medicare beneficiaries above a certain weight due to the payment being too low to cover the additional costs of construction for HD PSE systems.

According to the speaker, CRT PSE systems are equivalent to power tilt systems as they have the same physical components and comparable mechanical and electrical components. The only substantive difference is that CRT PSE systems require additional mechanical, and/or electrical components for the stability of the chair and the safety of the user. The speaker requested that CMS consider the American National Standards Developer Rehabilitation Engineering and Assistive Technology Society of North America (ANSI/RESNA) testing specifications for dynamic stability which they say supports their assertion that CRT PSE is a power seating system comparable with, or more sophisticated than power tilt. As such, the speaker believes CMS should re-examine power tilt as a comparable DMEPOS item when establishing the fee schedule for CRT PSE.

The speaker also asked CMS to defer the creation of a new HCPCS Level II code for standard seat elevation and the deletion of codes K0830 and K0831 to a subsequent cycle until such time as NCART has been able to thoroughly consider such changes. The suggested code language "Complex rehabilitative power wheelchair accessory, power seat elevation system, any type," would make it so that the wheelchair user would have to install power tilt or recline, both described as "power seating systems" in the current code set, to obtain additional components such as E1010 and E1012. Currently, the code language for those components, power leg elevation system and platform respectively, read as, "Wheelchair accessory, addition to power seating system."

CMS received many comments from manufacturers of CRT products, groups representing suppliers, consumers, providers, advocates and stakeholders, all in support of the primary speaker's comments and recommendations.

**CMS Final HCPCS Coding Decision**

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

1. Discontinue existing HCPCS Level II code E2300, "Wheelchair accessory, power seat elevation system, any type"

   Effective March 31, 2024

2. Establish E2298, "Complex rehabilitative power wheelchair accessory, power seat elevation system, any type"

   Effective April 1, 2024

Based on the public consultation, CMS is deferring creation of a new HCPCS Level II code for power seat elevation equipment used with non-complex rehabilitative power wheelchairs.

In the interim, HCPCS Level II codes K0830 and K0831 will continue to be used for non-complex rehabilitative power wheelchairs with seat elevation equipment. HCPCS Level II code K0108 ("Wheelchair component or accessory, not otherwise specified") can be used for claims for power seat elevation equipment added onto a non-complex rehabilitative power wheelchair owned by the beneficiary.

**Final Medicare Payment Determination**[20]

With respect to the HCPCS Level II code, E2298, "Complex rehabilitative power wheelchair accessory, power seat elevation system, any type:"

We appreciate the public comments provided in response to CMS's published preliminary payment determination. We recognize that seat elevation equipment for a bariatric patient population necessarily requires special attention to ensure that components are fabricated with the necessary specifications and that the seat elevation equipment meets stability testing requirements. However, the public comments confirmed that regardless of any differences in fabrication cost, there is no significant difference in the commercial pricing for seat elevation equipment for heavy duty power wheelchairs and seat elevation equipment for standard power wheelchairs.

As discussed in the preliminary determination, there are a number of important differences between power seat elevation equipment and power seat tilt equipment. Although both functions are intended to support patients with their mobility-related medical needs, the similarity goes no further. 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. Power seat elevation and tilt perform two fundamentally different functions: the former changes the vertical position of the seat while the latter changes the angle of the seat. These differing motions necessitate different physical and mechanical components. Various diagrams and written comments submitted to CMS support the differing stability implications of seat elevation and seat tilt. CMS continues to believe that power seat elevation and power seat tilt are not comparable for purposes of determining a Medicare payment amount.

As discussed in the preliminary payment determination, we compiled a list of all complex rehabilitative wheelchairs with power seat elevation options available on the Product Classification List for the relevant base wheelchair codes. While we made efforts to ensure the comprehensive nature of this list, the written public comments identified a number of other power wheelchair models with seat elevation equipment options that should be included. The complete list, including the additional power seat elevation options provided in the written comments, is in the table below.

| **Final List of Complex Rehabilitative Wheelchairs with Power Seat Elevation Equipment** | |
|---|---|
| Alltrack M3 | Alltrack M3 HD |
| Alltrack R3 | Alltrack R3 HD |
| Alltrack P3 (Avg of both wheel config) | F3 Corpus |

[20] Revised on June 13, 2024, to reflect an updated payment determination.

| | |
|---|---|
| F3 Corpus HD | F5 Corpus |
| Frontier V6 Hybrid | Frontier V6-C40 |
| M3 Corpus | M Corpus VS |
| TDX SP2 | Magic 360 |
| Aviva FX | Aviva Storm RX |
| Q6 Edge 2.0 X | Q6 Edge 2.0 |
| Q6 Edge 3 Stretto | Q6 Edge 3 |
| Quantum Rival 3 | Q6 Edge Z |
| Quickie Q300 M | Quantum 4Front 2 |
| Quickie Q700 M | Quickie Q500 M |
| Rovi A3 | R-Trak |
| Velocity | Rovi X3 |

Additionally, the written comments described an average MSRP that was significantly higher than average pricing that had been used in the preliminary payment determination. We reiterate that MSRPs do not, in and of themselves, represent prices at which commercial transactions take place; for this reason, MSRPs are not acceptable for use in gap-filling purposes. For each wheelchair model listed in the table above, we searched for the best internet pricing available for seat elevation equipment, following the methodology described in the preliminary payment determination. For some of these models, the commercial pricing we found is the same as the MSRP; for other models, we identified commercial pricing that was lower than the MSRP.

The average of the commercial prices of the models listed in the above table was $3,073.10. 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. Based on these adjustments, the 2024 purchase price would be approximately $2,013.96. Under the capped rental rules, the rental price would be approximately $201.40 for months 1-3 and $151.05 for months 4-13 for a total of $2,114.70 for 13 months of continuous use.

Pricing Indicator = 36

With respect to code K0830 and K0831, and claims for power seat elevation equipment added onto a non-complex rehabilitative power wheelchair owned by the beneficiary that are billed using code K0108, local fee schedule amounts would be calculated by the DME MACs for use in paying claims for any covered items.

Pricing Indicator = 36

## Informational Purposes Only: Final Determination for Dynamic Seating Component - Application #19.120

### Topic/Issues

Request for Medicare payment determination for existing HCPCS Level II code E2398, “Wheelchair accessory, dynamic positioning hardware for back”

### Summary of Applicant's Submission

The Dynamic Back consists of dynamic components, joints, linkages and elastomers, and is designed to be attached to a wheelchair frame. The system is designed to accommodate the wheelchair user's flexion and extension with minimal displacement at the pelvis during movement, and the variable spring returns the individual back to their initial posture. Static wheelchair frame components do not allow for an individual's abnormal and uncontrolled movement within the system and cannot withstand the high level of repeated force these individuals can exert. As the person extends, flexes, stretches, and shifts his or her weight due to high tone, uncontrolled movement, or relieve discomfort or pressure, the dynamic component responds to the forces that movement produces.

### Final CMS HCPCS Coding Action

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

### Final Benefit Category Determination

CMS determined that the Dynamic Back is DME, effective October 1, 2022.

### Preliminary Medicare Payment Determination

CMS published the following preliminary Medicare payment determination in May 2022, in advance of the June 2022 public meeting:

In accordance with regulations at 42 CFR § 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. The preliminary payment determination for code E2398, for this particular wheelchair dynamic hardware, is to establish the fee schedule amounts using existing fee schedule amounts for comparable items described by HCPCS Level II code E1015.

Dynamic positioning back hardware absorbs and diffuses the wheelchair user’s uncontrolled movements and forces using elastomers, joints, linkages, and other components. Devices that fall under E1015 absorb the impact of a force at the point of vibration, energy, or where the force occurs and disperses the energy through the frame, with minimal displacement of the patient. Both the dynamic positioning back hardware and devices under E1015 reduce shear forces and allows movement with return to a neutral position. Also, both the dynamic

positioning back hardware and devices under E1015 are mounted directly to the frame of a wheelchair. Common components include rubber, polymer, elastomer, hardware componentry (spring, screws, washers, etc.).

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

The 2022 fee schedule amounts for code E1015 when used with complex rehabilitative wheelchairs range from $140.34 to $168.37. The 2022 fee schedule amounts for code E1015 when used with standard wheelchairs furnished in rural and noncontiguous areas range from $137.55 to $152.59. The 2022 fee schedule amount for code E1015 when used with standard wheelchairs furnished in other areas ranges from $121.07 to $133.07. The fee schedule amounts for this item are generally less than $150 and therefore this item is inexpensive DME. Payment for the item would be made on a purchase or rental basis with total payments for any combination of claims for rental and/or purchase would be capped at the purchase fee schedule amount.

Pricing Indicator = 32

**Summary of Public Feedback**

In the June 2022 public meeting, three manufacturers and the National Coalition for Assistive and Rehab Technology (NCART) provided comments that the dynamic back hardware is not comparable to the E1015 (shock absorber for manual wheelchair), indicating that the dynamic back hardware is not comparable in function, strength, or durability and handles a vastly different set of forces than shock absorbing devices described by HCPCS Level II code E1015. Additional comments were provided by an occupational therapist familiar with the items who is also a consultant for several organizations and manufacturers, including Seating Dynamics, one of the three manufacturers of the item. The consultant provided written comments that items described by code E1015 are intended to provide suspension, which can reduce vibration and jarring from uneven terrain, but is different from dynamic seating, which is activated by client forces and then returns a client to a preferred starting position. All speakers asked CMS to delay a payment decision until they could provide a further analysis of the materials to CMS.

NCART followed up in writing to CMS both in June and October 2022, re-iterating that the dynamic back hardware is not comparable to devices described by HCPCS Level II code E1015. They stated that the dynamic back hardware is potentially comparable to E2295 ("manual wheelchair accessory, for pediatric size wheelchair, dynamic seating frame, allows coordinated movement of multiple positioning features") but that there is insufficient utilization of the code from which to establish pricing. Therefore, they suggested that a gap-fill pricing methodology be used for E2398, but that the establishment of pricing through this methodology be deferred until there is sufficient payment history with which to establish a price. CMS also met with NCART in May 2023 for further discussion and received additional supporting materials later that month.

**Final Medicare Payment Determination**

While we appreciate NCART's analysis and suggestion that the dynamic back hardware may be comparable to HCPCS Level II code E2295, we do not agree. HCPCS Level II code E2295 is used to describe the wheelchair back and shock absorbing or dynamic seating hardware; it is not used to only describe the dynamic back hardware feature. The code E2295 was first verified for the Kids Rock Active Component with an effective date of 1/1/2009. This device, unlike the Dynamic Back, was a complete seating frame with active hip, knee, and ankle pivot points. In addition, we believe that NCART did not demonstrate significant evidence or studies to suggest that Dynamic Back differs from shock absorption and is not comparable to E1015, "Shock absorber for manual wheelchair, each".

The final determination is as outlined in our preliminary payment determination, that for this particular wheelchair dynamic hardware, HCPCS Level II code E2398 is comparable to items described by HCPCS Level II code E1015. Regardless of the source of the force (from the ground/terrain below the wheelchair frame or from the patient sitting above the wheelchair base), when that force is applied, both the dynamic positioning back hardware and devices under E1015 reduce the shear forces and allow movement with return to a neutral or starting position. In addition, regardless of where the shock or force is absorbed (near the rails and frame or above the base of the wheelchair), the absorbing action minimizes patient displacement and allows movement to return to a more neutral or starting position. The dynamic positioning back hardware and devices under E1015, as well as this particular wheelchair dynamic hardware, absorb and reduce the fluctuation and oscillation to allow a return to a more neutral or starting position.

In the supplemental information provided to CMS after the June 2022 public meeting, NCART again stated that Dynamic Back hardware is not comparable to devices described by HCPCS Level II code E1015. However, the mechanism of both dynamic back hardware and E1015 (for example Retro Fit Suspension Kit) is to absorb the shock impact. The goal for both E1015 devices and Dynamic Back is to protect spinal alignment. They may absorb different types of forces but that will not impact the overall functionality. Dynamic Back diffuses the force that could otherwise lead to patient injury which is the same as the E1015 Retro Fit Suspension Kit, as it reduces and adjusts the mobility shock.

The supplemental information also states that code E1015 is intended to provide suspension, which can reduce vibration and jarring from uneven terrain, but is different from dynamic seating, which is activated by client forces and then returns a client to a preferred starting position. However, CMS has not received evidence that supports the claim that Dynamic

Back returns the patient to the neutral position but E1015 devices do not. The E1015 devices reduce the forces caused by unstable transportation such as uneven terrain. These systems can convert air suspension to coil springs and it is important that as the chair goes over each bump, that this bump is not felt by the patient or is limited as much as possible. If each bump is transmitted up to the user, then the user will likely not maintain their seated position. And this is the point of having a suspension system to provide as minimum displacement as possible. These wheelchairs aim to maintain the patient's position at their preferred starting point.

Therefore, the final payment determination for code E2398 is to establish the fee schedule amounts using existing fee schedule amounts for comparable items described by HCPCS Level II code E1015.

The current 2023 fee schedule amount ranges for code E1015 are as follows:

- when used with complex rehabilitative wheelchairs: $152.55 to $183.02;
- when used with standard wheelchairs furnished in rural and noncontiguous areas: $149.79 to $166.14;
- when used with standard wheelchairs furnished in other areas: $131.95 to $145.04.

This item meets the definition of inexpensive DME in the regulations at 42 CFR 414.220(a)(1). Payment for the item would be made on a purchase or rental basis with total payments for any combination of claims for rental and/or purchase would be capped at the purchase fee schedule amount.

Pricing Indicator = 32

## Sully Walker - HCP23051165PKK

### Topic/Issue

Request to establish a new HCPCS Level II code to identify the Sully Walker.

The applicant did not provide any suggested language.

### Summary of Applicant's Submission

Sully Walker LLC submitted a request to establish a new HCPCS Level II code to identify a powered walking aid, the Sully Walker. The Sully Walker is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). Most walking aid products, like geriatric walkers and rollators, require pushing to propel the device. The Sully Walker leverages electronic power to replace the lift-and-thrust or push actions by providing forward motion by controlled power through a thumb throttle for forward motion. It has built-in speed limiting controls matched to the user's capability.

### CMS Preliminary HCPCS Coding Recommendation

Establish a new HCPCS Level II code EXXXX, “Battery powered walking aid attachment for walker, per pair” to be used in conjunction with existing HCPCS Level II code E0143, “Walker, folding, wheeled, adjustable or fixed height” to describe the Sully Walker.

### Preliminary Medicare Benefit Category Determination

Walker: Durable Medical Equipment.

Walking Aid Attachment: No Medicare DMEPOS benefit category.

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

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

All five of these conditions must be met in order for equipment to be classified as DME. The traditional walker component of the Sully Walker falls within the DME benefit category. Although the power assist component (walking aid attachment) propels the walker forward while eliminating the need for the patient to lift, push, and thrust the walker, this added feature does not appear to us to serve a medical purpose and thus at this time we consider it to be a convenience item. Our preliminary determination is that the power assist component does not fall within the DME benefit category. We welcome more information demonstrating how the power assist component is used by the patient primarily and customarily to serve a medical purpose.

**Preliminary Medicare Payment Determination**

The payment rules and pricing associated with the existing code E0143 apply to the Sully Walker, if covered. The current average fee schedule amount for E0143 is $85.67.

The average fee schedule amount is the average of the 2023 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 32

There is no Medicare payment for new code EXXXX.

Pricing Indicator = 00

**Summary of Public Feedback**

Sully Walker LLC disagreed with CMS' preliminary determinations. According to the speaker, using a combination of E0141 or E0143 as the base structure with a separate code to describe the powered attachment does not cover the manufacturing costs of the Sully Walker. The speaker explained that while their product is FDA exempt because of its basic similarities to an existing bariatric frame, this device operates on an existing modified bariatric frame for continuity and performance history but with a custom power-pack, throttle, motors, wheels and charging unit. The speaker states the device is not a walker or a power operated vehicle (POV), rather it is an entirely new device that eliminates the requirement to push thus alleviating leg stress, hip pain, spinal misalignment along with arms, shoulder, and neck discomfort, thereby addressing the expanding needs and independence of the aging population.

During the public meeting, the PDAC clarified that it did not classify the Sully Walker as exceeding the standard functionality of a walker. Instead, the PDAC assigned two codes to distinguish between the walker's basic structure with E0141, "Walker, rigid, wheeled, adjustable or fixed height," and its supplementary powered component with A9900, "Miscellaneous dme supply, accessory, and/or service component of another hcpcs code." PDAC agreed with CMS preliminary decision that E0143 is the appropriate coding assignment for the base product.

**CMS Final HCPCS Coding Decision**

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

Establish a new HCPCS Level II code E0152, "Walker, battery powered, wheeled, folding, adjustable or fixed height"

We evaluated the Sully Walker, similarly and consistently, in the manner that we evaluate power wheelchairs, scooters, and safety rollers in terms of mobility equipment. We were persuaded based on the public meeting that the Sully Walker is best described as a single device, rather than as a walker plus a separate code describing the powered feature. We

believe the Sully Walker is a new category of walkers that provides power assist and is different than other manual walkers, therefore creating the need to establish a separate code for this new type of walker. The Sully Walker is not a power assist accessory that can be added on to any walker.

**Final Medicare Benefit Category Determination**

No Medicare DMEPOS benefit category. DME is defined in Medicare regulations at title 42 Code of Federal Regulations (CFR) 414.202 as equipment furnished by a supplier or a home health agency that meets all of the following conditions:

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

All five of these conditions must be met in order for equipment to be classified as DME. The Sully Walker, a powered walker, is appropriate for use outside of the home when extra power may be needed to ambulate uphill, across rugged terrain (a grassy field, a cobblestone street, etc.), and over longer distances. Since the capabilities of the Sully Walker relate to use of the walker outside the home, it does not appear that the walker serves a medical purpose for use in the home. Therefore, the Sully Walker does not fall within the DME benefit category. CMS recognizes this as a powered walker and suggests more evidence be presented that addresses certain safety concerns of the control trigger and ultimately the safety of the patient when the product is in motion. CMS also welcomes more evidence be presented that supports the manufacturer's medical claims of alleviating leg stress, hip pain, spinal misalignment along with arms, shoulder and neck discomfort. We welcome evidence (such as case studies) demonstrating the medical benefit of the Sully Walker specifically when used in the home.

**Final Medicare Payment Determination**

There is no Medicare payment for new HCPCS Level II code E0152.

Pricing Indicator = 00

## Anvil Walker - HCP230629WFQMH

**Topic/Issue**

Request to establish a new HCPCS Level II code to identify Anvil Walker.

The applicant did not submit any suggested language.

### Summary of Applicant's Submission

Advanced Brace Ltd. submitted a request to establish a new HCPCS Level II code to identify Anvil Walker. Anvil Walker is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The Anvil Walker is a custom device that is designed specifically for each patient's unique diagnoses. Due to the custom process, this device can be fabricated regardless of deformity location, size, or shape of foot. Patients with one or more of the following conditions: foot amputation(s), Charcot Marie Tooth, severely deformed ankle/foot, lymphedema, Charcot Foot, severe ankle contracture, and severe ankle deformity, would benefit from the Anvil Walker. This device is designed for anyone who has one or more of the previously listed conditions and has developed the inability to return to activities of daily living without rigid support. The Anvil Walker is 100% custom made to the patient model and is made of plastic and other materials. It is fabricated with a custom 3/8th inch tri-lam material insole, with an additional 1/8$^{th}$ neoprene to allow suspension. This custom insert is modified to apply pressure directly posterior, medial, or lateral to the deformity site, which is key in the suspension that allows the deformity to be tolerated and, in some cases, reversed. The device achieves an additional 1/2-inch pressure reduction by utilizing the actual sole of the Anvil Walker which allows patients to walk with ease while their deformity is being corrected. The Anvil Walker is designed with an Ankle Foot Orthosis rigid support, Varus/Valgus Correction to the plastic, complete breathable inner and outer soft interface, with the above-mentioned custom arch support. This device includes at minimum three straps, but due to the custom nature, more straps can be added as needed. A non-slip rocker bottom rubber sole is added to enhance the patient’s safety and ease of walking. The Anvil Walker is lightweight, breathable, washable, and overall, extremely effective. Depending on the referring physician’s preference, it can be made open toe or closed toe.

### CMS Preliminary HCPCS Coding Recommendation

The combination of existing HCPCS Level II codes listed below describe the Anvil Walker:

- L1904, “Ankle orthosis, ankle gauntlet or similar, with or without joints, custom fabricated”
- L2275, “Addition to lower extremity, varus/valgus correction, plastic modification, padded/lined”
- L2330, “Addition to lower extremity, lacer molded to patient model, for custom fabricated orthosis only”
- L2820, “Addition to lower extremity orthosis, soft interface for molded plastic, below knee section”
- L3002, “Foot, insert, removable, molded to patient model, plastazote or equal, each”

**Preliminary Medicare Benefit Category Determination**

Leg brace (Orthotic).

The application supports a preliminary benefit category determination that the Anvil Walker is used as a lower extremity brace and would fall under the Medicare benefit for Leg brace (Orthotic). Section 130 of Chapter 15 of the Medicare Benefit Policy Manual (CMS Pub. 100-02) defines a brace as a rigid or semi-rigid device used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body. The information submitted by the applicant was reviewed extensively and supports the preliminary benefit category determination of leg brace, as the Anvil Walker supports a weak leg.

**Preliminary Medicare Payment Determination**

The payment rules and pricing associated with the existing codes L1904, L2275, L2330, L2820, and L3002 apply to this product, if covered. The current average fee schedule amount is as follows:

L1904: $562.05 + L2275: $151.44 + L2330: $475.28 + L2820: $113.24 + L3002: $184.21 = $1,486.22.

The average fee schedule amount is the average of the 2023 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 38

**Summary of Public Feedback**

We received written comment from the applicant in agreement with CMS' published preliminary determination.

**CMS Final HCPCS Coding Decision**

We appreciate the comment provided in response to CMS' published preliminary recommendations. After further consideration of the information provided in the application, CMS is revising its preliminary recommendation. The combination of existing HCPCS Level II codes, listed below, describe the Anvil Walker:

- L1904, "Ankle orthosis, ankle gauntlet or similar, with or without joints, custom fabricated"
- L2275, "Addition to lower extremity, varus/valgus correction, plastic modification, padded/lined"
- L2330, "Addition to lower extremity, lacer molded to patient model, for custom fabricated orthosis only"
- L2820, "Addition to lower extremity orthosis, soft interface for molded plastic, below knee section"
- L3002, "Foot, insert, removable, molded to patient model, plastazote or equal, each"

- L2232, “Addition to lower extremity orthosis, rocker bottom for total contact ankle foot orthosis, for custom fabricated orthosis only”

The Anvil Walker, as stated in the application, has a non-slip rocker bottom feature. The non-slip rocker bottom rubber sole is added to enhance the patient’s safety and ease of walking with each step. As such, an additional HCPCS Level II code L2232, “Addition to lower extremity orthosis, rocker bottom for total contact ankle foot orthosis, for custom fabricated orthosis only” along with the other five proposed codes, is needed to describe Anvil Walker.

**Final Medicare Benefit Category Determination**

Leg brace (Orthotic).

**Final Medicare Payment Determination**

In the preliminary payment determination, CMS proposed the use of multiple codes for the device (L1904, L2275, L2330, L2820, and L3002). Based on written input received in the 2023 Biannual 2 HCPCS Public Meeting, we have determined that one additional code is needed to fully describe all components of the Anvil Walker. In particular, another code is needed to describe the rocker bottom component of the Anvil Walker. Therefore, the final payment determination is to use the codes proposed in the preliminary payment determination, as well as code L2232 (ADDITION TO LOWER EXTREMITY ORTHOSIS, ROCKER BOTTOM FOR TOTAL CONTACT ANKLE FOOT ORTHOSIS, FOR CUSTOM).

The payment rules and pricing associated with the existing codes L1904, L2275, L2330, L2820, L3002, and L2232 apply to this product, if covered. The current average fee schedule amount is as follows:

L1904: $576.66 + L2275: $155.37 + L2330: $487.64 + L2820: $116.19 + L3002: $189.08 +L2232: $114.30 = $1,639.24.

The average fee schedule amount is the average of the 2024 fee schedule amounts for the codes for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 38

## Scrunch Cloth - HCP2306305DJ7H

### Topic/Issue

Request to establish a new HCPCS Level II code to identify Scrunch Cloth.

Applicant's suggested language: XXXXX, “ADL Adaptive Washcloth for people with physical, mental, and visual disabilities to care for themselves and to conduct rehabilitation and maintenance therapies”

### Summary of Applicant's Submission

Mr. Paul Barnes, the sole proprietor of Scrunch Cloth, submitted a request to establish a new HCPCS Level II code to identify Scrunch Cloth. Scrunch Cloth is adaptive equipment that makes activities of daily living easier for people with physical, mental, and vision disabilities. Scrunch Cloth is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). Scrunch Cloth is a grip-free washcloth that hugs the wrist like a “scrunchie” and slips over the hand with one finger to wash and then slips back onto the wrist. It is also a device for rehabilitation and maintenance therapies.

### CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code A9286, “Hygienic item or device, disposable or non-disposable, any type, each” describes the Scrunch Cloth.

All washcloths of any type are included in the existing HCPCS Level II code A9286.

### Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

The current Medicare policy and prior established benefit category determination for code A9286 apply to this item.

### Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing code A9286 apply to this product. Items or services described by HCPCS Level II code A9286 are not covered under a Medicare Part B DMEPOS benefit.

No Medicare payment. Pricing Indicator = 00

### Summary of Public Feedback

The primary speaker disagreed with CMS’ published preliminary recommendations. According to the speaker, HCPCS Level II code A9286 does not adequately describe the Scrunch Cloth because unlike a washcloth, the Scrunch Cloth’s design makes activities of daily living easier and increases the independence of people with physical, cognitive, intellectual, and visual impairments. Also, according to the speaker, CMS’ preliminary recommendation did not properly consider the applicant’s request to have the Scrunch Cloth

deemed a piece of adaptive equipment. Other commenters stated their appreciation for the product as one that provided the clients and patients they served with a greater sense of autonomy.

**CMS Final HCPCS Coding Decision**

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

Existing HCPCS Level II code A9286, "Hygienic item or device, disposable or non-disposable, any type, each" to describe the Scrunch Cloth.

The Scrunch Cloth can be utilized by either a caregiver or patient to help maintain one's hygiene, similar to other devices in existing HCPCS Level II code A9286.

**Final Medicare Benefit Category Determination**

No Medicare DMEPOS benefit category.

Medicare is a defined benefit program. An item or service must fall within a benefit category as a prerequisite to Medicare coverage. Title XVIII of the Act governs the Medicare program. Under the Medicare program, the scope of benefits available to eligible beneficiaries is prescribed by law and divided into several main parts. Part A is the hospital insurance program and Part B is the voluntary supplementary medical insurance program. The scope of benefits under Medicare Part B is described in section 1832 of the Act. In the public meeting the speaker explained the request is to have Scrunch Cloth classified as either "Assistive Technology/Adaptive Equipment," "Activities of Daily Living Equipment," or durable medical equipment (DME). Section 1832 of the Act does not define "Assistive Technology/Adaptive Equipment" or "Activities of Daily Living Equipment" as unique benefit categories. It does include "medical and other health services" within the scope of the Medicare Part B benefit, which includes durable medical equipment (DME).

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. While Scrunch Cloth is appropriate for use in the home, it does not meet the four other requirements to be DME as it cannot be rented and used by successive patients, it does not have an expected life of at least 3 years, it does not primarily and customarily serve a medical

purpose as it can be used for general bathing/hygiene purposes, and it generally could be useful to an individual in the absence of illness or injury.

The current Medicare policy and prior established benefit category determination for code A9286 apply to this item.

**Final Medicare Payment Determination**

No Medicare payment. Pricing Indicator = 00

## OdorNuke™ - HCP230703Q5AW5

### Topic/Issue

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

Applicant's suggested language: AXXXX, “Deodorant tablet to neutralize urine odor for use in urine collection devices (e.g., bedpans, urinal bottles, bedside commodes, drainage bags, waterless toilets), solid, per tablet”

### Summary of Applicant's Submission

B&B Logical LLC submitted a request to establish a new HCPCS Level II code to identify OdorNuke™. OdorNuke™ is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). OdorNuke™ is a deodorant tablet used to neutralize powerful urine odor in hospitals, nursing homes, palliative care, and private homes. OdorNuke™ is specially formulated for use in temporary urine collection devices, like bedpans, urinal bottles, travel johns, piddle packs, drainage bags and waterless toilets.

### CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code A9270, “Non-covered item or service” describes OdorNuke™.

CMS welcomes information from the applicant and other insurers to demonstrate a claims processing need for a unique HCPCS Level II code to identify OdorNuke™.

### Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

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

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

All five of these conditions must be met for equipment to be classified as DME. OdorNuke™ is a disposable, one-time use deodorant tablet. This item cannot withstand repeated use and therefore, is not considered DME.

### Preliminary Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

**Summary of Public Feedback**

B&B Logical LLC acknowledged and accepted CMS' published preliminary recommendations.

**CMS Final HCPCS Coding Decision**

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

Existing HCPCS Level II code A9270, "Non-covered item or service" to describe OdorNuke™.

**Final Medicare Benefit Category Determination**

No Medicare DMEPOS benefit category.

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

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

All five of these conditions must be met for equipment to be classified as DME. OdorNuke™ is a disposable, one-time use deodorant tablet. This item cannot withstand repeated use and therefore, is not considered DME.

**Final Medicare Payment Determination**

No Medicare payment. Pricing Indicator = 00

## Curaco Carebidet - HCP230630EVUTF

### Topic/Issue

Request to establish a new HCPCS Level II code to identify Curaco Carebidet.

Applicant's suggested language: EXXXX, “Automated toileting system for both urine and feces, for male and female. The Carebidet can also be used by either male or female having a catheter, in which case the Carebidet is used only for the feces”

### Summary of Applicant's Submission

Connected Health Solutions, LLC submitted a request to establish a new HCPCS Level II code to identify Curaco Carebidet. Curaco Carebidet is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). Curaco Carebidet is a toileting system which uses suction to remove the urine and feces from a diaper cup. The diaper cup is the human interface at the sacral and perineal areas, connected to a waste tank that is inside the main body unit. After collection of the urine and feces, the Carebidet delivers a warm water bidet jet wash, followed by a 5-minute gentle air drying cycle. To manage moisture, the Carebidet automatically performs an hourly air-dry cycle, or other time interval per protocol that is set by the caregiving staff or an institution. This Carebidet system is used mostly for patients who are bedridden. In addition to cleaning, the Carebidet system sanitizes the area of the individual that is using the Carebidet to reduce fungal growth and the development of infections.

### CMS Preliminary HCPCS Coding Recommendation

Revise existing HCPCS Level II code K1006, “Suction pump, home model, portable or stationary, electric, any type, for use with external urine management system” to instead read “Suction pump, home model, portable or stationary, electric, any type, for use with external urine and/or fecal management system” to be used in conjunction with existing HCPCS Level II code A9286, “Hygienic item or device, disposable or non-disposable, any type, each” to describe Curaco Carebidet.

### Preliminary Medicare Benefit Category Determination

There are two preliminary benefit category decisions for this item, as we believe part of this product meets the definition of DME, while another part does not.

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

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

All five of these conditions must be met for equipment to be classified as DME. The suction function of the Carebidet meets the definition of DME. That is, the Carebidet function of suctioning urine and feces from a diaper cup and into a waste tank meets the definition of DME. We believe this fulfills the function of a home suction pump that is classified as DME. The bidet function of the Carebidet does not have a Medicare DMEPOS benefit category. That is, what the Carebidet does after the collection of the urine and feces, which includes delivering a warm water bidet jet wash and an air-drying cycle, does not meet the definition of DME. In particular, Chapter 1, Section 280.1 of the Medicare National Coverage Determinations (NCD) Manual (CMS Pub. 100-03) includes a DME Reference List that is used for determining the coverage status of certain pieces of DME. On this list are bidet toilet seat and toilet seats. This National Coverage Determination states that these items are not DME and to, "Deny not medical equipment (§1861(n) of the Act)." As the Curaco Carebidet uses a bidet, this part of the item would not fall under a DMEPOS benefit category.

**Preliminary Medicare Payment Determination**

There are two preliminary payment determinations for this item, as we believe part of this item meets the definition of DME, while another part of this item does not.

The payment rules and pricing associated with the existing code K1006 apply to the suction function of the Carebidet, if covered.

The average 2023 rental amount for K1006 is approximately $58.79 for months 1-3 and approximately $44.09 for months 4-13, which results in average 2023 payments over 13 months equaling approximately $617.27.

The average fee schedule amount is the average of the 2023 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 36

There is no Medicare payment for A9286, the bidet portion of Carebidet.

Pricing Indicator = 00

**Summary of Public Feedback**

Connected Health Solutions, LLC disagreed with CMS' preliminary recommendations. The speaker commented that the proposed modification of the existing HCPCS Level II code to describe the Carebidet falls short in addressing the significant technological advancements introduced by the Carebidet, the innovative Complete Intelligent (and Automated) Toileting System (CITS). CITS incorporates five distinct automated functions: detection, waste removal, washing, drying, and ongoing moisture management - and the existing HCPCS Level II code K1006, only addresses a manual suction function (waste removal). To optimize the CITS' impact on the healthcare system, including the home care and institutional settings, resulting in cost savings amounting to billions of dollars, the applicant proposed the creation of one new HCPCS Level II code with an optimal reimbursement of $600 per month or higher. This reimbursement level aligns with CMS healthcare objectives, promoting the adoption of CITS, leading to significant cost efficiencies, and ultimately enhancing patient

outcomes. The speaker confirmed receiving a current monthly payment of $678 (36-month term) for the CITS. The speaker noted that Japan and South Korea are reimbursing within the monthly range of $600 after adjusting for the USA market (including shipping), which supports the feasibility of the proposed reimbursement.

**CMS Final HCPCS Coding Decision**

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

Existing HCPCS Level II code E2001 (previously K1006), "Suction pump, home model, portable or stationary, electric, any type, for use with external urine management system" revised to instead read, "Suction pump, home model, portable or stationary, electric, any type, for use with external urine and/or fecal management system" to be used in conjunction with existing HCPCS Level II code A9286, "Hygienic item or device, disposable or non-disposable, any type, each" to describe Curaco Carebidet.

CITS incorporates five features: detection, waste removal, washing, drying, and ongoing moisture management. In order for waste removal to occur, CITS needs to detect that there is waste to be suctioned. As such, the detection and waste removal features are described within the newly revised HCPCS Level II code, E2001. Existing HCPCS Level II code E2001 is for any type of external urine management suction pump system, which could include manual or automatic waste removal. At this time, we have not identified a program need to separately identify manual versus automatic waste removal. The washing, drying, and moisture management features are described within A9286.

Note: In the B1 2023 cycle we finalized a preliminary recommendation to revise 25 temporary ("K" codes) HCPCS Level II codes, effective January 1, 2024. HCPCS Level II code K1006 was one of these codes and it was transferred to HCPCS Level II code E2001. These coding changes will be effective January 1, 2024. As such, our final payment determination will reflect this coding change to HCPCS Level II code E2001.

**Final Medicare Benefit Category Determination**

We are finalizing our two preliminary benefit category decisions for this item, as we believe part of this product meets the definition of DME, while another part does not.

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

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

All five of these conditions must be met for equipment to be classified as DME. The suction function of the Carebidet meets the definition of DME. That is, the Carebidet function of suctioning urine and feces from a diaper cup and into a waste tank meets the definition of DME. We believe this fulfills the function of a home suction pump that is classified as DME.

The bidet function of the Carebidet does not have a Medicare DMEPOS benefit category. That is, what the Carebidet does after the collection of the urine and feces, which includes delivering a warm water bidet jet wash and an air-drying cycle, does not meet the definition of DME. The bidet function is not DME because of Chapter 1, Section 280.1 of the Medicare National Coverage Determinations (NCD) Manual (CMS Pub. 100-03), which includes a DME Reference List that is used for determining the coverage status of certain pieces of DME. On this list are bidet toilet seat and toilet seats. This National Coverage Determination states that these items are not DME and to, "Deny not medical equipment (§1861(n) of the Act)." As the Curaco Carebidet uses a bidet, this part of the item would not fall under a DMEPOS benefit category.

**Final Medicare Payment Determination**

We are finalizing our two preliminary payment determinations. As previously discussed, we believe part of this item meets the definition of DME (suction function), while another part of this item does not (bidet). The applicant disagreed with the coding and payment determination and requested that the code and payment determination recognize the additional functions that the CareBidet provides. However, as discussed in our benefit category decision, we can only classify the suction part of the CareBidet under the DME benefit, whereas the bidet function of the Carebidet does not have a DMEPOS benefit category.

Additionally, as indicated in our above final HCPCS coding decision, in the B1 2023 cycle we finalized a preliminary recommendation to revise 25 temporary ("K" codes) HCPCS Level II codes, effective January 1, 2024. K1006 was one of these codes and it was transferred to E2001. These coding changes will be effective January 1, 2024. As such, our final payment determination will reflect this coding change to E2001.

The payment rules and pricing associated with the existing code E2001 apply to the suction function of the Carebidet, if covered.

The average 2024 rental amount for E2001 is approximately $60.32 for months 1-3 and approximately $45.24 for months 4-13, which results in average 2024 payments over 13 months equaling approximately $633.36.

The average fee schedule amount is the average of the 2024 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 36

There is no Medicare payment for A9286, the bidet portion of Carebidet.

Pricing Indicator = 00

**Ultrasound, Doppler, Echocardiogram, Holter Monitor, Bone Density - HCP23063085FVF**

## Topic/Issue

Request to revise an existing HCPCS Level II code Q0092, “Set-up portable x-ray equipment” to include reimbursement for other diagnostic imaging procedure set up.

Applicant's suggested language: Q0092, “A/B MACs (B) must pay a set-up component for each Portable x-ray and/or other portable diagnostic imaging procedure (other than retakes of the same procedure) during both single patient and multiple patient trips under Level II HCPCS code Q0092”

## Summary of Applicant's Submission

BioTech X-ray, Inc. submitted a request to revise existing HCPCS Level II code Q0092, “Set-up portable x-ray equipment” to include reimbursement for other diagnostic imaging procedure set up. HCPCS Level II code Q0092 is currently a reimbursement code for the set-up of diagnostic X-ray equipment where the procedure is performed at the patient's bedside. This should broaden the scope of Current Procedural Terminology (CPT®) codes for which the code can be reimbursed to include ultrasound, doppler, echocardiogram, bone densitometry, and other imaging studies now performed commonly at the bedside by the same providers that are paid for this code to set up their X-ray equipment. When the program manual instructions were updated last in 2003, the technology was not readily available to perform ultrasound, doppler and echocardiogram studies portably at the patient's bedside. The technology has advanced dramatically, and physician's that order portable X-ray exams on bedridden and home-bound patients in long term care facilities also expect providers to perform ultrasound imaging studies at the bedside. Providers have the ability to do this, but are not reimbursed for their travel (R0070/R0075). Q0092 currently reimburses portable X-ray providers for setting up the X-ray equipment at the patient's bedside, for each exam that is being performed. The reimbursement of Q0092 should similarly apply to setting up the ultrasound equipment for each exam being performed.

## CMS Preliminary HCPCS Coding Recommendation

We have received several requests in our recent HCPCS Level II coding cycles to revise existing codes related to X-ray equipment and will be grouping this application with those other similar applications. This application is being deferred for additional consideration in a subsequent biannual coding cycle. We believe more time is needed to consider revising existing HCPCS Level II code Q0092 and any implications that might occur. We welcome information from the applicant and other insurers who are currently paying for the set-up of portable X-ray equipment to demonstrate a claims processing need for a revision to HCPCS Level II code Q0092.

## Summary of Public Feedback

BioTech X-ray, Inc. disagreed with CMS’ preliminary recommendation to defer for additional consideration in a subsequent biannual coding cycle. According to the speaker, when the Q0092 code was established in 1992, ultrasound and other diagnostic imaging technologies were not advanced. The equipment, particularly for ultrasound, was not

portable, therefore the Q0092 code was written specifically and applied only for companies enrolled as a Portable X-ray Supplier Type 63. Since that time, technology has advanced significantly, and ultrasound and other diagnostic equipment are now quite portable. Ultrasound equipment can be easily transported to the patient's bedside in a carry-on size roller bag. Physicians treating long-term care and homebound patients frequently order and expect ultrasound and other diagnostic imaging services to be provided portably at the patient's bedside. The applicant proposed updates to the CMS description of HCPCS Level II code Q0092 to reflect the broader scope of services being provided at the patient's bedside.

**CMS Final HCPCS Coding Decision**

We are internally considering the request to revise existing HCPCS Level II code Q0092 and, currently, do not need any additional information.

## Portable X-ray and/or Other Portable Diagnostic Imaging Supplier - HCP230702YU2LU and HCP230102B51B5

### Topic/Issue

Request to revise an existing HCPCS Level II code R0070, “Transportation of portable x-ray equipment and personnel to home or nursing home, per trip to facility or location, one patient seen” to identify portable X-ray and/or other portable diagnostic imaging supplier.

Applicant's suggested language: R0070, “Transportation of portable x-ray and other portable imaging equipment and personnel to home or nursing home, per trip to facility or location, one patient seen”

### Summary of Applicant's Submission

The American Portable Diagnostic Association submitted a request to revise an existing HCPCS Level II code to identify transportation of portable X-ray and other portable imaging equipment and personnel to home or nursing home, per trip to facility or location, one patient seen. This request is to modify and expand the HCPCS Level II code R0070 transportation of equipment to include other portable diagnostic imaging services, such as ultrasound, dopplers and echocardiograms. Modifying the language for the use of HCPCS Level II transportation code under specialty 63 for the portable X-ray supplier (i.e., portable X-ray and/or other portable diagnostic imaging supplier) will extend the conditions of coverage. This would include the transportation component for portable imaging services, such as ultrasound, dopplers, and echocardiograms, which represents other commonly performed portable services by the portable X-ray suppliers that currently bill under an independent diagnostic testing facilities (IDTF) enrollment. Providers of portable diagnostic imaging services recommend merging the current IDTF enrollment into the portable X-ray and/or other portable diagnostic imaging services, (specialty 63). A portable imaging supplier moves its X-ray equipment and other portable diagnostic imaging equipment from place to place, performing X-ray, EKG and other diagnostic imaging services such as Ultrasound, venous and arterial dopplers and echocardiograms at various locations. A portable imaging supplier is a supplier using only portable unit’s in comparison to a mobile unit that is typically described as a vehicle that travels from place to place to perform services inside the vehicle. Examples of such vehicles include mobile semi-trailers. A portable unit exists when a supplier transports medical equipment to a particular location. Unlike with mobile facilities, the equipment - a portable unit is separate from and unattached to the vehicle. The equipment used to perform the test is unloaded from the vehicle and moved to the patient’s room, bed or appropriate area within the facility or location where the test is performed.

### CMS Preliminary HCPCS Coding Recommendation

These applications are being deferred for additional consideration in a subsequent biannual coding cycle. We continue to believe more time is needed to consider revising existing HCPCS Level II code R0070 and any implications that might occur.

### Summary of Public Feedback

The applicant and other commenters disagreed with CMS’ HCPCS preliminary recommendation defer for additional consideration in a subsequent biannual coding cycle.

According to the speaker, HCPCS Level II code R0070, as defined, demonstrates that the HCPCS Level II codes are not bundled with the technical component (TC). Therefore, CMS recognizes the distinct difference between the portable service HCPCS Level II codes, transportation components and set-up (R0070, R0075, R0076, Q0092) as separate components of the portable service. As a result, CMS silently validates that transportation and set-up codes are not TC. The HCPCS Level II codes should be recognized as a "cost component" to provide the service. While the evaluation of code distinction was conducted, it should be recognized that the rate of reimbursement for the TC is calculated within the Physician Fee Schedule along with the professional component, whereas the transportation component reimbursement is separately evaluated through a cost survey conducted by the Medicare Administrative Contractors.

The TC and the HCPCS Level II codes for portable services are not bundled codes. The portable service HCPCS Level II codes, (transportation and set-up) are specialty codes specifically assigned to portable X-ray suppliers upon enrollment for billing. In order to maintain a fair and equitable reimbursement these costs should be billable directly to Medicare Part B by the provider of the service. The portable X-ray HCPCS Level II codes are used only for billing the patient services provided by "portable X-ray and/or other portable diagnostic imaging supplier".

**CMS Final HCPCS Coding Decision**

We are internally considering the request to revise existing HCPCS Level II code R0070 and, currently, do not need any additional information.

## Portable X-ray and/or Other Portable Diagnostic Imaging Supplier, Transportation Component - HCP2307027BP8W and HCP2301034XATF

### Topic/Issue

Request to revise an existing HCPCS Level II code R0075, “Transportation of portable x-ray equipment and personnel to home or nursing home, per trip to facility or location, more than one patient seen” to identify portable X-ray and/or other portable diagnostic imaging supplier, transportation.

Applicant's suggested language: R0075, “Transportation of portable x-ray and other diagnostic imaging equipment and personnel to home or nursing home, per trip, to facility or location, more than one patient seen”

### Summary of Applicant's Submission

The American Portable Diagnostic Association submitted a request to revise an existing HCPCS Level II code R0075, “Transportation of portable x-ray equipment and personnel to home or nursing home, per trip to facility or location, more than one patient seen” to identify portable X-ray and/or other portable diagnostic imaging supplier, transportation. The code expansion should include provisions in the policy language for HCPCS Level II code R0075 and billing guidelines when portable X-ray and or other portable diagnostic imaging suppliers submit claims for other portable diagnostic imaging. Currently, HCPCS Level II code R0075 applies only to portable X-ray procedures performed under a portable X-ray supplier specialty 63. R0075 represents a billing component for portable X-ray transportation of equipment and personnel when more than one patient is seen during a visit to a facility. A transportation service code, R0075, may only be billed when the X-ray equipment are actually transported and used at the location where the examination was taken. The function of the code is to identify how many patients were seen at a single location and prorate the transportation fee across all patients. HCPCS Level II code R0075 must be billed with one of the following modifiers to indicate how many patients were served on that trip to the facility or location. The modifiers are UN (two patients served), UP (three patients served), UQ (four patients served), UR (five patients served), and US (six or more patients served). The allowable fee for R0075 will be adjusted based upon the modifier used on each patient claim. The supplier of portable X-ray and other portable diagnostic services was changed and updated through the National Uniform Claim Committee in 2016. The current title ‘Portable X-ray Supplier and Supplier’ description is no longer adequate for billing of the modern-day ‘Portable Diagnostic Imaging Supplier’. The title changed from ‘Portable X-ray Supplier’ to ‘Portable X-ray and/or Other Portable Diagnostic Imaging Supplier’ along with the new description.

### CMS Preliminary HCPCS Coding Recommendation

These applications are being deferred for additional consideration in a subsequent biannual coding cycle. We continue to believe more time is needed to consider revising existing HCPCS Level II code R0075 and any implications that might occur.

**Summary of Public Feedback**

The applicant and other commenters disagreed with CMS' HCPCS preliminary recommendation to defer for additional consideration in a subsequent biannual coding cycle. According to the applicant, the transportation costs for "other portable" diagnostic imaging is typically performed independently of a portable x-ray test. The applicant indicated that re-instatement of the "cost component" HCPCS Level II code R0076, and expanding R0070-R0075 is essential to preserve access to additional services for Medicare beneficiaries. In the 1990s and early 2000s R0076 was available to bill for a transportation component to cover cost for the transportation of EKG, ultrasound, and echocardiography. Currently a transportation component HCPCS Level II code applies only to portable X-ray tests. Other portable diagnostic tests performed by a "Portable X-ray and/or Other Portable Diagnostic Imaging Supplier" are therefore substantially and arbitrarily undervalued under Medicare's approach. A similar transportation component reimbursement policy for Other Portable Diagnostic Imaging is of significance and is favorably recommended by industry suppliers.

**CMS Final HCPCS Coding Decision**

We are internally considering the request to revise existing HCPCS Level II code R0075 and, currently, do not need any additional information.

## Portable X-ray and/or Other Portable Diagnostic Imaging Supplier, Transportation Component, and Portable EKG - HCP230102T6B2A

### Topic/Issue

Request to revise an existing HCPCS Level II code R0076, “Transportation of portable ekg to facility or location, per patient” to identify Portable X-ray and/or other portable diagnostic imaging supplier, transportation component, and portable EKG.

Applicant's suggested language: R0076, “Transportation of portable ekg to facility or location, per patient R0076 HCPCS code R0076 for Transportation of portable ekg to facility or location, per one patient seen”

### Summary of Applicant's Submission

Portable Diagnostic Imaging Supplier, Advocacy Dispatch Health Imaging, submitted a request to revise an existing HCPCS Level II code R0076 to identify transportation of portable EKG to facility or location, per patient. HCPCS Level II code R0076 appears available with a description, although when used for codification on a claim, there is no reimbursement. Therefore, the request for revision to the HCPCS Level II code R0076 is to revise, reinstate, and update the policy and coverage provisions for the code. This includes the ability to use code R0076 to bill for the transportation component of a portable EKG on claims and receive reimbursement for the trip on claims billed by portable X-ray supplier (specialty 63), billing independently. The EKG test is included in the provisions of services provided by portable X-ray suppliers. A modifier must be reported with R0076 when more than one patient is seen per trip. Only one of the following five modifiers shall be reported with R0076 when more than one patient is seen: UN (two patients served), UP (three patients served), UQ (four patients served), UR (five patients served), or US (six or more patients served). Payment for the modifiers must be consistent with the definition of the modifiers. R0076 must be billed in conjunction with the Current Procedural Terminology (CPT®) codes, and only when the diagnostic equipment used was actually transported to the location where the test was taken.

### CMS Preliminary HCPCS Coding Recommendation

These applications are being deferred for additional consideration in a subsequent biannual coding cycle. We continue to believe more time is needed to consider revising existing HCPCS Level II code R0076 and any implications that might occur.

### Summary of Public Feedback

The applicant and other commenters disagreed with CMS’ HCPCS preliminary recommendation to defer for additional consideration in a subsequent biannual coding cycle. According to the applicant, to secure beneficiary access to all portable diagnostics for elderly and other at-risk beneficiaries, Medicare should extend R-code reimbursement beyond just portable X-ray to all mobile diagnostics offered by specialty code 63 companies. R-code funding would reduce the excessive administrative burden on companies, which now, in order to provide vascular and abdominal ultrasounds, echocardiograms and other studies must register with Medicare as both a Portable X-ray Supplier and as an Independent Diagnostic Testing Facility (IDTF). The IDTF regulations require the registrant to re-file its 855 form with Medicare every time it adds or deletes any new ultrasound equipment, sonographer or

supervising physician.  Such protections, where necessary, could be incorporated into expanded regulations for Portable X-ray Supplier enrollment.

Commenters stated that by expanding R-Code reimbursement for Specialty Code 63 companies, Medicare would dramatically enhance the ability of portable diagnostics companies to keep elderly and other at-risk patients safe in their long-term care facility or other residential setting, improve patient satisfaction, and avoid costly, risky, and unnecessary transfers to the Emergency Room, which often result in avoidable hospital admissions.

**CMS Final HCPCS Coding Decision**

We are internally consider the request to revise existing HCPCS Level II code R0076 and, currently, do not need any additional information.

## Home Infused Iron Replacement Therapy - HCP230703AJHV1

### Topic/Issue

Request to establish a new HCPCS Level II code to identify home infusion of iron replacement therapy.

Applicant's suggested language: SXXXX, “Home infusion therapy, iron replacement; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem”

### Summary of Applicant's Submission

The National Home Infusion Association (NHIA) submitted a request to establish a new HCPCS Level II code to identify home infusion of iron replacement therapy. This new HCPCS Level II code would accurately reflect the items and services being provided and would reduce the use of the HCPCS Level II code S9379, “Home infusion therapy, infusion therapy, not otherwise classified; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem.” The current code set created more than twenty years ago, does not have a unique S code for iron replacement therapy.

### CMS Preliminary HCPCS Coding Recommendation

We welcome information from the applicant and any payers who are currently paying for this service to describe a claims processing need for a unique HCPCS Level II code to describe home infusion of iron replacement therapy.

CMS notes that the applicant has proposed a number of more specific home infusion therapy services that payers could use instead of the more general HCPCS Level II code S9379. We can appreciate that there may be more nuanced levels of work and service delivery involved in a range of home infusion services. In evaluating this request, it would be helpful for us to have a holistic understanding of the framework in which NHIA views home infusion services across all currently available Level I and Level II codes and why additional codes are useful for payers. It would also help CMS to hear from one or more payers about their views on the framework.

For instance, it would be helpful to understand why iron replacement therapy is different than antibiotic therapy in terms of how a payer would value the inputs of the service, particularly since the drugs are coded separately. As an example, one way in which we could better understand the program need is to see a chart or table that shows certain payers paying S9379 claims differently based upon the infused product.

### Summary of Public Feedback

The primary speaker stated that for home infusion therapy, when billing commercial payers, coverage is comprehensive and not based on the method of administration, but rather on the type of therapy being delivered. The current HCPCS Level II S codes are therapy specific codes that cover “administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per

diem". The current S code set (except for updates requested by NHIA in 2022) has not been updated in over 20 years, consequently Not Otherwise Classified (NOC) codes are being used more frequently for new infused drug therapies that have come to market. NOC codes are administratively burdensome for both the provider and the payer, requiring manual intervention to adjudicate claims and from a contractual prescriptive, the inability to differentiate payment amounts for a single NOC code. The speaker requests a new code for home infused iron replacement therapy in order to relieve the administrative burdens associated with NOC codes. According to the speaker, this code would help both payers and providers adequately distinguish home infused iron replacement therapy, improving the ability to contract and adjudicate claims home iron replacement therapies.

**CMS Final HCPCS Coding Decision**

We appreciate the comments provided in response to CMS' published preliminary recommendation. CMS shares interest in reducing administrative burden throughout the health care system, whenever possible, and generally reducing utilization of NOC codes on a routine basis. We would like to hear from other payers about their views for more granular coding; for instance, it would be particularly helpful to hear from other payers if they are supportive of the code requests from NHIA, have other suggestions, or prefer the current code set. At this time, we are not proceeding with the request to establish a new HCPCS Level II code to identify home infusion of iron replacement therapy. We are open to a reconsideration of this request, along with other requests from NHIA considered this cycle, but we strongly encourage any requests for reconsideration be accompanied by perspectives from other payers.

## Home Infused Antibiotic, Antiviral and Antifungal Therapies Administered Over Extended Timeframes - HCP230703FRY4H

### Topic/Issue

Request to establish a new HCPCS Level II code to identify antibiotic, antiviral or antifungal therapy drugs provided at home via extended infusion.

Applicant's suggested language: SXXXX, “Home infusion therapy, antibiotic, antiviral, or antifungal therapy; extended infusion; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem”

### Summary of Applicant's Submission

The National Home Infusion Association (NHIA) submitted a request to establish a new HCPCS Level II code to identify antibiotic, antiviral or antifungal therapy drugs being provided in the home via extended infusion. A new code would be used to differentiate extended infusions from the traditional once a day infusion, to appropriately contract for services. At the time the HCPCS S code set for home infusion was created, more than 20 years ago, home infusion of antibiotic, antiviral or antifungal therapy HCPCS Level II codes were created based on the number of infusions per day (e.g., once a day, every 12 hours, every 8 hours, every 6 hours, and every 4 hours.) These codes allow for per diem contracting based on frequency of administration. Twenty years ago, few, if any, antibiotic, antiviral or antifungal therapies were being infused over extended periods of time. Home infusion providers are increasingly receiving physician/practitioner orders for prolonged daily home infusions of anti-infectives. Drugs infused over extended periods of time are more resource intense than traditional bolus and intermittent infusions over 30 to 60 minutes.

### CMS Preliminary HCPCS Coding Recommendation

We welcome information from the applicant and any payers who are currently paying for this service to describe a claims processing need for a unique HCPCS Level II code to describe antibiotic, antiviral, or antifungal home infusion therapy administered over an extended timeframe.

CMS notes that the applicant has proposed a number of more specific home infusion therapy services that payers could use instead of the more general HCPCS Level II codes S9494 and S9500. We can appreciate that there may be more nuanced levels of work and service delivery involved in a range of home infusion services. In evaluating this request, it would be helpful for us to have a holistic understanding of the framework in which NHIA views home infusion services across all currently available Level I and Level II codes and why additional codes are useful for payers. It would also help CMS to hear from one or more payers about their views on the framework.

As an example, one way in which we could better understand the program need is to see a chart or table that shows certain payers paying S9494 and S9500 claims differently based upon the infusion time of a product.

**Summary of Public Feedback**

The primary speaker stated that for home infusion therapy, when billing commercial payers, coverage is comprehensive and not based on the method of administration, but rather the type of therapy being delivered. The current HCPCS Level II S codes are therapy specific codes that cover "administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem". The current S code set (except for updates requested by NHIA in 2022) has not been updated in over 20 years, consequently Not Otherwise Classified (NOC) codes are being used more frequently for new infused drug therapies that have come to market. NOC codes are administratively burdensome for both the provider and the payer, requiring manual intervention to adjudicate claims and from a contractual prescriptive, the inability to differentiate payment amounts for a single NOC code. The speaker requests a new code for home infused antibiotic, antiviral and antifungal therapies administered over extended timeframes as the existing anti-infective codes are based on the number of doses per day, not the timeframe over which the drug is infused. Extended infusion times, greater than the typical 15-60 minutes, have been shown to improve therapeutic effectiveness and reduce the risk of resistance. The extended infusion creates additional expense for the provider, in that they require external infusion pumps to administer and more pharmacy resources to develop administration and care plans for the patient. According to the speaker, this code would help both payers and providers more adequately distinguish extended infusions, improving the ability to contract and adjudicate claims for home anti-infective therapies.

**CMS Final HCPCS Coding Decision**

We appreciate the comments provided in response to CMS' published preliminary recommendation. CMS shares interest in reducing administrative burden throughout the health care system, whenever possible, and generally reducing utilization of NOC codes on a routine basis. We would like to hear from other payers about their views for more granular coding; for instance, it would be particularly helpful to hear from other payers if they are supportive of the code requests from NHIA, have other suggestions, or prefer the current code set. At this time, we are not proceeding with the request to establish a new HCPCS Level II code to identify antibiotic, antiviral or antifungal therapy drugs provided at home via extended infusion. We are open to a reconsideration of this request, along with other requests from NHIA considered this cycle, but we strongly encourage any requests for reconsideration be accompanied by perspectives from other payers.

## Service Code Associated with Immunotherapies Infused at Least Every 90 Days - HCP230703HEGEW

### Topic/Issue

Request to establish a new HCPCS Level II code to identify home infusion immunotherapy administered at least every 90 days.

Applicant's suggested language: SXXXX, “Home infusion therapy, immunotherapy; administered at least every 90 days; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem”

### Summary of Applicant's Submission

The National Home Infusion Association submitted a request to establish a new HCPCS Level II code to identify home infusion immunotherapy administered at least every 90 days. As the number of immunotherapy drugs has risen, so has utilization of “Not otherwise classified” code S9379, “Home infusion therapy, infusion therapy, not otherwise classified; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem,” to over 45,000 claims per month. The addition of a code would greatly aid in the ability to appropriately contract for the per diem items and services based on resource utilization.

### CMS Preliminary HCPCS Coding Recommendation

We welcome information from the applicant and any payers who are currently paying for this service to describe a claims processing need for a unique HCPCS Level II code to describe home infusion immunotherapy administered at least every 90 days.

CMS notes that the applicant has proposed a number of more specific home infusion therapy services that payers could use instead of the more general HCPCS Level II code S9379 and S9338. We can appreciate that there may be more nuanced levels of work and service delivery involved in a range of home infusion services. In evaluating this request, it would be helpful for us to have a holistic understanding of the framework in which NHIA views home infusion services across all currently available Level I and Level II codes and why additional codes are useful for payers. It would also help CMS to hear from one or more payers about their views on the framework.

### Summary of Public Feedback

The primary speaker stated that for home infusion therapy, when billing commercial payers, coverage is comprehensive and not based on the method of administration, but rather the type of therapy being delivered. The current HCPCS Level II S codes are therapy specific codes that cover “administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem”. HCPCS Level II code S9338 has long been used to identify home administered immune globulin (Ig). Many payers require that the growing number of infused immunotherapies, other than Ig, be coded with Not Otherwise Classified (NOC) HCPCS Level II code S9379. NOC codes are administratively burdensome for both the provider and the payer, requiring

manual intervention to adjudicate claims and from a contractual prescriptive, the inability to differentiate payment amounts for a single NOC code. This request to add a new code for service code associated with immunotherapies infused at least every 90 days (application # HCP230703HEGEW) is predicated on HCPCS Level II code S9338 being modified to limit its use to immune globulin therapies (application # HCP230703K43DD) and goes hand in hand with our request for a new code to indicate home immunotherapy, single dose, or dosing interval greater than 90 days (application # HCP230703N55EH). These three codes would help both payers and providers adequately distinguish home infused immunotherapies and Ig, thus improving the ability to contract and adjudicate home infused immunotherapies.

**CMS Final HCPCS Coding Decision**

We appreciate the comments provided in response to CMS' published preliminary recommendation. CMS shares interest in reducing administrative burden throughout the health care system, whenever possible, and generally reducing utilization of NOC codes on a routine basis. We would like to hear from other payers about their views for more granular coding; for instance, it would be particularly helpful to hear from other payers if they are supportive of the code requests from NHIA, have other suggestions, or prefer the current code set. At this time, we are not proceeding with the request to establish a new HCPCS Level II code to identify home infusion immunotherapy administered at least every 90 days. We are open to a reconsideration of this request, along with other requests from NHIA considered this cycle, but we strongly encourage any requests for reconsideration be accompanied by perspectives from other payers.

## Home Immunotherapy, Single Dose, or Dosing Interval Greater than 90 Days - HCP230703N55EH

### Topic/Issue

Request to establish a new HCPCS Level II code to identify home infusion immunotherapy single dose or administration interval greater than 90 days.

Applicant's suggested language: SXXXX, “Home infusion therapy, immunotherapy; single dose or administration interval greater than 90 days; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem”

### Summary of Applicant's Submission

The National Home Infusion Association submitted a request to establish a new HCPCS Level II code to identify home infusion immunotherapy single dose or administration interval greater than 90 days. The current home infusion S code set was created more than twenty years ago and since that time the Food and Drug Administration (FDA) has approved dozens of infused immunotherapies, many of which are administered in the home. The initiation of home infusion services requires an assessment of the patient diagnosis, clinical condition at the time of treatment, and potential for adverse events. When there a is a gap between infusions of more than 90 days, the initial assessment process needs to be repeated - not dissimilar from a home health episode of care where they need to requalify a patient every 60 days. As the number of FDA approved immunotherapy drugs has risen sharply the utilization of “not otherwise classified” HCPCS Level II code S9379, “Home infusion therapy, infusion therapy, not otherwise classified; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem,” has risen to over 45,000 claims per month. A new code would greatly aid in the ability to appropriately contract for the home infusion per diem items and services based on resource utilization.

### CMS Preliminary HCPCS Coding Recommendation

We welcome information from the applicant and any payers who are currently paying for this service to describe a claims processing need for a unique HCPCS Level II code to describe home infusion immunotherapy single dose or administration interval greater than 90 days.

CMS notes that the applicant has proposed a number of more specific home infusion therapy services that payers could use instead of the more general HCPCS Level II code S9379 and S9338. We can appreciate that there may be more nuanced levels of work and service delivery involved in a range of home infusion services. In evaluating this request, it would be helpful for us to have a holistic understanding of the framework in which NHIA views home infusion services across all currently available Level I and Level II codes and why additional codes are useful for payers. It would also help CMS to hear from one or more payers about their views on the framework.

### Summary of Public Feedback

The primary speaker stated that for home infusion therapy, when billing commercial payers, coverage is comprehensive and not based on the method of administration, but rather the type

of therapy being delivered. The current HCPCS Level II S codes are therapy specific codes that cover "administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem". HCPCS Level II code S9338 has long been used to identify home administered immune globulin (Ig). Many payers require that the growing number of infused immunotherapies, other than Ig, be coded with NOC code S9379. Not Otherwise Classified (NOC) codes are administratively burdensome for both the provider and the payer, requiring manual intervention to adjudicate claims and from a contractual prescriptive, the inability to differentiate payment amounts for a single NOC code. This request to add a new code for home immunotherapy, single dose, or dosing interval greater than 90 Days (application # HCP230703N55EH) is predicated on code S9338 being modified to limit its use to immune globulin therapies (application # HCP230703K43DD) and goes hand in hand with our request for a new service code associated with immunotherapies infused at least every 90 days (application # HCP230703HEGEW). These three codes would help both payers and providers adequately distinguish home infused immunotherapies and Ig, thus improving the ability to contract and adjudicate home infused immunotherapies.

**CMS Final HCPCS Coding Decision**

We appreciate the comments provided in response to CMS' published preliminary recommendation. CMS shares interest in reducing administrative burden throughout the health care system, whenever possible, and generally reducing utilization of NOC codes on a routine basis. We would like to hear from other payers about their views for more granular coding; for instance, it would be particularly helpful to hear from other payers if they are supportive of the code requests from NHIA, have other suggestions, or prefer the current code set. At this time, we are not proceeding with the request to establish a new HCPCS Level II code to identify home infusion immunotherapy single dose or administration interval greater than 90 days. We are open to a reconsideration of this request, along with other requests from NHIA considered this cycle, but we strongly encourage any requests for reconsideration be accompanied by perspectives from other payers.

## Home Infused Subcutaneous or Intravenous Immune Globulin Therapies – HCP230703K43DD

### Topic/Issue

Request to revise existing HCPCS Level II code S9338, which currently reads "Home infusion therapy, immunotherapy, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem" to instead read "Home infusion therapy, subcutaneous or intravenous immune globulin therapy; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem" to limit its use to immune globulin therapies provided in the home.

Applicant's suggested language: S9338, "Home infusion therapy, subcutaneous or intravenous immune globulin therapy; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem"

### Summary of Applicant's Submission

The National Home Infusion Association submitted a request to revise an existing HCPCS Level II code S9338, "Home infusion therapy, immunotherapy, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem" to limit its use to immune globulin therapies provided in the home, and to instead read "Home infusion therapy, subcutaneous or intravenous immune globulin therapy; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem." At the time the code was created more than twenty years ago there were few immunotherapy drugs provided in the home. Many payers continue to use HCPCS Level II code S9338 for immune globulin and instruct providers to use the "Not otherwise classified" infusion therapy code, S9379, "Home infusion therapy, infusion therapy, not otherwise classified; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem," for other immunotherapies. As the number of immunotherapy drugs has risen, so has utilization of HCPCS Level II code S9379, to over 45,000 claims per month. This change would allow for payers and providers to appropriately contract for the provision of immune globulin therapies in the home, as well as facilitate more accurate tracking and trending of utilization.

### CMS Preliminary HCPCS Coding Recommendation

We welcome information from the applicant and any payers who are currently paying for this service to describe a claims processing need for a change of HCPCS Level II code S9338, to limit its use to immune globulin therapies provided in the home.

CMS notes that the applicant has proposed a number of more specific home infusion therapy services that payers could use instead of the more general HCPCS Level II code S9379. We can appreciate that there may be more nuanced levels of work and service delivery involved in a range of home infusion services. In evaluating this request, it would be helpful for us to have a holistic understanding of the framework in which NHIA views home infusion services

across all currently available Level I and Level II codes and why additional codes are useful for payers. It would also help CMS to hear from one or more payers about their views on the framework.

**Summary of Public Feedback**

The primary speaker stated that for home infusion therapy, when billing commercial payers, coverage is comprehensive and not based on the method of administration, but rather the type of therapy being delivered. The current HCPCS Level II S-codes are therapy specific codes that cover "administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem". HCPCS Level II code S9338 has long been used to identify home administered immune globulin (Ig). Many payers require that the growing number of infused immunotherapies, other than Ig, be coded with HCPCS Level II Not Otherwise Classified (NOC) code S9379. NOC codes are administratively burdensome for both the provider and the payer, requiring manual intervention to adjudicate claims and from a contractual prescriptive, the inability to differentiate payment amounts for a single NOC code. We request a modification to the description of S9338, limiting its use to home Ig therapies (application # HCP230703K43DD). This request goes hand in hand with two other requests for new immunotherapy codes; one for immunotherapies administered at least every 90 days (application # HCP230703HEGEW) and one for single dose or administration interval greater than 90 days (application # HCP230703N55EH). These three codes would help both payers and providers adequately distinguish home infused immunotherapies and Ig, thus improving the ability to contract and adjudicate home infused immunotherapies.

**CMS Final HCPCS Coding Decision**

We appreciate the comments provided in response to CMS' published preliminary recommendation. CMS shares interest in reducing administrative burden throughout the health care system, whenever possible, and generally reducing utilization of NOC codes on a routine basis. We would like to hear from other payers about their views for more granular coding; for instance, it would be particularly helpful to hear from other payers if they are supportive of the code requests from NHIA, have other suggestions, or prefer the current code set. At this time, we are not proceeding with the request to revise existing HCPCS Level II code S9338 to limit its use to immune globulin therapies provided in the home. We are open to a reconsideration of this request, along with other requests from NHIA considered this cycle, but we strongly encourage any requests for reconsideration be accompanied by perspectives from other payers.

## Walkasins® Receptor Sole - HCP230630JGDD5

### Topic/Issue

Request to establish a new HCPCS Level II code to identify Walkasins® receptor sole.

Applicant's suggested language: LXXXX, “Receptor Sole for use with LXXXX, six-month replacement, each”

### Summary of Applicant's Submission

RxFunction, Inc. submitted a request to establish a new HCPCS Level II code to identify Walkasins® receptor sole. Walkasins® receptor sole is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). This request is associated with the external lower extremity sensory prosthesis. Walkasins® receptor sole is part of a non-invasive prosthetic device available by prescription for long-term daily use. Walkasins® replaces a part of the lost function of plantar mechanoreceptors, which are internal to the skin. It detects touch and pressure and is an integral part of the integumentary system. Walkasins® is intended for patients with sensory peripheral neuropathy (PN), a condition where plantar mechanoreceptors are permanently inoperative or malfunctioned. Sensory PN leads to uncoordinated balance with unsteady gait and interferes with ambulation, daily activities, and increase risk for falls. Walkasins® detects pressure between the foot and the ground during standing and walking, signaling sensory (afferent) plantar pressure information to the brain that is critical for the subconscious non-voluntary and automatic control of balance and gait function. The Walkasins® system consists of two components per leg: receptor sole and haptic module. Receptor Soles placed in the shoes have embedded sensors that measure foot pressure. Haptic modules worn around the lower leg above the ankle receive and analyze the measured pressure information through a real-time algorithm that runs on a microprocessor, continuously calculating a representation of the instantaneous balance point of the body. At relevant times during standing and walking, the algorithm activates vibratory actuators embedded in the Haptic Module, to provide non-invasive tactile sensory cutaneous stimulation to the lower leg. This stimulation creates new sensory balance stimuli that transmit signals along the same afferent pathways previously served by the plantar mechanoreceptors, thereby replacing part of the lost plantar sensation. The receptor soles worn in shoes receives extensive wear. The sensitivity of the sensors embedded in the soles decline with use. The effectiveness of the system depends on the receptor sole's ability to detect and measure plantar pressure. The receptor sole should be replaced every six months.

### CMS Preliminary HCPCS Coding Recommendation

CMS does not have clear information that any insurance sector has a claims processing need for a new HCPCS Level II code to identify Walkasins® receptor sole. Existing HCPCS Level II code A9279, “Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified” is available for insurers if they deem appropriate for the Walkasins® receptor sole.

### 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. Since the Walkasins® Receptor Sole cannot be used by successive patients, it does not fall within the DME benefit category.

Section 120 of Chapter 15 of the Medicare Benefit Policy Manual (CMS Pub. 100-2) defines prosthetic devices as items that replace all or part of an internal body organ or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ. Rather than replacing damaged, malfunctioning nerves or any other part of the nervous system or the function thereof that affect balance and sensation in the soles of the feet, the Walkasins® Receptor Sole and the Walkasins® external lower leg sensory attachment operates together to cue or alert the patient via vibrations to make changes in gait in order to improve ambulation and coordination. There are different classifications for the usage areas of "haptic" wearables according to the degree of sensory impairment in the individuals intended to use them (Shull and Damian. 2015)[21]. The first category involves sensory substitution in the situation when patients have completely lost a certain sense and the technology is used to replace the lost function, therefore acting as a prosthesis for the lost sense. In the second category, the concept of sensory augmentation would apply when there is partial sensory impairment where patients would benefit from supplementary sensory cues to enhance motor control during rehabilitation activities. Walkasins® external lower leg device falls under the second category. This device works by presumably emulating signals by fast-adapting cutaneous afferents. The participants in the published studies who went through the clinical trials using Walkasins® had to demonstrate formal diagnosis of sensory peripheral neuropathy.

Peripheral neuropathy develops in stages; during the stages one to three, the patient would show sporadic numbness and pain, persistent symptoms, and debilitating pain. Stages four and five are known for deduction of the pain and moderate to total loss of the sensation. There has been no indication as to which phases of peripheral neuropathy will benefit from utilization of Walkasins®.

Based on the information provided, it seems like Walkasins® is mainly relying on the residual peripheral nerves that are intact after the injury. The device optimizes the balance, gait function, and physical activity utilizing the nerves that are not damaged.

Therefore, we are not able to determine at this time that the Walkasins® device falls within the prosthetic device benefit category or any other DMEPOS benefit category. Further information would be beneficial to CMS, including clarification on the following items:

[21] Shull PB, Damian DD. Haptic wearables as sensory replacement, sensory augmentation, and trainer-A review. *J Neuroeng Rehabil*. 2015; 12: 59 10.1186/s12984-015-0055-z

1. Are there any studies or documents to support and demonstrate how the Walkasins® device replaces the function of the lost or damaged nerves of the peripheral nervous system?

2. What types of peripheral neuropathy symptoms do the patients require to benefit from Walkasins®?

**Preliminary Medicare Payment Determination**

No determination.

**Summary of Public Feedback**

RxFunction disagreed with CMS' published preliminary recommendations. The speaker stated that Walkasins® meets the definition of a prosthetic device as defined in Section 120 of Chapter 15 of the Medicare Benefit Policy Manual and therefore requests a new HCPCS Level II code to identify the Walkasins® System. Additionally, if a national Medicare fee schedule is developed, that the fee be developed based on the pricing information already provided to CMS. Walkasins® replaces part of the lost function of plantar mechanoreceptors in the bottom of the feet and transmits and analyzes the pressure information and signals it to functioning mechanoreceptors around the ankle that then transit the information to the brain. The long reaction time needed for any voluntary perception and action results in patients being unable to react to the stimuli provided by the device cognitively/voluntarily and then act by consciously altering their walking behavior.

**CMS Final HCPCS Coding Decision**

We appreciate the comments provided in response to CMS' published preliminary HCPCS coding recommendation. CMS continues to have questions regarding inconsistencies in information provided in the application and during the public meeting, as noted below in the discussion of the Medicare benefit category determination. Therefore, we are deferring a coding decision on this application to a subsequent biannual coding cycle.

**Final Medicare Benefit Category Determination**

Prosthetic Device (conditional).

As stated in the preliminary determination, the section 120 of Chapter 15 of the Medicare Benefit Policy Manual (CMS Pub. 100-2) defines prosthetic devices as items that replace all or part of an internal body organ or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ.

According to the applicant, the Walkasins® device replaces a part of the lost function of plantar mechanoreceptors, which are internal to the skin.

For the Walkasins® device to be considered a prosthetic device, it must fulfill the main requirements below from section 120 of Chapter 15 of the Medicare Benefit Policy Manual:

1. Is it replacing all or part of the function of a permanently inoperative or malfunctioning internal body organ?

We have conditionally determined that Walkasins® could be a prosthetic device because the actions of this device, when used to treat a certain type of neuropathy, replace the function of a permanently inoperative or malfunctioning organ. We are requesting evidence that this device replaces the permanent inoperative/malfunctioning receptors caused by sensory peripheral neuropathy so that we can determine that this a prosthetic device.

Walkasins® appears to replace all or part of the function of a permanently inoperative or malfunctioning internal body organ – namely, the peripheral nervous system (PNS), a collection of tissues and cells that are joined to perform the unique function of sending information from different areas of the body back to the brain, as well as carrying out commands from the brain to various parts of the body.

The PNS includes sensory plantar cutaneous mechanoreceptors which provide critical input signals for postural control during walking. The mechanoreceptors and nerves on the bottom of the feet are components of the system and integral to its function. Hence, we believe Walkasins® could be theoretically regarded as a prosthetic device, as it serves to partially substitute the function of the PNS and the mechanoreceptors.

According to Section 120 of Chapter 15 in the Medicare Benefit Policy Manual, a prosthetic device must substitute for a permanently malfunctioning internal body organ. For some patients, peripheral nerve damage may be temporary, and in these cases, a device used to replace all or part of the function of the PNS would not be considered a prosthetic device. Temporary nerve damage of this nature often arises in conditions induced by vascular disorders. Thus, we are requesting evidence supporting that Walkasins® treats permanent damage to the PNS.

2. What is the function the internal body organ normally performs that is being replaced?

The plantar cutaneous mechanoreceptors provide critical input signals for postural control during walking. In healthy patients, it is well established that sensory information from the cutaneous mechanoreceptors within the plantar surfaces of the feet are important for the control of standing and walking balance[22, 23]. Specifically, they aid in the perception of changes to the walking environment by responding to changes in pressure, stretch, and vibrations on the skin[24, 25].

In patients with the loss of sensation due to variable causes such as peripheral neuropathy, the absence of plantar cutaneous afferents affects gait. It has been suggested gait alterations are primarily mediated by a decrease in the self-selected walking speed of those patients. Additionally, the increased risk of falling is more likely due to the inability of neuropathic

[22] Inglis JT., Kennedy PM., Wells C., Chua R., (2002). The role of cutaneous receptors in the foot. Sensory Control of Movement and Posture, 508, 111-117

[23] Felicetti, G., Thoumie, P., Do, M. C., & Schieppati, M. (2021). Cutaneous and muscular afferents from the foot and sensory fusion processing: Physiology and pathology in neuropathies. In Journal of the Peripheral Nervous System (Vol. 26, Issue 1, pp. 17–34). John Wiley and Sons Inc.

[24] Inglis et al. 2002

[25] Kavounoudias, A., Roll, R., & Roll, J.-P. (1998). The plantar sole is a 'dynamometric map' for human balance control. NeuroReport, 9, 3247–3252

patients to execute appropriate response strategies when exposed to unexpected perturbations or obstacles during walking[26, 27].

In this scenario, Walkasins® serves to replace the function of the internal body organ (PNS) concerning walking and postural control.

3. How does Walkasins® replace this function?

According to the manufacturer of the Walkasins® device, the device partially substitutes lost nerve function related to plantar sensation providing directional tactile cues and vibrotactile stimulation during standing and walking. This device is designed to replace lost nerve function used for detection and signaling of foot pressure sensation in patients with peripheral neuropathy.

CMS believes that additional information is needed to further verify that the Walkasins® device meets the Medicare definition of prosthetic device at section 120 of Chapter 15 of the Medicare Benefit Policy Manual. As suggested in the literature[28], vibrotactile stimulation has demonstrated a significant change in the measure of tactile perception and voluntary motion. The voluntary movement affects the simultaneous perception of auditory and tactile stimuli. This contradicts a previous statement by the manufacturer of the Walkasins® device that the device relies on involuntary reaction to cues or alerts for functional walking. There is also a deficiency in the documents that were provided by the applicant to demonstrate how this device replaces the function of the lost or damaged nerves of the peripheral nervous system. The Walkasins® device potentially provides sufficient sensory information during walking and standing to improve gait and balance functions. Most studies involving wearable haptics such as Walkasins® have extracted various gait characteristics, such as foot pressure patterns or gait phase detection, from force-sensing insoles and then mapped these characteristics to patients via haptic feedback[29, 30]. Hence, additional evidence is required to elucidate how the sensors compensate for permanently damaged nerve function and the mechanism and process by which they contribute to improving balance and gait.

If information is not received to address these issues in a sufficient manner, the benefit category determination of prosthetic device may need to be revisited.

**Final Medicare Payment Determination**

No Determination.

[26] Inglis et al. 2002
[27] Kavounoudias et al. 1998
[28] Seim C., Wolf S., Starner T. (2021) Wearable vibrotactile stimulation for upper extremity rehabilitation in chronic stroke: clinical feasibility trial using the VTS Glove
[29] Kavounoudias et al. 1998
[30] Seim et al. 2021

## Walkasins® Lower Extremity Sensory Prosthesis – HCP230630P62DH

### Topic/Issue

Request to establish a new HCPCS Level II code to identify Walkasins® lower extremity sensory prosthesis.

Applicant's suggested language: LXXXX, "External Lower Extremity Sensory Prosthesis, Cutaneous Stimulation of Mechanoreceptors, Per Leg"

### Summary of Applicant's Submission

RxFunction, Inc. submitted a request to establish a new HCPCS Level II code to identify Walkasins® lower extremity sensory prosthesis. Walkasins® lower extremity sensory prosthesis is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). Walkasins® lower extremity sensory prosthesis is a non-invasive prosthetic device available by prescription for long-term daily use. Walkasins® replaces a part of the lost function of plantar mechanoreceptors, which are internal to the skin. It detects touch and pressure and is an integral part of the integumentary system. Walkasins® is intended for patients with sensory peripheral neuropathy (PN), a condition where plantar mechanoreceptors are permanently inoperative or malfunctioned. Sensory PN leads to uncoordinated balance with unsteady gait and interferes with ambulation, daily activities, and increase risk for falls. Walkasins® detects pressure between the foot and the ground during standing and walking, signaling sensory (afferent) plantar pressure information to the brain that is critical for the subconscious non-voluntary and automatic control of balance and gait function. The Walkasins® system consists of two components per leg: receptor sole and haptic module. Haptic modules worn around the lower leg above the ankle receive and analyze the measured pressure information through a real-time algorithm that runs on a microprocessor, continuously calculating a representation of the instantaneous balance point of the body. At relevant times during standing and walking, the algorithm activates vibratory actuators embedded in the Haptic Module, to provide non-invasive tactile sensory cutaneous stimulation to the lower leg. This stimulation creates new sensory balance stimuli that transmit signals along the same afferent pathways previously served by the plantar mechanoreceptors, thereby replacing part of the lost plantar sensation.

### CMS Preliminary HCPCS Coding Recommendation

CMS does not have clear information that any insurance sector has a claims processing need for a new HCPCS Level II code to identify Walkasins® lower extremity sensory prosthesis. Existing HCPCS Level II code A9279, "Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified" is available for insurers if they deem appropriate for the Walkasins® lower extremity sensory prosthesis.

### 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. Since the Walkasins® external lower extremity sensory device cannot be used by successive patients, it does not fall within the DME benefit category.

Section 120 of Chapter 15 of the Medicare Benefit Policy Manual (CMS Pub. 100-2) defines prosthetic devices as items that replace all or part of an internal body organ or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ. Rather than replacing damaged, malfunctioning nerves or any other part of the nervous system or the function thereof that affect balance and sensation in the soles of the feet, the Walkasins® Receptor Sole and the Walkasins® external lower leg sensory attachment operate together to cue or alert the patient via vibrations to make changes in gait in order to improve ambulation and coordination. There are different classifications for the usage areas of "haptic" wearables according to the degree of sensory impairment in the individuals intended to use them (Shull and Damian. 2015)[31]. The first category involves sensory substitution in the situation when patients have completely lost a certain sense and the technology is used to replace the lost function, therefore acting as a prosthesis for the lost sense. In the second category, the concept of sensory augmentation would apply when there is partial sensory impairment where patients would benefit from supplementary sensory cues to enhance motor control during rehabilitation activities. Walkasins® external lower leg device falls under the second category. This device works by presumably emulating signals by fast-adapting cutaneous afferents. The participants in the published studies who went through the clinical trials using Walkasins® had to demonstrate formal diagnosis of sensory peripheral neuropathy.

Peripheral neuropathy develops in stages; during the stages one to three, the patient would show sporadic numbness and pain, persistent symptoms, and debilitating pain. Stages four and five are known for deduction of the pain and moderate to total loss of the sensation. There has been no indication as to which phases of peripheral neuropathy will benefit from utilization of Walkasins®.

Based on the information provided, it seems like Walkasins® is mainly relying on the residual peripheral nerves that are intact after the injury. The device optimizes the balance, gait function, and physical activity utilizing the nerves that are not damaged.

Therefore, we are not able to determine at this time that the Walkasins® device falls within the prosthetic device benefit category or any other DMEPOS benefit category. Further research is needed, including clarification on the following items:

[31] Shull PB, Damian DD. Haptic wearables as sensory replacement, sensory augmentation, and trainer-A review. *J Neuroeng Rehabil*. 2015; 12: 59 10.1186/s12984-015-0055-z

1. Are there any studies or documents to support and demonstrate how the Walkasins® device replaces the function of the lost or damaged nerves of the peripheral nervous system?

2. What types of peripheral neuropathy symptoms do the patients require to have to benefit from Walkasins®?

**Preliminary Medicare Payment Determination**

No determination.

**Summary of Public Feedback**

RxFunction disagreed with CMS' published preliminary recommendations. The speaker stated that Walkasins® meets the definition of a prosthetic device as defined in Section 120 of Chapter 15 of the Medicare Benefit Policy Manual and therefore requests a new HCPCS Level II code to identify the Walkasins® System. Additionally, if a national Medicare fee schedule is developed, that the fee be developed based on the pricing information already provided to CMS. Walkasins® replaces part of the lost function of plantar mechanoreceptors in the bottom of the feet and transmits and analyzes the pressure information and signals it to functioning mechanoreceptors around the ankle that then transit the information to the brain. The long reaction time needed for any voluntary perception and action results in patients being unable to react to the stimuli provided by the device cognitively/voluntarily and then act by consciously altering their walking behavior.

**CMS Final HCPCS Coding Decision**

We appreciate the comments provided in response to CMS' published preliminary HCPCS coding recommendation. CMS continues to have questions regarding inconsistencies in information provided in the application and during the public meeting, as noted below in the discussion of the Medicare benefit category determination. Therefore, we are deferring a coding decision on this application to a subsequent coding cycle.

**Final Medicare Benefit Category Determination**

Prosthetic Device (conditional).

As stated in the preliminary determination, the section 120 of Chapter 15 of the Medicare Benefit Policy Manual (CMS Pub. 100-2) defines prosthetic devices as items that replace all or part of an internal body organ or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ.

According to the applicant, the Walkasins® device replaces a part of the lost function of plantar mechanoreceptors, which are internal to the skin. For the Walkasins® device to be considered a prosthetic device, it must fulfill the main requirements below from section 120 of Chapter 15 of the Medicare Benefit Policy Manual:

1. Is it replacing all or part of the function of a permanently inoperative or malfunctioning internal body organ?

We have conditionally determined that Walkasins® could be a prosthetic device because the actions of this device, when used to treat a certain type of neuropathy, replace the function of a permanently inoperative or malfunctioning organ. We are requesting evidence that this device replaces the permanent inoperative/malfunctioning receptors caused by sensory peripheral neuropathy so that we can determine that this a prosthetic device.

Walkasins® appears to replace all or part of the function of a permanently inoperative or malfunctioning internal body organ – namely, the peripheral nervous system (PNS), a collection of tissues and cells that are joined to perform the unique function of sending information from different areas of the body back to the brain, as well as carrying out commands from the brain to various parts of the body.

The PNS includes sensory plantar cutaneous mechanoreceptors which provide critical input signals for postural control during walking. The mechanoreceptors and nerves on the bottom of the feet are components of the system and integral to its function. Hence, we believe Walkasins® could be theoretically regarded as a prosthetic device, as it serves to partially substitute the function of the PNS and the mechanoreceptors.

According to Section 120 of Chapter 15 in the Medicare Benefit Policy Manual, a prosthetic device must substitute for a permanently malfunctioning internal body organ. For some patients, peripheral nerve damage may be temporary, and in these cases, a device used to replace all or part of the function of the PNS would not be considered a prosthetic device. Temporary nerve damage of this nature often arises in conditions induced by vascular disorders. Thus, we are requesting evidence supporting that Walkasins® treats permanent damage to the PNS.

2. What is the function the internal body organ normally performs that is being replaced?

The plantar cutaneous mechanoreceptors provide critical input signals for postural control during walking. In healthy patients, it is well established that sensory information from the cutaneous mechanoreceptors within the plantar surfaces of the feet are important for the control of standing and walking balance[32, 33]. Specifically, they aid in the perception of changes to the walking environment by responding to changes in pressure, stretch, and vibrations on the skin[34, 35].

In patients with the loss of sensation due to variable causes such as peripheral neuropathy, the absence of plantar cutaneous afferents affects gait. It has been suggested gait alterations are primarily mediated by a decrease in the self-selected walking speed of those patients. Additionally, the increased risk of falling is more likely due to the inability of neuropathic

[32] Inglis JT., Kennedy PM., Wells C., Chua R., (2002). The role of cutaneous receptors in the foot. Sensory Control of Movement and Posture, 508, 111-117

[33] Felicetti, G., Thoumie, P., Do, M. C., & Schieppati, M. (2021). Cutaneous and muscular afferents from the foot and sensory fusion processing: Physiology and pathology in neuropathies. In Journal of the Peripheral Nervous System (Vol. 26, Issue 1, pp. 17–34). John Wiley and Sons Inc.

[34] Inglis et al. 2002

[35] Kavounoudias, A., Roll, R., & Roll, J.-P. (1998). The plantar sole is a 'dynamometric map' for human balance control. NeuroReport, 9, 3247–3252

patients to execute appropriate response strategies when exposed to unexpected perturbations or obstacles during walking[36, 37].

In this scenario, Walkasins® serves to replace the function of the internal body organ (PNS) concerning walking and postural control.

3. How does Walkasins® replace this function?

According to the manufacturer of the Walkasins® device, the device partially substitutes lost nerve function related to plantar sensation providing directional tactile cues and vibrotactile stimulation during standing and walking. This device is designed to replace lost nerve function used for detection and signaling of foot pressure sensation in patients with peripheral neuropathy.

CMS believes that additional information is needed to further verify that the Walkasins® device meets the Medicare definition of prosthetic device at section 120 of Chapter 15 of the Medicare Benefit Policy Manual. As suggested in the literature[38], vibrotactile stimulation has demonstrated a significant change in the measure of tactile perception and voluntary motion. The voluntary movement affects the simultaneous perception of auditory and tactile stimuli. This contradicts a previous statement by the manufacturer of the Walkasins® device that the device relies on involuntary reaction to cues or alerts for functional walking. There is also a deficiency in the documents that were provided by the applicant to demonstrate how this device replaces the function of the lost or damaged nerves of the peripheral nervous system. The Walkasins® device potentially provides sufficient sensory information during walking and standing to improve gait and balance functions. Most studies involving wearable haptics such as Walkasins® have extracted various gait characteristics, such as foot pressure patterns or gait phase detection, from force-sensing insoles and then mapped these characteristics to patients via haptic feedback[39, 40]. Hence, additional evidence is required to elucidate how the sensors compensate for permanently damaged nerve function and the mechanism and process by which they contribute to improving balance and gait.

If information is not received to address these issues in a sufficient manner, the benefit category determination of prosthetic device may need to be revisited.

**Final Medicare Payment Determination**

No Determination.

[36] Inglis et al. 2002
[37] Kavounoudias et al. 1998
[38] Seim et al. 2021
[39] Kavounoudias et al. 1998
[40] Seim et al. 2021

## DART Device, DART-Reach and EZ-Spray - HCP230124KCGPN

### Topic/Issue

Request to establish a new HCPCS Level II code to identify DART device (nasal atomizer), DART- Reach device (laryngeal atomizer), and EZ-Spray device (gas powered atomizer).

Applicant's suggested language: XXXXX, “Medication atomizer”

### Summary of Applicant's Submission

Pulmodyne, Inc. submitted a request to establish a new HCPCS Level II code to identify medication atomizer. DART and EZ-Spray are exempt from the premarket notification procedures by the Food and Drug Administration (FDA). DART-Reach (Topical applicator) received the Food and Drug Administration’s (FDA’s) 510(k) clearance on May 25, 2007. Pulmodyne, Inc. makes three products that pertain to the requested medication atomizer code. The DART device (nasal atomizer) sprays medication for delivery and absorption through the nasal passage. The DART-Reach device (laryngeal atomizer) sprays medication laryngeally to topically anesthetize the airway. The EZ-Spray device (gas powered atomizer) can be used in the mouth or the nose to widely anesthetize the upper and lower airway. Each device is used in conjunction with medications for airway topicalization, sedation, pain management, opiate overdoses, anxiolysis, seizure control, awake intubations, etc. All these devices have been used in conjunction with Lidocaine, Midazolam, Naloxone, Fentanyl, Sufentanil, Hydromorphone-opioids, Ketamine, Flumazenil, Glucagon, Insulin, Butorphanol, Precedex, Lorazepam, Haldol, and other medications.

### CMS Preliminary HCPCS Coding Recommendation

Our understanding is that the medication atomizer is not suitable for inclusion in the HCPCS Level II code set because it is used for a procedure and certain items are considered bundled into the facility payment. We have not identified a specific need for the medication atomizer to be separately paid, since we believe that a particular payer may elect to pay for the service in which this device is used. For instance, Medicare would typically reflect the costs of the device in the payment for the procedure, if it is used, and as such it would not be separately payable.

### Summary of Public Feedback

No verbal or written comments were provided in response to CMS’ published preliminary coding recommendation.

### CMS Final HCPCS Coding Decision

Based on the information provided in the application and considering that no comments were received, CMS is finalizing its preliminary recommendation. Our understanding is that the medication atomizer is not suitable for inclusion in the HCPCS Level II code set because it is used for a procedure and certain items are considered bundled into the facility payment. We have not identified a specific need for the medication atomizer to be separately paid, since we believe that a particular payer may elect to pay for the service in which this device is used. For instance, Medicare would typically reflect the costs of the device in the payment for the procedure, if it is used, and as such it would not be separately payable.

## HEMIGARD® - HCP2307020DN93

### Topic/Issue

Request to establish a new HCPCS Level II code to identify HEMIGARD® Adhesive Suture Retention Device (ASRD).

Applicant's suggested language: XXXXX, “Use of adhesive suture retention device to assist in closure of fragile or at-risk skin wound”

### Summary of Applicant's Submission

SUTUREGARD Medical, Inc. submitted a request to establish a new HCPCS Level II code to identify HEMIGARD® ASRD. HEMIGARD® ASRD is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). HEMIGARD® is a sterile single use device that allows surgeons to quickly and safely close and heal high tension or at-risk surgical wounds that normally cannot be closed successfully with standard closure materials. Patients with failed open (or postoperatively dehisced) wounds must undergo prolonged wound care during which time they may require costly products, hospitalization or additional surgery and are at risk for further complications. Surgical wound dehiscence occurs when a surgically repaired wound failing to heal, becoming an open wound. In the recent peer reviewed publication, 131 patients (mean MBI 32) underwent emergent/elective foot and ankle surgery. In this study, postop complications were: 1.5% surgical site infection, 3% dehiscence. A new code is needed to cover the HEMIGARD® device cost. HCPCS Level II supply code A4649, “Surgical supply, miscellaneous” is intended for passive wound dressings and does not account for patient value brought by the HEMIGARD® device, which directly improves surgical outcomes. It is the first of its kind hybrid device combining suture and adhesive technology. It is a simple but very effective load transferring skin anchor that mitigates the risk of conventional suture/staple skin closures. It protects skin edge blood flow and prevents suture-induced skin tearing.

### CMS Preliminary HCPCS Coding Recommendation

We appreciate the applicant submitting the study along with the application. Again, our understanding is that the HEMIGARD® ASRD is not suitable for inclusion in the HCPCS Level II code set because it is used for a procedure and certain items are considered bundled into the facility payment. We have not identified a specific need for the HEMIGARD® ASRD to be separately paid, since we believe that a particular payer may elect to pay for the service in which this device is used. For instance, Medicare would typically reflect the costs of the device in the payment for the procedure, if it is used, and as such it would not be separately payable.

### Summary of Public Feedback

SUTUREGARD Medical, Inc. disagreed with CMS’ HCPCS preliminary recommendation not to issue a unique HCPCS Level II code for HEMIGARD® ASRD. The speaker stated that wound dehiscence is one of the worst complications of surgery, requiring further care that may include additional visits to a clinic, an emergency room or hospitalization. Additional surgery is often required and in severe cases, there is risk of loss of a limb. The impact on the patient-surgeon trust relationship is especially difficult, as each perceives the other as potentially at fault. Dehiscence creates chaos and stress in the life of the patient and

surgeon and adds significant cost and inefficiency to surgical care. It should be noted that the primary cause of chronic wounds in the United States are failed (dehisced) surgical wounds. This adds $13 billion in cost annually to medical care. Foot and ankle surgery is especially prone to wound healing difficulties, as the foot is farthest from the heart and often suffers reduced arterial blood flow, compromised venous and lymphatic drainage and is prone to swelling postoperative. The speaker stated that their company has developed a simple, easy to use product that has been proven in multiple peer reviewed published studies to reduce wound dehiscence by 80 percent after foot and ankle surgery. This has led to reduction in revisional surgery and in hospital days. The speaker asked CMS to consider that this new category of product actually reduces the number of wounds requiring additional wound care treatment products and their attendant costs.

One speaker stated that people with diabetes have very poor healing due to the severe chronic inflammation that affect every system in the body. They said that HEMIGARD® ASRD is a unique product in that there is nothing in the surgical arena like it. They asked CMS to establish a new HCPCS Level II code for HEMIGARD® ASRD as this should be used in every site of service in every surgical specialty for these high-risk population groups.

Another speaker said that HEMIGARD® ASRD is different and unique from traditional suture closures. It is similar to pass through codes for bone anchors (HCPCS Level II code C1713) and mesh (HCPCS Level II code C1781). HEMIGARD® ASRD is a safe and effective product that has been proven to reduce wound dehiscence by 80 percent. The speaker stated that HEMIGARD® ASRD deserves a pass through HCPCS Level II code.

**CMS Final HCPCS Coding Decision**

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary recommendation. Our understanding is that the HEMIGARD® ASRD is not suitable for inclusion in the HCPCS Level II code set because it is used for a procedure and certain items are considered bundled into the facility payment. We have not identified a specific need for the HEMIGARD® ASRD to be separately paid, since we believe that a particular payer may elect to pay for the service in which this device is used. For instance, Medicare would typically reflect the costs of the device in the payment for the procedure, if it is used, and as such it would not be separately payable.

## Hummingbird® Tympanostomy Tube System (HTTS) - HCP2306297BBG1

### Topic/Issue

Request to establish a new HCPCS Level II code to identify Hummingbird® Tympanostomy Tube System (HTTS).

Applicant's suggested language: SXXXX, “Insertion of ventilation tube using one-pass tympanostomy tube system in pediatric patients (list separately in addition to code for primary procedure)”

### Summary of Applicant's Submission

Preceptis Medical (Preceptis) submitted a request to establish a new HCPCS Level II code to identify HTTS. The HTTS was initially cleared by the Food and Drug Administration (FDA) on June 5, 2020 through the 510(k) pathway for use in patients that are 6 months to 24 months in age. The HTTS received a second 510(k) clearance on July 27, 2022 for use in pediatric patients that are 6 months and older in age. This HCPCS Level II code would describe this device used to place tympanostomy tube(s) in pediatric patients in the physician office setting using an innovative surgical technology that combines the separate functions of creating a myringotomy (incision in the eardrum), and positioning and placing a ventilation tube across the tympanic membrane. The HTTS is intended to deliver a tympanostomy tube (also referred to as a ventilation tube) through the tympanic membrane of the patient and is indicated to be used in office settings for pediatric patients 6 months and older. Using the HTTS, the surgeon manually advances the sharpened sheath to create a myringotomy and simultaneously positions the ventilation tube within the myringotomy, always under direct visualization. The user then manually retracts the sharpened sheath away from the myringotomy using the manual actuator located on the handle. The retraction of the sheath releases the tube within the myringotomy. This device allows the tympanostomy service to be furnished to pediatric patients without general anesthesia and the service can therefore be performed in the physician office setting. Tympanostomy (requiring insertion of ventilating tube), local or topical anesthesia, as it describes the base procedure and adequately describes the majority of the surgeon's work and facility resources. However, procedures that utilize the HTTS have incremental intra-service work that is meaningful from a resource standpoint, including, the child must be swaddled and/or physically stabilized prior to the procedure, the child's head must be held by a nurse throughout the procedure, and then the surgeon uses this specialized HTTS device to complete the procedure. While the existing American Medical Association (AMA) Current Procedural Terminology (CPT®) Level I code 69433 is not age-specific, the vignette and the Relative Value Units (RVU) associated with this procedure are established for patients who can respond to surgeon direction, and do not have risk of movement during the procedure. The existing CPT® Level I code 69433 without the add-on S code creates a programmatic need for payers, including commercial insurers, Medicaid Fee-for-Service (FFS), and managed Medicaid payers, by not allowing payers to identify services performed using this technology. Private payers and Medicaid managed care plans have consistently expressed the need of a universal code for properly identifying the use of this device when used with the CPT® Level I code 69433.

**CMS Preliminary HCPCS Coding Recommendation**

The HTTS is not suitable for inclusion in the HCPCS Level II code set because it is used for a procedure and certain items are considered typically bundled into the facility payment. CMS would like to know if other insurers, particularly individual state Medicaid programs and private insurers, would pay for an add-on code if we were to establish one.

We note the following excerpt: While the existing American Medical Association (AMA) Current Procedural Terminology (CPT®) Level I code 69433 is not age-specific, the vignette and the Relative Value Units (RVU) associated with this procedure are established for patients who can respond to surgeon direction, and do not have risk of movement during the procedure.

Why has Preceptis Medical not considered pursuing a more descriptive CPT® code that can be valued more consistently with the age-specific population that is involved in the procedure? CMS is aware of a similar new technology that is used for children 6 months old and older to allow for ear tubes to be placed in the office setting without undergoing general anesthesia that is utilizing a CPT® code (0583T). We understand that CPT® code 0583T may preclude the Hummingbird® Tympanostomy Tube System due to a reference to iontophoresis local anesthesia in the code descriptor language, however, we would suggest the applicant to approach the AMA for an editorial change.

**Summary of Public Feedback**

Preceptis Medical disagreed with CMS' preliminary recommendation that the HTTS is not suitable for inclusion in the HCPCS Level II code. According to the speaker, payers, providers, and specialty medical societies have agreed that a procedural add-on S code makes the most sense to address the commercial and Medicaid payer programmatic needs of identifying additional incremental staffing and supply costs required to perform pediatric in-office ear tube procedures, like the HTTS. Payers, including Medicaid, have stated that they would use an add-on S code if CMS were to establish one. Medicaid and other commercial payers have specifically requested an add-on code to the existing CPT® code 69433 for in-office ear tube procedures performed for pediatric populations. Payers also continue to highlight the need for a universal coding identifier for pediatric tympanostomy procedures that utilize a specialized one-pass tympanostomy device insertion system, and that an add-on code is appropriate. Furthermore, payers have stated that they want to continue utilizing the existing primary procedure CPT® code 69433 as the baseline for reimbursement (as it adequately describes the surgeon's work and facility resources), but as stated above, CPT® code 69433 has limitations. These limitations would be addressed with an add-on S code to be used with pediatric patients under local anesthesia. While payers have developed workarounds to enable adoption by using modifiers, without this add-on code, they must manual process claims and perform internal reviews, which lead to an administrative burden and the potential for human error.

**CMS Final HCPCS Coding Decision**

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the responses received, we believe this request should be considered under the Potentially Misvalued Codes Initiative which examines concerns regarding valuation of

existing Current Procedural Terminology (CPT®) codes. At this time, no additional information is needed from the applicant.

## SurgiLock® - HCP2304138EFP5

### Topic/Issue

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

The applicant did not submit any suggested language.

### Summary of Applicant's Submission

Medical Lock Corporation submitted a request to establish a new HCPCS Level II code to identify SurgiLock®. SurgiLock® is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). SurgiLock® instrument platform is a class II medical device used by surgeons in the operating room and cardiologists and technicians in the cath-lab. SurgiLock® Platform has a direct impact in reducing the risk of infection, improving operating room efficiencies, and increasing safety. It improves efficiency and safety by helping to protect the sterile field and keeping instruments and other surgical supplies organized and readily available as well as reducing the need to hand sharps back and forth between surgeon and scrub nurse.

### CMS Preliminary HCPCS Coding Recommendation

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

### Summary of Public Feedback

Medical Lock Corporation disagreed with CMS' preliminary recommendation. The speaker stated that SurgiLock® helps in a number of ways. SurgiLock® is a line of defense against anything dropping below the sterile field, virtually eliminating drops, thus being a line of defense for infection. SurgiLock® makes the transfer and management of sharps on the sterile field between the nurse and surgeon, virtually accident free. The properties of SurgiLock® platforms makes it a near impossibility for an improperly handled needle driver to perforate and or break the sterile field; by not breaking the sterile barrier the needle driver placed upside down on the field eliminates an incident. SurgiLock® elastic technology will take temperatures in excess of 260 degrees of heat.

### CMS Final HCPCS Coding Decision

Based on the information provided in the application to establish a new HCPCS Level II code and considering the comments that were received, CMS is finalizing its preliminary recommendation. CMS' understanding is that SurgiLock® would generally be used in a procedure reported with a HCPCS Level I Current Procedural Terminology (CPT®) code. We have not identified a specific need for this item to be separately paid, since we believe that a particular payer may elect to pay for the service in which this product is used. For

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

## Pulse Irrigation Evacuation (PIE) - IHC230502YKN10

### Topic/Issue

Request for benefit category determination for the PIE device.

### Summary of Applicant's Submission

PIEMed submitted a DMEPOS benefit category determination (BCD) request for the Pulse Irrigation Evacuation (PIE) device for classification as durable medical equipment (DME). The PIE Device is an at-home device that uses pulses of water to irrigate the colon and remove stool. PIE is the treatment of choice for patients with neurogenic bowel, recurrent fecal impactions, or severe constipation when traditional bowel maintenance programs are ineffective or not tolerated. The PIE Device is cleared for home use, and is covered by many commercial medical insurance plans and the Veterans Administration, but not by Medicare. The PIE Device lasts more than three years, is rentable, can be used by more than one patient, and has no purpose other than for the treatment of an illness.

### CMS HCPCS Coding

The PIE Device is currently coded under existing HCPCS Level II codes E0350, “Control unit for electronic bowel irrigation/evacuation system” and E0352, “Disposable pack (water reservoir bag, speculum, valving mechanism and collection bag/box) for use with the electronic bowel irrigation/evacuation system”.

### Preliminary Medicare Benefit Category 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.

In order to help decide if the PIE Device can be classified as DME, CMS is interested in finding out more information about how this device is used in the home. CMS has the following questions:

1. The applicant states that the PIE Device is an FDA-cleared Class II at-home medical device. Can the applicant send CMS any FDA documentation indicating this at-home designation?

2. The applicant mentions that the PIE Device is now routinely used in the home setting. Was the PIE Device previously not routinely used in the home setting? If so, what has

changed over the years to allow the PIE Device to now be routinely used in the home?

3. Can the applicant explain the type of caregiver needed to help operate this device in the home? Do they need training? Can a caregiver who is not a health care professional, such as a family member or the patient themselves, operate this device?

**Summary of Public Feedback**

PIEMed responded to address specific questions about the PIE Device related to CMS' published preliminary benefit category determination. The applicant reiterated their view that the PIE Device qualifies as durable medical equipment (DME).

The applicant addressed that they do not have documentation from the FDA indicating an at-home designation, but they are an FDA-cleared Class II device. The applicant contacted the FDA who also did not have documentation of the at-home designation. The applicant said the PIE Device became FDA 510(k) cleared in 1986 and since then, it has been primarily used in the home (the applicant claims 90 percent of the device usage has been in the home). The applicant referenced 21 CFR 876.5220, which is where the FDA identifies colonic irrigation systems, for which the classification for Class II (performance standards) states that the device can be used "when the device is intended for colon cleansing when medically indicated, such as before radiological or endoscopic examinations." The applicant said that this wording is quite vague, and that all colon irrigation systems (such as colonic systems) are Class II devices under the FDA. The applicant addressed that the PIE Device has been routinely used in the home setting for the last 30 years. The applicant said that has always been the case, but some hospitals purchase the device for their inpatient and outpatient use. The applicant said many commercial insurers cover the device, such as United Healthcare, Aetna, and Blue Cross Blue Shield on a case-by-case basis and when medically necessary. The applicant commented that the majority of current patients have their spouse, parent, or caregiver use the device on them. The applicant said it is recommended that the patient does not operate the device by oneself as the patient will be lying in bed during the PIE session. The applicant said the training to train the caregiver is a few hours long (a couple of PIE sessions), supplemented with video training. Currently, there are no published studies of the PIE Device in the home setting.

**Final Medicare Benefit Category Determination**

This application is being deferred for additional consideration in a subsequent biannual coding cycle. CMS needs additional time to make a benefit category determination for this device.

**Final Medicare Payment Determination**

No determination.

## Mobility+ - HCP221220WF9Y

### Topic/Issue

Request for Medicare payment determination for Mobility+.

### Summary of Applicant's Submission

Rockfield Medical Devices submitted a request to establish a new HCPCS Level II code to identify Mobility+ in the first biannual 2023 cycle. Mobility+ received the Food and Drug Administration's (FDA's) 510(k) clearance on October 27, 2022. Mobility+ is a portable, lightweight, non-electronic, disposable enteral feeding system intended to deliver commercially available liquid nutrition formula to a patient using a standard feeding tube (or extension tube) with an ENFit connector. Mobility+ can be used in a clinical or home care setting, in patients aged two and older. Mobility+ has an internal elastomeric pouch, filled by the user with formula, that consistently deflates once feeding begins. The deflation of the elastomeric pouch generates a constant, low-pressure force that pushes the formula from the pouch through the supplied tubing set ("Giving Set") to an already implanted feeding tube. The System is self-contained, portable and does not require an external pump, nor a power source, nor an IV pole/clamp which are common among other enteral feeding systems. Mobility+ is designed to provide the patient and caregiver improved mobility, discretion, and ease of use. The Mobility+ Feeding pouch, an elastomeric pump, operates silently, in comparison to the noise generated by many of the current pumps on the market. According to the applicant, existing pump noises can be disruptive not only during the day but also during sleeping hours for patients that are night feeding. According to the applicant, Mobility+ offers the simplicity of a gravity-fed system without the requirements of being sedentary and tethered to an IV pole while feeding. Mobility+ brings mobility and discretion to all patient populations whether gravity/bolus fed or infusion pump fed.

### CMS HCPCS Final Coding Decision

On August 23, 2023, CMS published the decision to establish a new HCPCS Level II code B4148, "Enteral feeding supply kit; elastomeric control fed, per day, includes but not limited to feeding/flushing syringe, administration set tubing, dressings, tape" to describe Mobility+, effective October 1, 2023.

### Medicare Benefit Category Determination

CMS determined that Mobility+ is a Prosthetic Device and published that determination on August 23, 2023.

### 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. As a result, the preliminary pricing methodology for new HCPCS Level II code B4148 is to use the existing

fee schedule amounts for comparable items described by HCPCS Level II code B4035 ("Enteral feeding supply kit; pump fed, per day, includes but not limited to feeding/flushing syringe, administration set tubing, dressings, tape"), with an additional amount added to account for the elastomeric technology that allows for infusion of the nutrients without the aid of separate equipment (infusion pump or IV pole).

CMS has compared two HCPCS Level II codes to Mobility+: B4036 ("Enteral feeding supply kit; gravity fed, per day, includes but not limited to feeding/flushing syringe, administration set tubing, dressings, tape") and B4035, as shown in the below comparability table. Mobility+, B4035, and B4036 are all comparable with respect to physical components, function and intended use, and with respect to numerous additional attributes and features. We have concluded that Mobility+ is more comparable to B4035 than B4036 due to greater portability and the continuous feeding functionality.

| | **Mobility+** | **B4035** | **B4036** |
|---|---|---|---|
| **Physical Components** | Feeding pouch, filling set, giving set, EnFit connector, extension set, and additional supplies (gauze, tape, dressings, etc.)<br><br>The feeding pouch can hold up to 500ml of feed | Feeding pouch, filling set, giving set, EnFit connector, extension set, and additional supplies (gauze, tape, dressings, etc.)<br><br>The catheter tip or oral syringe can hold up to 1200 ml of feed | Feeding pouch, filling set, giving set, EnFit connector, extension set, and additional supplies (gauze, tape, dressings, etc.)<br><br>The catheter tip or oral syringe can hold up to 600 ml of feed |
| **Mechanical Components** | Feeding pouch is made using elastomeric material which creates a force to administer the nutrition. Multiple extension sets (tubing) of different lengths are provided to allow for different rates of infusion. | Poly vinyl chloride (PVC) pouch (uses separate pump to control rate of infusion) | Poly vinyl chloride (PVC) pouch (uses gravitational force to administer nutrition without controlling rate of infusion) |
| **Electrical Components** | NA | NA | NA |
| **Function and Intended Use** | Function: Provide nutritional content to patients unable to eat or drink in a controlled and sterile fashion<br><br>Intended Use: To treat tube fed patients with swallowing difficulties such as Gastrointestinal dysfunction | Function: Provide nutritional content to patients unable to eat or drink in a controlled and sterile fashion<br><br>Intended Use: To treat tube fed patients with swallowing difficulties such as Gastrointestinal dysfunction | Function: Provide nutritional content to patients unable to eat or drink in a controlled and sterile fashion<br><br>Intended Use: To treat tube fed patients with swallowing difficulties such as Gastrointestinal dysfunction |

| | | | |
|---|---|---|---|
| **Additional Aspects and Features** | Does not require separate equipment. | Requires separate equipment (pump to control rate of infusion) | Requires separate equipment (IV pole) |
| | Very Portable | Less portable (some pumps can be carried in backpacks) | Least portable (IV pole with wheels) |
| | Continuous feeding | Can be continuous, dose, or bulbus feeding | Non-continuous feeding |
| | Disposable feeding set | Disposable feeding set | Disposable feeding set |
| | No power source/ electricity | Battery power source | No power source/ electricity |

As indicated above, the preliminary payment determination is to use the pricing for code B4035 and an additional amount to account for the ability of the Mobility+ supplies to administer the nutrients without the aid of either an infusion pump or IV pole. We believe the added cost of the elastomeric technology can be accounted for by the daily payment rate for a durable infusion pump, HCPCS Level II code B9002 ("Enteral nutrition infusion pump, any type"), which is computed by dividing the purchase fee schedule amount for a new infusion pump by the number of days in the five-year life of the pump (1,826). We believe the type of infusion provided by the Mobility+ modality is more comparable to the type of infusion provided by the infusion pump modality rather than gravity drip modality.

Payment for the daily supplies described by HCPCS Level II code B4148 would be established using the daily fee schedule amounts for HCPCS Level II code B4035 plus the daily fee schedule payment for a new infusion pump (HCPCS Level II code B9002NU). HCPCS modifier NU is a pricing modifier used to describe "new equipment." The average 2023 non-rural fee schedule amount for code B4148 would be approximately $8.72 and the average 2023 rural fee schedule amount for code B4148 would be approximately $11.21.

Pricing Indicator = 39

**Summary of Public Feedback**

Rockfield Medical Devices agreed that HCPCS Level II code B4035, "Enteral feeding supply kit; pump fed, per day, includes but not limited to feeding/flushing syringe, administration set tubing, dressings, tape" in combination with HCPCS Level II code B9002NU, "Enteral nutrition infusion pump, any type" are the appropriate codes to use in establishing the payment determination for Mobility+. However, they requested that CMS also add an amount for maintenance and servicing costs by including the fee schedule amount for HCPCS Level II code B9002 with the HCPCS modifier MS ("Six month maintenance and servicing fee for reasonable and necessary parts and labor which are not covered under any manufacturer or supplier warranty").

**Final Medicare Payment Determination**

We appreciate the public comments provided in response to CMS's published preliminary determination. However, the Mobility+ system is a self-contained, portable disposable enteral feeding system for daily use. The application describes Mobility+ as packaged individually (1 day supply) for single patient use in a 24-hour period once filled with liquid nutrition. Each package includes one Mobility+ feeding pouch, filling tubing, and giving tubing. It is distributed in 30 packages in a box. Therefore, the item does not require maintenance and servicing for reasonable and necessary parts and labor. As a result, we do not agree with adding an amount for maintenance and servicing costs using a fee schedule amount for a HCPCS Level II code with a MS modifier because maintenance and servicing of the item is not required for this portable disposable item for daily use.

We are finalizing our preliminary payment determination to use the pricing for code B4035 and an additional amount to account for the ability of the Mobility+ supplies to administer the nutrients using elastomeric technology (i.e., without the aid of either an infusion pump or IV pole). The 2024 average fee schedule amounts in the continental United States for B4035 are $6.37 (non-rural) and $10.85 (rural). The added cost of the elastomeric technology can be accounted for by the daily payment rate for a durable infusion pump, HCPCS Level II code B9002 ("Enteral nutrition infusion pump, any type"), which is computed by dividing the purchase fee schedule amount for a new infusion pump by the number of days in the five-year life of the pump (1,826). The 2024 average fee schedule amounts in the continental United States for a new B9002 infusion pump are $ 745.50 (non-rural) and $1,182.39 (rural) which when divided by 1,826 results in daily rates of $0.41 (non-rural) and $0.65 (rural).

Payment for the daily supplies described by HCPCS Level II code B4148 is established using the daily fee schedule amounts for HCPCS Level II code B4035 plus the daily fee schedule payment for a new infusion pump (HCPCS Level II code B9002NU). The average 2024 non-rural fee schedule amount for code B4148 would be approximately $6.78 ($6.37 + $0.41). The average 2024 rural fee schedule amount for code B4148 would be approximately $11.50 ($10.85 + $0.65).

Please note that the 2024 fee schedule amount is slightly lower than the 2023 fee schedule amount. On December 29, 2022, the Consolidated Appropriations Act (CAA), 2023 was signed into law. In accordance with the CAA during the COVID-19 public health emergency and until it ended on May 11, 2023, fee schedule amounts for items and services furnished in non-rural contiguous non-competitive bidding areas (CBAs) were based on a blend of 75 percent of the adjusted fee schedule amounts and 25 percent of the unadjusted fee schedule amounts for claims with dates of service for the remainder of the COVID-19 public health emergency. Therefore, beginning January 1, 2024, the fee schedule amounts for items and services furnished in non-rural contiguous non-CBAs is based on 100 percent of the fee schedule amounts adjusted in accordance with 42 CFR 414.210(g). The fully adjusted fee schedule amounts result in a decrease for CY 2024 DMEPOS fee schedule amounts that are calculated under this method including the fee schedule amounts for codes B4035 and B9002NU incorporated into the payment amount for new code B4148. Additional details are available in the Home Health Prospective Payment System final rule (CMS-1780-F) published on November 13, 2023 in the Federal Register which is available at https://www.cms.gov/medicare/payment/fee-schedules/dmepos-fee-schedule/dmepos-laws-regulations.
Pricing Indicator = 39

## ONTAK® - HCP230702AUMJK

### Topic/Issue

Request to delete an existing HCPCS Level II code J9160, “Injection, denileukin diftitox, 300 micrograms”.

### Summary of Applicant's Submission

Citius Pharmaceuticals, Inc. submitted a request to delete an existing HCPCS Level II code J9160, “Injection, denileukin diftitox, 300 micrograms”, which identifies ONTAK® (denileukin diftitox). ONTAK® was approved by the Food and Drug Administration (FDA) under the Biologics License Application (BLA) pathway on October 15, 2008. This application requests the deletion of an existing HCPCS Level II code that is no longer used. J9160 is no longer used because the item that it previously described was withdrawn from the U.S. market in 2014 and has not been marketed or available in the United States for nearly ten years.

### CMS Final HCPCS Coding Decision

CMS published a final determination for this application during our third quarterly (Q3) 2023 HCPCS coding cycle for drugs and biological products on October 18, 2023 to discontinue existing HCPCS Level II code J9160, “Injection, denileukin diftitox, 300 micrograms” effective January 1, 2024. Consistent with our usual practice for public requests to discontinue a code, we welcome information from other insurers who are currently paying for this product.

### Summary of Public Feedback

No verbal or written comments were provided. Therefore, we are not making any changes to our published final determination for this application.

## Traditional Healing Services - HCP22082337YAR

### Topic/Issue

Request to establish a new HCPCS Level II code to identify traditional healing services.

Applicant's suggested language: XXXXX, "Traditional healing services"

### Summary of Applicant's Submission

Blue Cross Blue Shield of Minnesota, doing business as Blue Plus (serving the Medicaid and Dual eligible populations in Minnesota), submitted a request to establish a new HCPCS Level II code to identify traditional healing services. According to the applicant, this new code will be used in Minnesota for Tribal Members to receive and bill the health plan for traditional healing services. According to the applicant, this code will be used initially for programs including Medicaid and dual-eligible members. Types of services that would be included in this code would include but not be limited to smudging, storytelling/healing circles, or sweat lodges and would expand to other traditional healing services in the future. According to the applicant, there are no codes already in place that fit this description.

### CMS Preliminary HCPCS Coding Recommendation

CMS welcomes public comments from Tribal members, State Medicaid agencies, payers, and other interested parties regarding the two considerations described below:

1. Should traditional healing services be included in the HCPCS Level II code set for electronic claims processing requirements according to the current transaction standards of the Health Insurance Portability and Accountability Act (HIPAA)?

   In 2000, the HCPCS Level II codes were established by CMS regulations to implement the HIPAA requirement for a standardized coding system to describe and identify health care, equipment, and supplies that are not identified by the HCPCS Level I, Current Procedural Terminology (CPT®) codes in electronic transactions. Most claims are submitted electronically using HCPCS codes to insurers using various bill types, such as an 837P bill type. This means that a traditional healing service, when covered and paid, would most likely be electronically submitted to a payer, such as Blue Cross Blue Shield of Minnesota, using a standardized claim form.

   CMS also welcomes comments discussing whether it may be more appropriate for traditional healing services to not be described by a HCPCS code, but rather for services to continue to engage with each payer directly in an approach that is more tailored for all involved.

2. How general should the suggested language be for a HCPCS Level II code?

   Traditional healing services are recognized by the Indian Healthcare Improvement Act, but there is no statutory definition for traditional healing services. If CMS was to create a HCPCS Level II code, CMS welcomes comments about the code descriptor language. Is the suggested code description of "Traditional healing services" too broad? Should CMS consider developing tiers of codes? For instance, CMS might

designate one code as “Traditional healing services, tier 1” and another code as “Traditional healing services, tier 2”. Payers could then indicate with billing instructions which code is appropriate for a particular traditional healing service that is covered and payable by the payer.

**Summary of Public Feedback**

The comment during the public meeting and from the Tribal Technical Advisory Group (TTAG) consultation, which was held on June 14th, 2023, resulted in varied responses to our questions in the preliminary recommendation. In general, all commenters emphasized the need to consider the diverse healing practices amongst the 574 federally-recognized tribes and many more state-recognized tribes. Many commenters agreed that one broad code describing “traditional healing services” is sufficient, while other commenters suggested the need to more closely consider multiple codes for these services. Some commenters also stated that no code is needed at all.

**CMS Final HCPCS Coding Decision**

Based on the information provided in the application and after consideration of the comments we received from the first biannual public meeting of 2023 and from the CMS Tribal Technical Advisory Group (TTAG) consultations held on June 14, 2023 and January 10, 2024, CMS is finalizing the decision to:

Establish a new HCPCS Level II code H0051, “Traditional healing service”

## Intermittent Urinary Catheters - HCP220701G0DRV, HCP220701Q1RK8, and HCP220701EYPYU

### Topic/Issue

CMS has received several applications to expand the group of current HCPCS Level II codes that describes intermittent catheters. Of note, in our final HCPCS coding decisions for the B2 2022 coding cycle for non-drugs and non-biological items and services, we stated that we want to understand the clinical support for the distinction among intermittent urinary catheters before we announce a final coding decision. For instance, some of the public comments we received through the B2 2022 HCPCS Public Meeting suggested that particular devices are related to decreasing morbidity and mortality, which suggests possible clinical improvement. However, we noted that we are still looking to learn more about the evidence base to support such claims.

We are continuing to examine the evidence base for potentially expanding the group of HCPCS Level II codes that describes intermittent catheters, and intend to address this further at an upcoming biannual coding cycle in 2024.

## 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.