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

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

## First Biannual (B1), 2024 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' First Biannual 2024 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 October 1, 2024, unless otherwise indicated.

The HCPCS Level II coding decisions below will also be included in the October 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.

# Table of Contents

Final Coding, Benefit Category, and Payment Determinations from the HCPCS Level II Virtual Public Meeting on May 28, 2024 to May 30, 2024.

**Intermittent Urinary Catheters - HCP220701G0DRV, HCP220701Q1RK8, and HCP220701EYPYU**

**Topic/Issue**

Request to discontinue three existing HCPCS Level II codes A4351, "Intermittent urinary catheter; straight tip, with or without coating (teflon, silicone, silicone elastomer, or hydrophilic, etc.), each," A4352, "Intermittent urinary catheter; coude (curved) tip, with or without coating (teflon, silicone, silicone elastomeric, or hydrophilic, etc.), each," and A4353," Intermittent urinary catheter, with insertion supplies" and establish nineteen new codes.

Applicant's suggested language:

1. AXXXX, "Intermittent urinary catheter; straight tip, without coating, each"

2. AXXXX, "Intermittent urinary catheter; straight tip, with pre-lubricated gel coating, without protective elements, each"

3. AXXXX "Intermittent urinary catheter; straight tip, with pre-lubricated gel coating, with protective elements (e.g., gripper, partial sleeve, full length sleeve, etc.), each"

4. AXXXX, "Intermittent urinary catheter; straight tip, with manually activated hydrophilic coating, without protective elements, each"

5. AXXXX, "Intermittent urinary catheter; straight tip, with manually activated hydrophilic coating, with protective elements (e.g., gripper, partial sleeve, full length sleeve, etc.), each"

6. AXXXX, "Intermittent urinary catheter; straight tip, with pre-activated hydrophilic coating, without protective elements, each"

7. AXXXX, "Intermittent urinary catheter; straight tip, with pre-activated hydrophilic coating, with protective elements (e.g., gripper, partial sleeve, full length sleeve, etc.), each"

8. AXXXX, "Intermittent urinary catheter; coude (curved) tip (e.g. fixed, flexible, olive, ball, etc.), without coating, each"

9. AXXXX, "Intermittent urinary catheter; coude (curved) tip (e.g. fixed, flexible, olive, ball, etc.), with pre-lubricated gel coating, without protective elements, each"

10. AXXXX, "Intermittent urinary catheter; coude (curved) tip (e.g. fixed, flexible, olive, ball, etc.), with pre-lubricated gel coating, with protective elements (e.g. gripper, partial sleeve, full length sleeve, etc.), each"

11. AXXXX, "Intermittent urinary catheter; coude (curved) tip (e.g. fixed, flexible, olive, ball, etc.), with manually activated hydrophilic coating, without protective elements, each"

12. AXXXX, “Intermittent urinary catheter; coude (curved) tip (e.g. fixed, flexible, olive, ball, etc.), with manually activated hydrophilic coating, with protective elements (e.g. gripper, partial sleeve, full length sleeve, etc.), each”

13. AXXXX, “Intermittent urinary catheter; coude (curved) tip (e.g. fixed, flexible, olive, ball, etc.), with pre-activated hydrophilic coating, without protective elements, each”

14. AXXXX, “Intermittent urinary catheter; coude (curved) tip (e.g. fixed, flexible, olive, ball, etc.), with pre-activated hydrophilic coating, with protective elements (e.g. gripper, partial sleeve, full length sleeve, etc.), each”

15. AXXXX, “Intermittent urinary catheter with insertion supplies, straight or coude tip, includes catheter without coating, each”

16. AXXXX, “Intermittent urinary catheter with insertion supplies, straight or coude tip, includes catheter with pre-lubricated gel coating, each”

17. AXXXX, “Intermittent urinary catheter with insertion supplies, straight or coude tip, includes catheter with manually activated hydrophilic coating, each”

18. AXXXX, “Intermittent urinary catheter with insertion supplies, straight or coude tip, includes catheter with pre-activated hydrophilic coating, each”

19. AXXXX, “Sterile no-touch catheter system, each”

**Summary of Applicant's Submission**

The American Association for Homecare and its incontinence care manufacturer members, Coloplast, Hollister, and Wellspect submitted a request to discontinue existing HCPCS Level II codes A4351, A4352, and A4353. They requested nineteen new HCPCS Level II codes are to further distinguish the functionalities of straight tip intermittent urinary catheters, curved tip intermittent urinary catheters, and insertion supplies. The wide variation in functionality between products currently classified under HCPCS Level II codes A4351 A4352, and A4353 creates a lack of transparency, which may result in patients receiving the least expensive intermittent urinary catheter or supply. However, this catheter or supply may not meet the patient’s clinical needs to consistently perform successful self-catheterization. Lastly, because HCPCS Level II codes A4351, A4352, and A4353 do not accurately reflect the different features and functionalities of various intermittent urinary catheters, payors other than the Medicare program have been forced to implement a variety of coding “workarounds” in order to better identify and separately reimburse for catheters with different features. This conflicts with the federal requirement and purpose of the uniform code set that CMS has been charged with overseeing for the benefit of all payors, not just the Medicare program. The nineteen recommended HCPCS Level II codes for straight tip, curved tip, and supplies for urinary catheters identify differences in catheters that are not coated; require a coating to be separately provided and manually applied; pre-coated catheters that need to be manually activated; ready-to-use catheters that include hydrophilic technology that reduce the risk of urethral trauma; and catheters that have protective elements, which helps aid with insertion into the urethra.

**CMS Preliminary HCPCS Coding Recommendation**

CMS has been extensively evaluating this application. To inform our deliberation, CMS contracted with the Health Federally Funded Research and Development Center (FFRDC), operated by MITRE, to conduct an environmental scan and inform our clinical understanding of the use of intermittent urinary catheters. MITRE provided a report to CMS with their findings. The report represents MITRE's expertise and information available to MITRE (for instance, page 24 of the report may not reflect more recent experience) and should not be construed as CMS coding policy.

The report provides a number of findings and observations. Among the most salient to our preliminary HCPCS coding recommendation are the following:

- There is good evidence that, for some patients, hydrophilic catheters may reduce the incidence of a urinary tract infection (UTI).
- …for most of the potential codes considered [from the applicant's request] there is a lack of evidence to support performance differentiation when compared to current catheter codes.
- Coding is not a barrier to writing an accurate prescription or for revising a prescription for urinary catheters. However, suppliers do have latitude in what is supplied unless the prescribing physician includes a "dispense as written" notation on the written order. Physicians hesitate to take this step since doing may result in increased costs for patients who may not have sufficient insurance to fully cover the cost of the ordered supplies.
- From its systematic review, MITRE concluded that the evidence base is insufficient to determine that all coatings impact health outcomes, but there was evidence supporting that hydrophilic coating may influence health outcomes. Specifically, it identified studies demonstrating that catheters with hydrophilic coating can reduce the risk of UTIs and hematuria. MITRE could not identify studies that differentiated between hydrophilic coating catheter types (i.e., pre-activated, manually activated) or discern the impact of hydrophilic coating on quality-of-life outcomes.
- Further, MITRE could not identify any studies that assessed whether catheter shape, tip configuration (i.e., straight, coudé), or firmness led to differences in patient outcomes. While MITRE identified studies that assessed whether protective elements (i.e., introducer tip, no-touch sleeve) and re-use (vs. single use) catheters influenced health outcomes, the evidence was inconclusive. MITRE also examined whether patient characteristics led to differences in health outcomes, but it could not identify studies that assessed differences by patient age, sex, disease, or condition, or whether administration assistance was present.

CMS notes that MITRE did not observe significant workarounds by payers in regard to extensive use of modifiers to differentiate what types of catheters were covered and paid, in a way that was otherwise distinct from HCPCS Level II codes. CMS also notes that MITRE identified circumstances in which a history of UTIs or infection control (e.g., sterile techniques) may guide payer coverage, including prior authorization and step therapy.

Considering the information presented by MITRE and our review of the application, CMS believes that clinical evidence and current payer policies would support HCPCS Level II codes to identify hydrophilic coatings, particularly as there is evidence that, for some patients, hydrophilic catheters may reduce the incidence of UTIs. As such, we propose to:

1. Establish a new HCPCS Level II code AXXXX, “Intermittent urinary catheter; straight tip, with or without coating (teflon, silicone, silicone elastomer, etc.), each”

2. Establish a new HCPCS Level II code AXXXX, “Intermittent urinary catheter; coude (curved) tip, with or without coating (teflon, silicone, silicone elastomeric, etc.), each”

3. Establish a new HCPCS Level II code AXXXX, “Intermittent urinary catheter; straight tip, hydrophilic coating, each”

4. Establish a new HCPCS Level II code AXXXX, “Intermittent urinary catheter; coude (curved) tip, hydrophilic coating, each”

5. Establish a new HCPCS Level II code AXXXX, Intermittent urinary catheter; hydrophilic coating, with insertion supplies”

6. Discontinue existing HCPCS Level II code A4351, “Intermittent urinary catheter; straight tip, with or without coating (teflon, silicone, silicone elastomer, or hydrophilic, etc.), each”

7. Discontinue existing HCPCS Level II code A4352, “Intermittent urinary catheter; coude (curved) tip, with or without coating (teflon, silicone, silicone elastomeric, or hydrophilic, etc.), each”

We do not see a claims processing need to discontinue or modify existing HCPCS Level II code A4353, “Intermittent urinary catheter, with insertion supplies.”

CMS also recognizes that adoption of these codes would likely necessitate updating long-established coverage policies and/or payment instructions across nearly every payer. As such, we believe it would be prudent to implement these coding changes effective on January 1, 2026, to allow for a seamless transition. We welcome comment on this timeline.

Considering the likelihood for significant comments on this recommendation and the considerable information presented in the MITRE report, CMS is likely to issue a final determination at a date later than our anticipated July/August 2024 timeframe for this cycle.

**Preliminary Medicare Benefit Category Determination**

The prior established benefit category determination for HCPCS Level II code A4351 applies to new HCPCS Level II code AXXXX, “Intermittent urinary catheter; straight tip, with or without coating (teflon, silicone, silicone elastomer, etc.), each”, and to new HCPCS Level II code AXXXX, “Intermittent urinary catheter; straight tip, hydrophilic coating, each.”

The prior established benefit category determination for HCPCS Level II code A4352 applies to new HCPCS Level II code AXXXX, “Intermittent urinary catheter; coude (curved) tip, with or without coating (teflon, silicone, silicone elastomeric, etc.), each” and to new HCPCS Level II code AXXXX, “Intermittent urinary catheter; coude (curved) tip, hydrophilic coating, each.”

The prior established benefit category determination for HCPCS Level II code A4353 applies to new HCPCS Level II code AXXXX, "Intermittent urinary catheter; hydrophilic coating, with insertion supplies."

**Preliminary Medicare Payment Determination**

Our regulations at 42 CFR 414.236 require continuity of pricing when HCPCS Level II codes are divided or combined. Specifically, § 414.236(a) holds that if a new HCPCS Level II code is added, CMS or contractors make every effort to determine whether the item and service has a fee schedule pricing history. If there is a fee schedule pricing history, the previous fee schedule amounts for the old code(s) are mapped to the new code(s) to ensure continuity of pricing.

Additionally, § 414.236(b) specifies that when the code for an item is divided into several codes for the components of that item, the total of the separate fee schedule amounts established for the components must not be higher than the fee schedule amount for the original item. When there is a single code that describes two or more distinct complete items (for example, two different but related or similar items), and separate codes are subsequently established for each item, the fee schedule amounts that applied to the single code continue to apply to each of the items described by the new codes.

In the Second Biannual 2022 HCPCS Level II coding cycle public meeting, a speaker for this application confirmed their understanding of these regulations and said that it was not their objective to modify the payment levels for these items.

We will be following our continuity of pricing regulations at § 414.236 for this preliminary payment determination as follows:

1. New HCPCS Level II code AXXXX, "Intermittent urinary catheter; straight tip, with or without coating (teflon, silicone, silicone elastomer, etc.), each" will have a fee that is mapped from existing HCPCS Level II code A4351.

   The payment rules and pricing associated with HCPCS Level II code A4351 apply to new HCPCS Level II code AXXXX, if covered. The average 2024 fee schedule for HCPCS Level II code A4351 is $2.30. 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 = 37

2. New HCPCS Level II code AXXXX, "Intermittent urinary catheter; coude (curved) tip, with or without coating (teflon, silicone, silicone elastomeric, etc.), each" will have a fee that is mapped from existing HCPCS Level II code A4352.

   The payment rules and pricing associated with HCPCS Level II code A4352 apply to new HCPCS Level II code AXXXX, if covered. The average 2024 fee schedule for HCPCS Level II code A4352 is $8.48. 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 = 37

3. New HCPCS Level II code AXXXX, "Intermittent urinary catheter; straight tip, hydrophilic coating, each" will have a fee that is mapped from existing HCPCS Level II code A4351.

   The payment rules and pricing associated with HCPCS Level II code A4351 apply to new HCPCS Level II code AXXXX, if covered. The average 2024 fee schedule for HCPCS Level II code A4351 is $2.30. 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 = 37

4. New HCPCS Level II code AXXXX, "Intermittent urinary catheter; coude (curved) tip, hydrophilic coating, each" will have a fee that is mapped from existing HCPCS Level II code A4352.

   The payment rules and pricing associated with HCPCS Level II code A4352 apply to new HCPCS Level II code AXXXX, if covered. The average 2024 fee schedule for A4352 is $8.48. 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 = 37

5. New HCPCS Level II code AXXXX, "Intermittent urinary catheter; hydrophilic coating, with insertion supplies" will have a fee that is mapped from existing HCPCS Level II code A4353.

   The payment rules and pricing associated with HCPCS Level II code A4353 apply to new HCPCS Level II code AXXXX, if covered. The average 2024 fee schedule for A4353 is $9.59. 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 = 37

**Summary of Public Feedback**

The American Association for Homecare, the members of the Independence Through Enhancement of Medicare and Medicaid (ITEM) Coalition and other organizations agreed with CMS' preliminary recommendation to discontinue two existing HCPCS Level II codes A4351 and A4352 and establish five new HCPCS Level II codes to recognize hydrophilic intermittent catheters. However, many speakers requested that CMS further clarify the code descriptors. Some speakers mentioned that two of the new HCPCS Level II codes

should be revised to specify that they do not include hydrophilic catheters (e.g., non-hydrophilic). The descriptor change request is because some clinicians and suppliers may think of hydrophilic catheters as being "coated." Other speakers mentioned that differentiating between hydrophilic and non-hydrophilic catheters may be appropriate so long as the hydrophilic categories are understood to include pre-lubricated, gel coated, and other ready-to-use catheters. According to a speaker, the MITRE report notes, expressly on page 23, that "the term pre-lubricated includes hydrophilic catheters." According to another speaker, pre-lubricated catheters cause less trauma or stricture formation of the urethra as they slide through the tissue with less resistance. It protects and expands patients' compliance, flexibility selecting catheters, improved patient care and decreased the risk of catheter-associated urinary tract infections. One speaker acknowledged that clinical literature suggests that urinary tract infection reduction benefits provided by hydrophilic catheters are either matched or exceeded by pre-lubricated catheters. As such, these speakers and written comments from patients recommend that CMS change the preliminary code language from hydrophilic to pre-lubricated. In addition, one speaker suggested that based on current Local Coding Determination language, CMS should revise the preliminary coding descriptors to identify intermittent urinary catheters, from "each" to include "each catheterization."

Another speaker commented that the new HCPCS Level II codes will allow payors to clearly identify the use of intermittent catheters, allow for collection of data, enable researchers to better link patient outcomes to specific types of catheters, and build evidence base for coverage decisions in the future. The speaker mentioned that there are different variations of pre-lubricated catheters, both gel-based and hydrophilic, ready-to-use and manually activated. Ideally, it would be preferred to have both hydrophilic and pre-lubricated catheters identified by different codes to know which catheters patients are using.

Another speaker recommended that instead of discontinuing the existing HCPCS Level II codes A4351 and A4352, to revise those existing HCPCS Level II codes to remove "with" to instead read, "Intermittent urinary catheter; straight tip, without coating, each" and "Intermittent urinary catheter; coude (curved) tip, without coating, each." Then establish two new HCPCS Level II codes AXXXX, "Intermittent urinary catheter; straight tip with coating (teflon, silicone, silicone elastomer, or hydrophilic, etc.), each and AXXXX, "Intermittent urinary catheter; coude (curved) tip, with coating (teflon, silicone, silicone elastomer, or hydrophilic, etc.), each." According to the speaker, this approach effectively addresses concerns related to Medicare beneficiary access, prescription renewals or updates, and ensures beneficiary access to essential medical devices. This will also enable commercial plans, who do not always update policies in line with CMS, to continue to be serviced with A4351 and A4352 as prescribed today.

Another speaker disagreed with CMS' preliminary recommendation to establish new HCPCS Level II codes. According to the speaker, the existing HCPCS Level II codes A4351, A4352 and A4353, are sufficient to describe these supplies and that the applicant has not met the criteria established by the HCPCS Level II review team for creating new HCPCS Level II codes to describe the intermittent urinary catheters. The speaker stated, there is no program operating need to discontinue the existing HCPCS Level II codes A4351 and A4352. In addition, the speaker pointed to the MITRE report cited in the preliminary decision that "further specificity through coding may not provide benefits in claims processing because costs are typically equivalent across a size range." Secondly, based on the organization's review of the current, peer-reviewed clinical literature, they are unaware of any studies that concluded that the urinary catheters identified in the CMS preliminary coding

recommendation perform significantly different function or operate differently when compared to the catheters currently billed using the existing HCPCS Level II codes A4351, A4352, and A4353; the MITRE report supports their conclusion. The speaker made multiple references to the MITRE report indicating that there is no need for new HCPCS Level II codes.

Speakers recommended that CMS finalize its preliminary coding decisions with the clarification detailed above in the current coding cycle and allow time for CMS and the Medicare Administrative Contractors to update the Local Coverage Determination, Policy Article, and other Medicare policy documents, other payer policies, clinicians, and suppliers to be educated on the new HCPCS Level II codes and related policies by July 1, 2025. It was mentioned that CMS should be clear in the final decision that creating new codes is not to be construed as an authorization to restrict current coverage policies or to adopt step therapy policies or additional barriers to qualify for a current A4351 and A4352 intermittent urinary catheter with hydrophilic coating. Likewise, as suggested by some speakers, if the proposed recommendation goes into effect in January 2026, it means that all new prescriptions will have to be activated simultaneously with reverification of Medicare beneficiary status. This could create significant administrative burden for durable medical equipment suppliers and healthcare providers, and may potentially cause delays in patient care as they navigate new requirements. CMS' confirmation that there will be no cross-walking of codes will require hundreds of submissions to the Medicare Contractor for Pricing, Data Analysis, and Coding (PDAC) for assignment to the new codes, resulting in extended lead times for completion. Again, speakers asserted that the majority of Medicare beneficiaries will require a new prescription, which may pose challenges for those unable to access their healthcare provider for a new prescription. Delays in obtaining new prescriptions may lead to interruptions in patient care and impact the ability to receive supplies in a timely manner. The proposed changes may restrict the Medicare beneficiary's ability to explore and try new products that could potentially address their healthcare needs.

Speakers recognized that current Medicare payment levels will be cross-walked to the newly proposed codes, which will place no greater burden on patient cost-sharing. Further, a speaker confirmed their agreement with the preliminary pricing determination. Speakers indicated that increased coverage and access through the implementation of additional HCPCS codes could alleviate financial burdens and reduce out-of-pocket expenses.

**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. Revise existing HCPCS Level II code A4351, "Intermittent urinary catheter; straight tip, with or without coating (teflon, silicone, silicone elastomer, or hydrophilic, etc.), each" to instead read "Intermittent urinary catheter; straight tip, with or without coating (teflon, silicone, or silicone elastomer, etc.), each"

2. Revise existing HCPCS Level II code A4352, "Intermittent urinary catheter; coude (curved) tip, with or without coating (teflon, silicone, silicone elastomeric, or hydrophilic, etc.), each" to instead read "Intermittent urinary catheter; coude

(curved) tip, with or without coating (teflon, silicone, or silicone elastomeric, etc.), each"

3. Establish a new HCPCS Level II code A4295, "Intermittent urinary catheter; straight tip, hydrophilic coating, each"

4. Establish a new HCPCS Level II code A4296, "Intermittent urinary catheter; coude (curved) tip, hydrophilic coating, each"

5. Establish a new HCPCS Level II code A4297, Intermittent urinary catheter; hydrophilic coating, with insertion supplies"

CMS acknowledges that revising the existing HCPCS Level II codes could reduce the administrative burden for durable medical equipment suppliers, in particular by aligning with multiple payers' coverage policies. However, establishing new and revising existing HCPCS Level II codes is not anticipated to impact the care for Medicare beneficiaries. As noted in the MITRE report, prescriptions are not typically written with a HCPCS Level II code, as thus we do not believe that changes in HCPCS Level II codes likely warrants a new prescription under current coverage determinations; suppliers should know what type(s) of catheters they are providing to each person and be able to submit claims accordingly. As such, CMS does not anticipate any issue related to Medicare beneficiary access to essential medical devices, prescription renewals, or updates.

Considering the information presented by MITRE and our review of the application, CMS believes that clinical evidence and current payer policies would support HCPCS Level II codes to identify hydrophilic coatings, particularly as there is evidence that, for some patients, hydrophilic catheters may reduce the incidence of UTIs. Also, hydrophilic catheter is a type of (not same as) pre-lubricated catheter having a polymer coating that binds water to the catheter to make it slippery. The hydrophilic coating on a catheter is intrinsic to the catheter product (i.e., you cannot wipe the coating off). CMS did not receive any clinical evidence to support the claim that urinary tract infection reduction benefits provided by hydrophilic catheters are either matched or exceeded by pre-lubricated catheters. Additionally, adding the word catheterization to each would not improve the code, as the code describes the device, not the act of inserting the catheter or catheterization.

CMS also recognizes that adoption of these codes would likely necessitate updating long-established coverage policies and/or payment instructions across nearly every payor. As such, we believe it would be prudent to implement these coding changes effective on January 1, 2026, to allow for a seamless transition.

**Final Medicare Benefit Category Determination**

Prosthetic Device.

**Final Medicare Payment Determination**

Based on the revisions indicated in the CMS final HCPCS coding decision, the final Medicare payment determination is as follows:

1. The payment rules and pricing associated with the existing HCPCS Level II code A4351 apply to this product, if covered.

The average 2024 fee schedule for HCPCS Level II code A4351 is $2.30. 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 = 37

2. The payment rules and pricing associated with the existing HCPCS Level II code A4352 apply to this product, if covered.

   The average 2024 fee schedule for A4352 is $8.48. 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 = 37

3. New HCPCS Level II code A4295, “Intermittent urinary catheter; straight tip, hydrophilic coating, each” will have a fee that is mapped from existing HCPCS Level II code A4351. The payment rules and pricing associated with HCPCS Level II code A4351 apply to new HCPCS Level II code A4295, if covered.

   The average 2024 fee schedule for HCPCS Level II code A4351 is $2.30. 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 = 37

4. New HCPCS Level II code A4296, “Intermittent urinary catheter; coude (curved) tip, hydrophilic coating, each” will have a fee that is mapped from existing HCPCS Level II code A4352. The payment rules and pricing associated with HCPCS Level II code A4352 apply to new HCPCS Level II code A4296, if covered.

   The average 2024 fee schedule for A4352 is $8.48. 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 = 37

5. New HCPCS Level II code A4297, Intermittent urinary catheter; hydrophilic coating, with insertion supplies” will have a fee that is mapped from existing HCPCS Level II code A4353.

   The payment rules and pricing associated with HCPCS Level II code A4353 apply to new HCPCS Level II code A4297, if covered. The average 2024 fee schedule for A4353 is $9.59. 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 = 37

## Lower Body Rehabilitation Kit - HCP231213W7UMD

### Topic/Issue

Request to establish a new HCPCS Level II code to identify Lower Body Rehabilitation Kit.

The applicant did not submit any suggested language.

### Summary of Applicant's Submission

PT Pro Shop submitted a request to establish a new HCPCS Level II code to identify Lower Body Rehabilitation Kit for lumbar, hip, and knee body regions. The Lower Body Rehabilitation Kit is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The Lower Body Kit is an all-in-one kit that includes a towel, 65 cm yoga ball, 8-loop stretch strap, foam roller, foam peanut, foam ball, 5-piece loop band set, 11-piece resistance tube set, and a set of 3 resistance bands. The equipment is necessary for provider prescribed rehabilitation and/or pre-habilitation of the lumbar, hip and knee regions. Existing codes describe individual items in the Lower Body Kit, but do not describe the kit as a whole.

### CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a program operating need for Medicare or other payers to establish a bundled, unique HCPCS Level II code to describe Lower Body Rehabilitation Kit. We welcome information from the applicant and other insurers who are currently paying for this kit to demonstrate a claims processing need for a unique HCPCS Level II code. The Lower Body Rehabilitation Kit consists of equipment that is considered to be exercise equipment. As such, existing HCPCS Level II code A9300, “Exercise equipment” describes the Lower Body Rehabilitation Kit.

### Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

There is not a benefit category under Medicare Part B for exercise equipment used in the home. The current Medicare policy and prior established benefit category determination for HCPCS Level II code A9300 apply to this item.

In addition, 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 Lower Body Rehabilitation Kit does not meet three of these conditions as follows:

> **Can withstand repeated use** – The Lower Body Rehabilitation Kit is a single-patient use item, as explained in the application. Also, as explained in the application, it is not intended to be rented. 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 3 years** – While the applicant has stated that the Lower Body Rehabilitation Kit has an expected lifetime of three years, it is unclear whether the entire kit is, in fact, durable especially given the inclusion of the towel in the kit.
>
> **Generally not useful to an individual in the absence of an illness or injury** – The Lower Body Rehabilitation Kit contains exercise equipment that can be useful to an individual in the absence of an illness or injury.

**Preliminary Medicare Payment Determination**

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

No Medicare payment. Pricing Indicator = 00

**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 and considering that no comments were received, CMS is finalizing its preliminary recommendation to assign:

Existing HCPCS Level II code A9300, "Exercise equipment" to describe the Lower Body Rehabilitation Kit.

The Lower Body Rehabilitation Kit consists of equipment that is considered to be exercise equipment. CMS has not identified a program operating need for Medicare or other payers to establish a bundled, unique HCPCS Level II code to describe Lower Body Rehabilitation Kit.

**Final Medicare Benefit Category Determination**

No Medicare DMEPOS benefit category.

**Final Medicare Payment Determination**

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

No Medicare payment. Pricing Indicator = 00

## Shoulder Rehabilitation Kit - HCP231213LDUD1

### Topic/Issue

Request to establish a new HCPCS Level II code to identify Shoulder Rehabilitation Kit.

The applicant did not submit any suggested language.

### Summary of Applicant's Submission

PT Pro Shop submitted a request to establish a new HCPCS Level II code to identify Shoulder Rehabilitation Kit. The Shoulder Rehabilitation Kit is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The Shoulder Kit is an all-in-one kit that includes a towel, door frame mounted shoulder pulley, 8-loop stretch strap, collapsible cane, 5-piece loop band set, 11-piece resistance tube set, and a set of 3 resistance bands. The equipment is necessary for doctor prescribed or nonprescribed rehabilitation and/or pre-habilitation of the shoulder region. Existing codes describe individual items in the Shoulder Kit, but do not describe the kit as a whole.

### CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a program operating need for Medicare or other payers to establish a bundled, new unique HCPCS Level II code to describe Shoulder Rehabilitation Kit. We welcome information from the applicant and other insurers who are currently paying for this kit to demonstrate a claims processing need for a unique HCPCS Level II code. The Shoulder Rehabilitation Kit consists of equipment that is considered to be exercise equipment. As such, existing HCPCS Level II code A9300, “Exercise equipment” describes the Shoulder Rehabilitation Kit.

### Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

There is not a benefit category under Medicare Part B for exercise equipment used in the home. The current Medicare policy and prior established benefit category determination for HCPCS Level II code A9300 apply to this item.

In addition, 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 Shoulder Rehabilitation Kit does not meet three of these conditions as follows:

**Can withstand repeated use** – The Shoulder Rehabilitation Kit is a single-patient use item, as explained in the application. Also, as explained in the application, it is not intended to be rented. 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 3 years** – While the applicant has stated that the Shoulder Rehabilitation Kit has an expected lifetime of three years, it is unclear whether the entire kit is, in fact, durable especially given the inclusion of the towel in the kit.

**Generally not useful to an individual in the absence of an illness or injury** – The Shoulder Rehabilitation Kit contains exercise equipment that can be useful to an individual in the absence of an illness or injury.

**Preliminary Medicare Payment Determination**

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

No Medicare payment. Pricing Indicator = 00

**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 and considering that no comments were received, CMS is finalizing its preliminary recommendation to assign:

Existing HCPCS Level II code A9300, "Exercise equipment" to describe the Shoulder Rehabilitation Kit.

The Shoulder Rehabilitation Kit consists of equipment that is considered to be exercise equipment. CMS has not identified a program operating need for Medicare or other payers to establish a bundled, unique HCPCS Level II code to describe Shoulder Rehabilitation Kit.

**Final Medicare Benefit Category Determination**

No Medicare DMEPOS benefit category.

**Final Medicare Payment Determination**

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

No Medicare payment. Pricing Indicator = 00

## Wrist Rehabilitation Kit - HCP231213NNX41

### Topic/Issue

Request to establish a new HCPCS Level II code to identify Wrist Rehabilitation Kit.

The applicant did not submit any suggested language.

### Summary of Applicant's Submission

PT Pro Shop submitted a request to establish a new HCPCS Level II code to identify Wrist Rehabilitation Kit. The Wrist Rehabilitation Kit is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The Wrist Kit is an all-in-one kit that includes a towel, bend and twist bar, finger extension with cuff, 6-piece grip strength set, and a 3-piece finger web set. The equipment is necessary for provider prescribed rehabilitation and/or pre-habilitation of the wrist region. Existing codes describe individual items in the Wrist Kit, but do not describe the kit as a whole.

### CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a program operating need for Medicare or other payers to establish a bundled, new unique HCPCS Level II code to describe Wrist Rehabilitation Kit. We welcome information from the applicant and other insurers who are currently paying for this kit to demonstrate a claims processing need for a unique HCPCS Level II code. The Wrist Rehabilitation Kit consists of equipment that is considered to be exercise equipment. As such, existing HCPCS Level II code A9300, “Exercise equipment” describes the Wrist Rehabilitation Kit.

### Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

There is not a benefit category under Medicare Part B for exercise equipment used in the home. The current Medicare policy and prior established benefit category determination for HCPCS Level II code A9300 apply to this item.

In addition, 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 Wrist Rehabilitation Kit does not meet three of these conditions as follows:

**Can withstand repeated use** – The Wrist Rehabilitation Kit is a single-patient use item, as explained in the application. Also, as explained in the application, it is not intended to be rented. 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 3 years** – While the applicant has stated that the Wrist Rehabilitation Kit has an expected lifetime of three years, it is unclear whether the entire kit is, in fact, durable especially given the inclusion of the towel in the kit.

**Generally not useful to an individual in the absence of an illness or injury** – The Wrist Rehabilitation Kit contains exercise equipment that can be useful to an individual in the absence of an illness or injury.

**Preliminary Medicare Payment Determination**

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

No Medicare payment. Pricing Indicator = 00

**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 and considering that no comments were received, CMS is finalizing its preliminary recommendation to assign:

Existing HCPCS Level II code A9300, "Exercise equipment" to describe the Wrist Rehabilitation Kit.

The Wrist Rehabilitation Kit consists of equipment that is considered to be exercise equipment. CMS has not identified a program operating need for Medicare or other payers to establish a bundled, unique HCPCS Level II code to describe Wrist Rehabilitation Kit.

**Final Medicare Benefit Category Determination**

No Medicare DMEPOS benefit category.

**Final Medicare Payment Determination**

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

No Medicare payment. Pricing Indicator = 00

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

### Topic/Issue

Request for Medicare payment determination for Dynamic Adjustable Elbow Extension/Flexion Device.

### Summary of Applicant's Submission

Dynasplint Systems, Inc. submitted a request to establish two new HCPCS modifiers to be used with HCPCS Level II code 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). HCPCS Level II code E1800 is an inadequate and confusing description. The short and long descriptors for HCPCS Level II code E1800 create the assumption that one device described by HCPCS Level II code E1800 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, HCPCS Level II code 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 (HCPCS Level II codes 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 HCPCS Final Coding Decision

On February 29, 2024, CMS published 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.

### Medicare Benefit Category Determination

CMS determined that the Dynasplint, Dynamic Adjustable Elbow Extension/Flexion Device is DME and published that determination on February 29, 2024.

**Preliminary Medicare Payment Determination**

For HCPCS Level II code 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 HCPCS Level II code 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 HCPCS Level II 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 the 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 HCPCS Level II codes E1803 and E1804 have a pricing history based on HCPCS Level II code E1800. When there is a single code that describes two or more distinct complete items (with HCPCS Level II code E1800, that would be flexion and extension), and separate codes are subsequently established for each item (HCPCS Level II code E1804 for flexion and HCPCS Level II code 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 HCPCS Level II 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 HCPCS Level II codes E1803 and E1804 is represented by the following formula: E1800*.5. Therefore the 2024 average capped rental fee schedule amount for both HCPCS Level II codes 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

**Summary of Public Feedback**

Dynasplint Systems disagreed with the preliminary payment determination, stating that the fee schedule for both new HCPCS Level II codes should be equal to, and not half of, the fee schedule for the original HCPCS Level II code E1800. The speaker agreed that new HCPCPS Level II codes E1803 and E1804 have an established fee on the DMEPOS fee schedule based on the fee schedule for HCPCS Level II E1800. They suggested that CMS apply the second sentence of § 414.236(b) when establishing payment: “When there is a single code that describes two or more distinct complete items (for example, two different but related or similar items), and separate codes are subsequently established for each item, the fee schedule amounts that applied to the single code continue to apply to each of the items described by the new codes.”

**Final Medicare Payment Determination**

Upon considering the speaker's input and reviewing our preliminary determination, we have concluded that we should apply the continuity of pricing regulations differently than was done for the preliminary determination. Both the Dynasplint elbow extension device (E1803) and the Dynasplint elbow flexion device (E1804) have been on the product classification list (PCL) of HCPCS Level II code E1800 and have been paid under the fee schedule for that code. Therefore, both devices have a pricing history based on HCPCS Level II code E1800. 42 CFR §414.236(a) holds that if there is a fee schedule pricing history, the previous fee schedule amounts for the old code(s) are mapped to the new code(s) to ensure continuity of pricing.

The final payment determination for new HCPCS Level II codes E1803 and E1804 is to establish the fee schedule amount using the existing (current) fee schedule amount for HCPCS Level II code E1800. Therefore the 2024 average capped rental fee schedule amount for both HCPCS Level II codes E1803 and E1804 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 revised HCPCS Level II code 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 HCPCS Level II code 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.

Pricing Indicator = 36

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

### Topic/Issue

Request for Medicare payment determination for Dynamic Adjustable Wrist Extension/Flexion Device.

### Summary of Applicant's Submission

Dynasplint Systems, Inc. submitted a request to establish two new HCPCS modifiers to be used with HCPCS Level II code 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). HCPCS Level II code E1805 is an inadequate and confusing description. The short and long descriptors for HCPCS Level II code E1805 create the assumption that one device described by HCPCS Level II code E1805 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, HCPCS Level II code 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 (HCPCS Level II codes 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 HCPCS Final Coding Decision

On February 29, 2024, CMS published 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.

### Medicare Benefit Category Determination

CMS determined that the Dynasplint, Dynamic Adjustable Wrist Extension/Flexion Device is DME and published that determination on February 29, 2024.

**Preliminary Medicare Payment Determination**

For HCPCS Level II code 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 HCPCS Level II code 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 HCPCS Level II 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 the 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 HCPCS Level II codes E1807 and E1808 have a pricing history based on HCPCS Level II code 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 (HCPCS Level II code E1808 for flexion and HCPCS Level II code E1807 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 HCPCS Level II 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 HCPCS Level II codes E1807 and E1808 is represented by the following formula: E1805*.5. Therefore the 2024 average capped rental fee schedule amount for both HCPCS Level II codes 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

**Summary of Public Feedback**

Dynasplint Systems disagreed with the preliminary payment determination, stating that the fee schedule for both new HCPCS Level II codes should be equal to, and not half of, the fee schedule for the original HCPCS Level II code E1805. The speaker agreed that new HCPCPS Level II codes E1807 and E1808 have an established fee on the DMEPOS fee schedule based on the fee schedule for HCPCS Level II E1805. They suggested that CMS apply the second sentence of § 414.236(b) when establishing payment: “When there is a single code that describes two or more distinct complete items (for example, two different but related or similar items), and separate codes are subsequently established for each item, the fee schedule amounts that applied to the single code continue to apply to each of the items described by the new codes.”

**Final Medicare Payment Determination**

Upon considering the speaker's input and reviewing our preliminary determination, we have concluded that we should apply the continuity of pricing regulations differently than was done for the preliminary determination. Both the Dynasplint wrist extension device (E1807) and the Dynasplint wrist flexion device (E1808) have been on the product classification list (PCL) of HCPCS Level II code E1805 and have been paid under the fee schedule for that code. Therefore, both devices have a pricing history based on HCPCS Level II code E1805. 42 CFR §414.236(a) holds that if there is a fee schedule pricing history, the previous fee schedule amounts for the old code(s) are mapped to the new code(s) to ensure continuity of pricing.

The final payment determination for new HCPCS Level II codes E1807 and E1808 is to establish the fee schedule amount using the existing (current) fee schedule amount for HCPCS Level II code E1805. Therefore the 2024 average capped rental fee schedule amount for both HCPCS Level II codes E1807 and E1808 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 revised HCPCS Level II code 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 HCPCS Level II code 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.

Pricing Indicator = 36

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

### Topic/Issue

Request for Medicare payment determination for Dynamic Adjustable Knee Extension/Flexion Device.

### Summary of Applicant's Submission

Dynasplint Systems, Inc. submitted a request to establish two new HCPCS modifiers to be used with HCPCS Level II code 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). HCPCS Level II code E1810 is an inadequate and confusing description. The short and long descriptors for HCPCS Level II code E1810 create the assumption that one device described by HCPCS Level II code E1810 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, HCPCS Level II code 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 (HCPCS Level II codes 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 HCPCS Final Coding Decision

On February 29, 2024, CMS published 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.

### Medicare Benefit Category Determination

CMS determined that the Dynasplint, Dynamic Adjustable Knee Extension/Flexion Device is DME and published that determination on February 29, 2024.

**Preliminary Medicare Payment Determination**

For HCPCS Level II code 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 HCPCS Level II code 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 HCPCS Level II 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 the 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 HCPCS Level II codes E1813 and E1814 have a pricing history based on HCPCS Level II code 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 (HCPCS Level II codes E1814 for flexion and E1813 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 HCPCS Level II 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 HCPCS Level II codes 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

**Summary of Public Feedback**

Dynasplint Systems disagreed with the preliminary payment determination, stating that the fee schedule for both new HCPCS Level II codes should be equal to, and not half of, the fee schedule for the original HCPCS Level II code E1810. The speaker agreed that new HCPCPS Level II codes E1813 and E1814 have an established fee on the DMEPOS fee schedule based on the fee schedule for HCPCS Level II E1810. They suggested that CMS apply the second sentence of § 414.236(b) when establishing payment: “When there is a single code that describes two or more distinct complete items (for example, two different but related or similar items), and separate codes are subsequently established for each item, the fee schedule amounts that applied to the single code continue to apply to each of the items described by the new codes.”

**Final Medicare Payment Determination**

Upon considering the speaker's input and reviewing our preliminary determination, we have concluded that we should apply the continuity of pricing regulations differently than was done for the preliminary determination. Both the Dynasplint knee extension device (E1813) and the Dynasplint knee flexion device (E1814) have been on the product classification list (PCL) of HCPCS Level II code E1810 and have been paid under the fee schedule for that code. Therefore, both devices have a pricing history based on HCPCS Level II code E1810. 42 CFR §414.236(a) holds that if there is a fee schedule pricing history, the previous fee schedule amounts for the old code(s) are mapped to the new code(s) to ensure continuity of pricing.

The final payment determination for new HCPCS Level II codes E1813 and E1814 is to establish the fee schedule amount using the existing (current) fee schedule amount for HCPCS Level II code E1810. Therefore the 2024 average capped rental fee schedule amount for both HCPCS Level II codes E1813 and E1814 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 revised HCPCS Level II code 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 HCPCS Level II code 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.

Pricing Indicator = 36

## Dynasplint, Adjustable Ankle Extension/Flexion Device – HCP23063066K8A

### Topic/Issue

Request for Medicare payment determination for Dynamic Adjustable Ankle Extension/Flexion Device.

### Summary of Applicant's Submission

Dynasplint Systems, Inc. submitted a request to establish two new HCPCS modifiers to be used with HCPCS Level II code 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 descriptor for HCPCS Level II code E1815 code is inadequate and confusing. The short and long descriptors for HCPCS Level II code E1815 create the assumption that one device described by HCPCS Level II code E1815 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, HCPCS Level II code 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 (HCPCS Level II codes 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 HCPCS Final Coding Decision

On February 29, 2024, CMS published 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.

### Medicare Benefit Category Determination

CMS determined that the Dynasplint, Dynamic Adjustable Knee Extension/Flexion Device is DME and published that determination on February 29, 2024.

**Preliminary Medicare Payment Determination**

For HCPCS Level II code 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 HCPCS Level II code 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 HCPCS Level II 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 the 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 HCPCS Level II codes E1822 and E1823 have a pricing history based on HCPCS Level II code 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 (HCPCS Level II code E1823 for flexion and HCPCS Level II code 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 HCPCS Level II 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 HCPCS Level II codes E1822 and E1823 is represented by the following formula: E1815*.5. Therefore the 2024 average capped rental fee schedule amount for both HCPCS Level II codes 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

**Summary of Public Feedback**

Dynasplint Systems disagreed with the preliminary payment determination, stating that the fee schedule for both new HCPCS Level II codes should be equal to, and not half of, the fee schedule for the original HCPCS Level II code E1815. The speaker agreed that new HCPCPS Level II codes E1822 and E1823 have an established fee on the DMEPOS fee schedule based on the fee schedule for HCPCS Level II E1815. They suggested that CMS apply the second sentence of § 414.236(b) when establishing payment: “When there is a single code that describes two or more distinct complete items (for example, two different but related or similar items), and separate codes are subsequently established for each item, the fee schedule amounts that applied to the single code continue to apply to each of the items described by the new codes.”

**Final Medicare Payment Determination**

Upon considering the speaker's input and reviewing our preliminary determination, we have concluded that we should apply the continuity of pricing regulations differently than was done for the preliminary determination. Both the Dynasplint ankle extension device (E1822) and the Dynasplint ankle flexion device (E1823) have been on the product classification list (PCL) of HCPCS Level II code E1815 and have been paid under the fee schedule for that code. Therefore, both devices have a pricing history based on HCPCS Level II code E1815. 42 CFR §414.236(a) holds that if there is a fee schedule pricing history, the previous fee schedule amounts for the old code(s) are mapped to the new code(s) to ensure continuity of pricing.

The final payment determination for new HCPCS Level II codes E1822 and E1823 is to establish the fee schedule amount using the existing (current) fee schedule amount for HCPCS Level II code E1815. Therefore the 2024 average capped rental fee schedule amount for both HCPCS Level II codes E1822 and E1823 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 revised HCPCS Level II code 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 HCPCS Level II code 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.

Pricing Indicator = 36

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

### Topic/Issue

Request for Medicare payment determination for Dynamic Adjustable Finger Extension/Flexion Device.

### Summary of Applicant's Submission

Dynasplint Systems, Inc. submitted a request to establish two new HCPCS modifiers to be used with HCPCS Level II code 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 descriptor for HCPCS Level II code E1825 code is inadequate and confusing. The short and long descriptors for HCPCS Level II code E1825 create the assumption that one device described by HCPCS Level II code E1825 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, HCPCS Level II code 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 (HCPCS Level II codes 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 HCPCS Final Coding Decision

On February 29, 2024, CMS published 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.

### Medicare Benefit Category Determination

CMS determined that the Dynasplint, Dynamic Adjustable Finger Extension/Flexion Device is DME and published that determination on February 29, 2024.

**Preliminary Medicare Payment Determination**

For HCPCS Level II code 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 HCPCS Level II code 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 HCPCS Level II 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 the 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 HCPCS Level II codes E1826 and E1827 have a pricing history based on HCPCS Level II code E1825. When there is a single code that describes two or more distinct complete items (with HCPCS Level II code E1825, that would be flexion and extension), and separate codes are subsequently established for each item (HCPCS Level II code E1827 for flexion and HCPCS Level II code 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 HCPCS Level II 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 HCPCS Level II codes E1826 and E1827 is represented by the following formula: E1825*.5. Therefore the 2024 average capped rental fee schedule amount for both HCPCS Level II codes 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

**Summary of Public Feedback**

Dynasplint Systems disagreed with the preliminary payment determination, stating that the fee schedule for both new HCPCS Level II codes should be equal to, and not half of, the fee schedule for the original HCPCS Level II code E1825. The speaker agreed that new HCPCPS Level II codes E1826 and E1827 have an established fee on the DMEPOS fee schedule based on the fee schedule for HCPCS Level II E1825. They suggested that CMS apply the second sentence of § 414.236(b) when establishing payment: “When there is a single code that describes two or more distinct complete items (for example, two different but related or similar items), and separate codes are subsequently established for each item, the fee schedule amounts that applied to the single code continue to apply to each of the items described by the new codes.”

**Final Medicare Payment Determination**

Upon considering the speaker's input and reviewing our preliminary determination, we have concluded that we should apply the continuity of pricing regulations differently than was done for the preliminary determination. Both the Dynasplint finger extension device (E1826) and the Dynasplint finger flexion device (E1827) have been on the product classification list (PCL) of HCPCS Level II code E1825 and have been paid under the fee schedule for that code. Therefore, both devices have a pricing history based on HCPCS Level II code E1825. 42 CFR §414.236(a) holds that if there is a fee schedule pricing history, the previous fee schedule amounts for the old code(s) are mapped to the new code(s) to ensure continuity of pricing.

The final payment determination for new HCPCS Level II codes E1826 and E1827 is to establish the fee schedule amount using the existing (current) fee schedule amount for HCPCS Level II code E1825. Therefore the 2024 average capped rental fee schedule amount for both HCPCS Level II codes E1826 and E1827 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 revised HCPCS Level II code 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 HCPCS Level II code 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.

Pricing Indicator = 36

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

### Topic/Issue

Request for Medicare payment determination for Dynamic Adjustable Toe Extension/Flexion Device.

### Summary of Applicant's Submission

Dynasplint Systems, Inc. submitted a request to establish two new HCPCS modifiers to be used with HCPCS Level II code 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 descriptor for HCPCS Level II code E1830 code is inadequate and confusing. The short and long descriptors for HCPCS Level II code E1830 create the assumption that one device described by HCPCS Level II code E1830 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 (HCPCS Level II codes 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 HCPCS Final Coding Decision

On February 29, 2024, CMS published 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.

### Medicare Benefit Category Determination

CMS determined that the Dynasplint, Dynamic Adjustable Toe Extension/Flexion Device is DME and published that determination on February 29, 2024.

**Preliminary Medicare Payment Determination**

For HCPCS Level II code 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 HCPCS Level II 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 the 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 HCPCS Level II codes E1828 and E1829 have a pricing history based on HCPCS Level II code E1830. When there is a single code that describes two or more distinct complete items (with HCPCS Level II code E1830, that would be flexion and extension), and separate codes are subsequently established for each item (HCPCS Level II code E1829 for flexion and HCPCS Level II code 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 HCPCS Level II 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 HCPCS Level II codes E1828 and E1829 is represented by the following formula: E1830*.5. Therefore the 2024 average capped rental fee schedule amount for both HCPCS Level II codes 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

**Summary of Public Feedback**

Dynasplint Systems disagreed with the preliminary payment determination, stating that the fee schedule for both new HCPCS Level II codes should be equal to, and not half of, the fee schedule for the original HCPCS Level II code E1830. The speaker agreed that new HCPCPS Level II codes E1828 and E1829 have an established fee on the DMEPOS fee schedule based on the fee schedule for HCPCS Level II E1830. They suggested that CMS apply the second sentence of § 414.236(b) when establishing payment: “When there is a single code that describes two or more distinct complete items (for example, two different but related or similar items), and separate codes are subsequently established for each item, the fee schedule amounts that applied to the single code continue to apply to each of the items described by the new codes.”

**Final Medicare Payment Determination**

Upon considering the speaker's input and reviewing our preliminary determination, we have concluded that we should apply the continuity of pricing regulations differently than was done for the preliminary determination. Both the Dynasplint toe extension device (E1828) and the Dynasplint toe flexion device (E1829) have been on the product classification list (PCL) of HCPCS Level II code E1830 and have been paid under the fee schedule for that code. Therefore, both devices have a pricing history based on HCPCS Level II code E1830. 42 CFR §414.236(a) holds that if there is a fee schedule pricing history, the previous fee schedule amounts for the old code(s) are mapped to the new code(s) to ensure continuity of pricing.

The final payment determination for new HCPCS Level II codes E1828 and E1829 is to establish the fee schedule amount using the existing (current) fee schedule amount for HCPCS Level II code E1830. Therefore the 2024 average capped rental fee schedule amount for both HCPCS Level II codes E1828 and E1829 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 revised HCPCS Level II code 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.

Pricing Indicator = 36

## Off the Shelf Orthotics, Not Otherwise Classified (NOC) - HCP220222L7KH2

### Topic/Issue

Request to establish two new HCPCS Level II codes to identify prefabricated off the shelf orthotics that will parallel the current custom fitted codes L1820 and L1652.

Applicant's suggested language:

1. LXXXX: "Knee orthosis, elastic with condylar pads and joints, with or without patellar control, prefabricated, off the shelf"

2. LXXXX: "Hip orthosis, bilateral thigh cuffs with adjustable abductor spreader bar, adult size, prefabricated, off the shelf"

### Summary of Applicant's Submission

Palmetto GBA submitted a request to establish two orthotic HCPCS Level II codes to describe a prefabricated off the shelf (OTS) hip and knee orthosis. These two new OTS orthotics HCPCS Level II codes would parallel the current custom fitted HCPCS Level II codes L1820, "Knee orthosis, elastic with condylar pads and joints, with or without patellar control, prefabricated, includes fitting and adjustment" and L1652, "Hip orthosis, bilateral thigh cuffs with adjustable abductor spreader bar, adult size, prefabricated, includes fitting and adjustment, any type." There has been a significant increase in claim submissions using HCPCS Level II code L2999 ("Lower extremity orthoses, not otherwise specified") to describe the OTS version of HCPCS Level II codes L1820 and L1652. This increase in HCPCS Level II code L2999 claim submissions has increased the workload burden on the Durable Medical Equipment Medicare Administrative Contractors.

### CMS Preliminary HCPCS Coding Recommendation

We believe there is a claims processing need to split the codes, as suppliers are already billing the OTS versions of the braces under NOC/miscellaneous codes (HCPCS Level II code L2999) and then each claim needs to go through manual review. This will eliminate the need for manual review. In addition, we would further revise the existing HCPCS Level II codes to be clear they are now for custom-fitted items. As such, CMS proposes to:

1. Establish a new HCPCS Level II code LXXX1, "Knee orthosis, elastic with condylar pads and joints, with or without patellar control, prefabricated, off the shelf"

2. Establish a new HCPCS Level II code LXXX2, "Hip orthosis, bilateral thigh cuffs with adjustable abductor spreader bar, adult size, prefabricated, off the shelf"

3. Revise existing HCPCS Level II code L1820, "Knee orthosis, elastic with condylar pads and joints, with or without patellar control, prefabricated, includes fitting and adjustment" to instead read "Knee orthosis, elastic with condylar pads and joints, with or without patellar control, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise"

4. Revise existing HCPCS Level II code L1652, “Hip orthosis, bilateral thigh cuffs with adjustable abductor spreader bar, adult size, prefabricated, includes fitting and adjustment, any type” to instead read “Hip orthosis, bilateral thigh cuffs with adjustable abductor spreader bar, adult size, prefabricated, includes fitting and adjustment, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise”

**Preliminary Medicare Benefit Category Determination**

Orthotic

**Preliminary Medicare Payment Determination**

For new HCPCS Level II codes LXXX1 and LXXX2, in accordance with regulations at 42 CFR 414.236(a) if a new HCPCS Level II code is added for a DMEPOS item, CMS makes an effort 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 HCPCS Level II codes LXXX1 and LXXX2 have a pricing history. For HCPCS Level II code LXXX1, the pricing history is based on L1820. For HCPCS Level II code LXXX2, the pricing history is based on L1652.

When there is a single code that describes two or more distinct complete items (that would be off-the-shelf and custom-fitted items), and separate codes are subsequently established for each item (using the original HCPCS Level II codes L1820 and L1652 for custom fitted and establishing HCPCS Level II codes LXXX1 and LXXX2 for off-the-shelf), the payment amount that applied to the original code is also applied to the new code. Thus, the preliminary payment determination for new HCPCS Level II codes LXXX1 and LXXX2 is to establish the fee schedule amount by mapping the existing fee schedule amount for the related item described by HCPCS Level II codes L1820 and L1652.

The average 2024 purchase fee schedule amount for HCPCS Level II codes L1820 and LXXX1 is $159.97. The average 2024 purchase fee schedule amount for HCPCS Level II codes L1652 and LXXX2 is $417.34.

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

**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:

1. Establish a new HCPCS Level II code L1821, “Knee orthosis, elastic with condylar pads and joints, with or without patellar control, prefabricated, off the shelf”

2. Establish a new HCPCS Level II code L1653 “Hip orthosis, bilateral thigh cuffs with adjustable abductor spreader bar, adult size, prefabricated, off the shelf”

3. Revise existing HCPCS Level II code L1820, “Knee orthosis, elastic with condylar pads and joints, with or without patellar control, prefabricated, includes fitting and adjustment” to instead read “Knee orthosis, elastic with condylar pads and joints, with or without patellar control, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise”

4. Revise existing HCPCS Level II code L1652, “Hip orthosis, bilateral thigh cuffs with adjustable abductor spreader bar, adult size, prefabricated, includes fitting and adjustment, any type” to instead read “Hip orthosis, bilateral thigh cuffs with adjustable abductor spreader bar, adult size, prefabricated, includes fitting and adjustment, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise”

**Final Medicare Benefit Category Determination**

Brace (Orthotic)

**Final Medicare Payment Determination**

We are finalizing our preliminary payment determination to establish the Medicare payment amounts in accordance with the pricing history regulations outlined in 42 CFR 414.236(a). For HCPCS Level II code L1821, the pricing history is based on L1820. For HCPCS Level II code L1653, the pricing history is based on L1652.

When there is a single code that describes two or more distinct complete items (that would be off-the-shelf and custom-fitted items), and separate codes are subsequently established for each item (using the original HCPCS Level II codes L1820 and L1652 for custom fitted and establishing HCPCS Level II codes L1821and L1653 for off-the-shelf), the payment amount that applied to the original code is also applied to the new code. Thus, the final payment determination for new HCPCS Level II codes L1821and L1653 is to establish the fee schedule amount by mapping the existing fee schedule amount for the related item described by HCPCS Level II codes L1820 and L1652, respectively. The average 2024 purchase fee schedule amount for HCPCS Level II codes L1820 and L1821 is $159.97. The average 2024 purchase fee schedule amount for HCPCS Level II codes L1652 and L1653 is $417.34.

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.

Pricing Indicator = 38

## Scoliosis Brace - HCP211020YNN4T

### Topic/Issue

Request to establish a new HCPCS Level II code to identify spinal orthosis designed to support the adult scoliotic spinal curve deformities in the adult patient population.

Applicant's suggested language: LXXXX, “Scoliosis orthosis, sagittal-coronal control provided by a rigid lateral frame, extends from axilla to trochanter, includes all accessory pads, straps and interface, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise”

### Summary of Applicant's Submission

Palmetto GBA submitted a request to establish a new HCPCS Level II code to identify spinal orthosis designed to support adult scoliotic spinal curve deformities in the adult patient population. The new code would describe a prefabricated spinal orthosis designed to support the scoliotic curvature in the adult patient population to immobilize and aid in support of the spine for pain control associated with a scoliotic curve deformity. The design parameters would include a rigid lateral frame extending from the axilla to the trochanter with a lumbar sacral support to stabilize the position of the rigid lateral frame. Two manufacturers submitted four different devices for Pricing, Data Analysis and Coding (PDAC) contractor HCPCS Level II code verification and two of these devices (Peak Scoliosis Bracing System and TechnoSpine TLSO-Scoliosis Brace) have products that include a rigid lateral frame extending from the axilla to the trochanter with a lumbar sacral support that stabilizes the position of the rigid lateral frame. A new HCPCS Level II code LXXXX would more accurately describe the Peak Scoliosis Bracing System and TechnoSpine TLSO-Scoliosis Brace rather than HCPCS Level II code L1005, “Tension based scoliosis orthosis and accessory pads, includes fitting and adjustment.” Other products listed on the product classification list, maintained by PDAC, under HCPCS Level II code L1005 were not submitted for review. If new HCPCS Level II code LXXXX is established, the PDAC plans to determine if the products currently coded in HCPCS Level II code L1005 should be coded under the new HCPCS Level II code.

### CMS Preliminary HCPCS Coding Recommendation

Establish a new HCPCS Level II code LXXXX, “Scoliosis orthosis, sagittal-coronal control provided by a rigid lateral frame, extends from axilla to trochanter, includes all accessory pads, straps and interface, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise”

The FLEXpineBrace, manufactured by StandingTall, is currently coded under HCPCS Level II code L1005. We believe that the proposed HCPCS Level II code LXXXX would describe FLEXpineBrace.

### Preliminary Medicare Benefit Category Determination

Back Brace.

The Peak Scoliosis Bracing System and the TechnoSpine TLSO-Scoliosis Brace fall under the definition of a brace. Section 130 of Chapter 15 of the Medicare Benefit Policy Manual (CMS Pub. 100-02) states that braces are covered under Medicare Part B when furnished incident to physicians' services or on a physician's order. This section of the Manual 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. These devices are a prefabricated rigid spinal orthosis designed to support the scoliotic curvature in the adult patient population to immobilize and aid in support of the spine for pain control associated with a scoliotic curve deformity.

**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 the Medicare Claims Processing Manual, Chapter 23, Section 60.3 and the deflated amounts are then increased by the update factors specified in section 1834(h)(4) of the Social Security Act for orthotics and prosthetics.

In determining whether the items that would be classified in HCPCS Level II code LXXXX are comparable to items with existing codes, we undertook a detailed examination of its physical, mechanical, and components along with its function and intended use.

The Peak Scoliosis Bracing System and the TechnoSpine TLSO-Scoliosis Brace are fabricated from non-elastic and heat-moldable materials, integrating rigid panels. Currently, the assigned existing code for these items (HCPCS Level II code L1005) pertains to orthoses made from elastic materials. Furthermore, aside from the material contrast, the existing code primarily focuses on addressing scoliosis and hyperkyphosis in the pediatric population, whereas these new products primarily cater to scoliosis treatment in adults.

Taking into account these noted differences, we have concluded that while the two items falling under HCPCS Level II code LXXXX share some similarities with devices described in HCPCS Level II code L1005, they are not comparable. Therefore, we have decided that it is most appropriate to establish the Medicare payment amount using the "gap filling" procedure outlined in 42 CFR 414.238(c).

We have found a number of internet retail prices for items that would be classified in HCPCS Level II code LXXXX, retrieved in September 2023.[1] The median of these prices is $1,868. After applying the annual deflation and update factors, the 2024 payment amount for HCPCS Level II code LXXXX would be approximately $1,368.16.

Pricing Indicator = 38

[1] For example, https://www.dme-direct.com/peak-scoliosis-bracing-system, https://justbrace.com/product/aspen-peak-scoliosis-bracing-system-adjustable, https://www.vitalitymedical.com/aspen-peak-scoliosis-bracing-system.html, https://www.scriphessco.com/products/aspen-peak-scoliosis-bracing-system/, https://www.alimed.com/peak-scoliosis-bracing-system.html, https://www.rehab-store.com/p-aspen-peak-scoliosis-bracing-system.html

**Summary of Public Feedback**

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

**CMS Final HCPCS Coding Decision**

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

Establish a new HCPCS Level II code L1006, "Scoliosis orthosis, sagittal-coronal control provided by a rigid lateral frame, extends from axilla to trochanter, includes all accessory pads, straps and interface, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise"

**Final Medicare Benefit Category Determination**

Back Brace.

**Final Medicare Payment Determination**

The fee schedule amount will be established as discussed in the preliminary determination. For L1006, the 2024 payment amount will be approximately $1,368.16.

Pricing Indicator = 38

## NeuroNode® - HCP221230PJ0M6

### Topic/Issue

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

Applicant's suggested language: EXXXX, “Accessory for speech generating device, sEMG sensor”

### Summary of Applicant’s Submission

Control Bionics Limited submitted a request to establish a new HCPCS Level II code to identify NeuroNode®. NeuroNode® is a class II device, exempt from the premarket notification procedures by the Food and Drug Administration (FDA). NeuroNode® is an augmentative and alternative communication (AAC) device intended to provide noninvasive, electromyographic (EMG) mediated computer access, communication, robotic, and environmental control capability for users with impaired speech and/or motor function. NeuroNode® uses the body’s EMG signals or 3D spatial movements to give the user precise control of their AAC device. The user sends an initiating signal from their motor cortex to the fibers of the target muscle. If any action potential is generated along those muscle fibers, or a vector shift occurs in the electrical field, NeuroNode® can generate a coherent, unambiguous command to the target speech generating device (SGD). The NeuroNode® functionally enhances the results of the speech generating system for people with conditions like progressive amyotrophic lateral sclerosis, spinal cord injury, spinal muscular atrophy, cerebral palsy, and certain traumatic brain injury. Individuals can access their technology, including but not limited to, an AAC device, computer, phone or tablet with the device. NeuroNode® interprets coherent volitional commands and these minute bioelectric signals can be detected even if the muscle’s ability to contract is significantly diminished. The existing HCPCS Level II code E2599 is a miscellaneous code that is used to describe a variety of speech generating technologies such as joysticks, buttons, and keyguards, which are different from NeuroNode® in terms of technology, functionality, and cost. The other control devices require tactile or physical input from the user, such as the ability to press a button or grasp and maneuver a joystick. NeuroNode® detects EMG to allow the user to control the SGD through any type of intentional, detectable movement, or by using a range of motion or 3D spatial awareness. NeuroNode® can be placed on almost any muscle that the user can control. The NeuroNode® is needed when a patient cannot use, or the prescriber does not recommend, standard input devices. A new unique code will allow health care providers to accurately report, and payers to accurately capture product-specific information to adjudicate claims efficiently.

### CMS Preliminary HCPCS Coding Recommendation

This application was deferred from the First Biannual 2023 HCPCS Level II coding cycle for additional consideration. NeuroNode® uses an electromyographic sensor to assist with control for an SGD, and it is an alternative to many other standard input devices such as joysticks, buttons, and keyguards, which are also billable under existing HCPCS Level II code E2599, “Accessory for speech generating device, not otherwise classified.” As such, CMS is proposing to:

Establish a new HCPCS Level II code, EXXXX, “Accessory for speech generating device, electromyographic sensor” to describe NeuroNode®.

**Preliminary Medicare Benefit Category Determination**

Durable Medical Equipment.

Speech generating devices are considered to fall within the durable medical equipment (DME) benefit category established by section 1861(n) of the Social Security Act. They are used for patients who suffer from a severe speech impairment and have a medical condition that warrants the use of a device. The NeuroNode® is a DME accessory used with speech generating devices. Section 110.3 of the Medicare Benefit Policy Manual (CMS Pub. 100-02) indicates that payment may be made for supplies and accessories that are necessary for the effective use of durable medical equipment. Because the NeuroNode® is an accessory to an item of DME, the control interface input device falls under the DME benefit category.

**Preliminary Medicare Payment Determination**

In accordance with regulations at 42 CFR 414.238(c), fee schedule amounts for items and services without a fee schedule pricing history described by new HCPCS Level II codes that are not comparable to items and services with existing fee schedule amounts may be established using supplier price lists, including catalogs and other retail price lists (such as internet retail prices) that provide information on commercial pricing for the item. If the 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 to approximate the base period price. The annual deflation factors are specified in Medicare Claims Processing Manual, Chapter 23, Section 60.3 and the deflated amounts are then increased by the update factors specified in section 1834(a)(14) of the Social Security Act for DME.

We carefully reviewed the existing HCPCS Level II codes and fee schedule amounts as part of our payment review for new HCPCS Level II code EXXXX and were unable to identify codes that adequately compare to the features of the NeuroNode®. We believe this accessory is not comparable to any existing coded device and for this reason, have determined that the gap-filling methodology is appropriate for establishing fees for this device.

To gap-fill the fee schedule amount for HCPCS Level II code EXXXX, we used verifiable commercial pricing as the source, including non-Medicare payer data. The average 2023 commercial pricing for the NeuroNode® was $6,783.33. The annual deflation factors are specified in program instructions and the deflated amounts are then increased by the update factors specified in section 1834(a)(14) of the Act for DME. Payment for the HCPCS Level II code EXXXX would be made on a purchase or rental basis in accordance with section 1834(a)(2)(A)(iv) of the Social Security Act because the product is an accessory that is needed for an individual to effectively use a speech generating device. The average 2024 purchase fee schedule amount for HCPCS Level II code EXXXX would be approximately $4,299.75.

Pricing Indicator = 32

**Summary of Public Feedback**

Control Bionics Limited agreed with the preliminary HCPCS coding and payment recommendations.

**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 and finalizing the decision to:

Establish a new HCPCS Level II code E2513, "Accessory for speech generating device, electromyographic sensor" to describe NeuroNode®.

**Final Medicare Benefit Category Determination**

Durable Medical Equipment.

**Final Medicare Payment Determination**

The fee schedule amounts will be established as discussed in the preliminary payment determination. To gap-fill the fee schedule amounts for HCPCS Level II code E2513, we used verifiable commercial pricing as the source, including non-Medicare payer data. The average 2023 commercial pricing for the NeuroNode® was $6,783.33. The annual deflation factors are specified in program instructions and the deflated amounts are then increased by the update factors specified in section 1834(a)(14) of the Act for DME. Payment for the HCPCS Level II code E2513 will be made on a purchase or rental basis in accordance with section 1834(a)(2)(A)(iv) of the Social Security Act because the product is an accessory that is needed for an individual to effectively use a speech generating device.

The average 2024 purchase fee schedule amount for HCPCS Level II code E2513 will be approximately $4,299.75.

Pricing Indicator = 32

## Serena Nylon ema® FH - HCP2312287XKQL

### Topic/Issue

Request to be assigned 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” for Serena Nylon ema® FH obstructive sleep apnea (OSA) appliance.

The applicant did not submit any suggested language.

### Summary of Applicant's Submission

Serena Sleep Solutions submitted a request to be assigned a HCPCS Level II code to identify Serena Nylon ema® FH OSA appliance. Serena Nylon ema® FH OSA appliance was approved by the Food and Drug Administration (FDA) under the 510(k) pathway on March 10, 2021. The Serena Nylon ema® FH OSA appliance is indicated for snoring and OSA. The Serena Nylon ema® FH is a custom fabricated, OSA appliance that utilizes a fixed hinged located on the buccal surfaces of the appliance that holds the mandibular jaw forward, reducing upper airway collapsibility. Originally, the Pricing, Data Analysis and Coding contractor assigned this appliance to HCPCS Level II code K1027, “Oral device/appliance used to reduce upper airway collapsibility, without fixed mechanical hinge, custom fabricated, includes fitting and adjustment.” Existing HCPCS Level II code K1027 does not adequately describe this item, as it states, “without fixed mechanical hinge.” The Serena Nylon ema® FH OSA appliance meets all the conditions set forth in existing HCPCS Level II code E0486. The Nylon ema® FH can be adjusted by the beneficiary after 90-day period and like a Herbst device, cannot be separated into its basic components inside or outside the mouth.

### 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 Serena Nylon ema® FH OSA appliance. CMS believes the Serena Nylon ema® FH OSA appliance does not feature a fixed, inseparable hinge that always remains integrated, including during adjustments. Serena Nylon ema® FH OSA appliance is similar to other devices in existing HCPCS Level II code K1027.

### 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.

As stated in the Preliminary 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.

**Summary of Public Feedback**

Serena Sleep Solutions disagreed with CMS' preliminary HCPCS recommendation to assign Serena Nylon ema® FH OSA appliance to 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." The speakers stated that Serena Nylon ema® FH OSA appliance can only be separated when done so intentionally, just like the predicate Herbst appliance. Also, Serena Nylon ema® FH OSA appliance uses rigid hinges to advance the mandibular jaw that are secured on inseparable pivot points, similar to Panthera D-SAD Classic and the Glidewell Silent Nite®, which are currently assigned to HCPCS Level II code E0486. The speakers believe Serena Nylon ema® FH OSA appliance meets all the requirements stated in Policy Article A52512. The speakers mentioned if the Serena Nylon ema® FH OSA appliance was used to evaluate the existing products that have already been assigned code E0486, many of them would not and do not meet the requirements in Policy Article A52512.

**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 K1027, "Oral device/appliance used to reduce upper airway collapsibility, without fixed mechanical hinge, custom fabricated, includes fitting and adjustment" to describe Serena Nylon ema® FH OSA appliance.

The Serena Nylon ema® FH OSA appliance does not feature a fixed, inseparable hinge that always remains integrated, including during adjustments. Serena Nylon ema® FH OSA appliance is similar to other devices in existing HCPCS Level II code K1027. There were two products mentioned by the applicant to be comparable to the Serena Nylon ema® FH OSA appliance: Panthera D-SAD Classic and the Glidewell Silent Nite®. For the Glidewell Silent Nite® Sleep appliance, the band that connects the top and bottom stays fixed whether inside or outside the mouth with adjustments being made by moving the screws along a track, which is not similar to the Serena Nylon ema® FH OSA appliance, and is properly coded under E0486. CMS will review the Panthera D-SAD Classic product at another time.

**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.

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).

## SnoreHook - HCP2312035AJRX

### Topic/Issue

Request to be assigned 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" for the SnoreHook.

The applicant did not submit any suggested language.

### Summary of Applicant's Submission

Boyd Research submitted a request to be assigned an existing HCPCS Level II code K1027 to describe the SnoreHook. SnoreHook was approved by the Food and Drug Administration (FDA) under the 510(k) pathway on May 3, 2005. SnoreHook is described as an oral device/appliance used to reduce upper airway collapsibility for the treatment of snoring and mild to moderate obstructive sleep apnea.

### 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 SnoreHook.

### Preliminary Medicare Benefit Category Determination

No determination.

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

### Preliminary Medicare Payment Determination

No determination.

As stated in the Preliminary Medicare Benefit Category 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.

### Summary of Public Feedback

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

### CMS Final HCPCS Coding Decision

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

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

**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 Preliminary Medicare Benefit Category 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.

## xenoPATCH - HCP2312290X848

### Topic/Issue

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

Applicant's suggested language: AXXXX, “xenoPATCH, 1 sq cm”

### Summary of Applicant's Submission

Extremity Care submitted a request to establish a new HCPCS Level II code to identify xenoPATCH. Extremity Care is a licensed distributor for xenoPATCH, which is manufactured by DSM Biomedical. Meso Wound Matrix received the Food and Drug Administration’s (FDA’s) 510(k) clearance on February 12, 2012; however, “xenoPATCH” has since been added to the FDA’s 510(k) listing and is sold under this brand name exclusively by Extremity Care. xenoPATCH is a thin, flexible, yet strong acellular biologic dermal substitute scaffold which acts to support the body’s own regenerative tissue repair process during wound healing. xenoPATCH is indicated for the management of topical wounds, including partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, surgical wounds, trauma wounds (including second degree burns), draining wounds, and tunneled/undermined wounds.

### CMS Preliminary HCPCS Coding Recommendation

It is our understanding that Meso Wound Matrix was never commercially marketed or sold by DSM Biomedical. Parametrics obtained the rights to license the product from DSM Biomedical and rebranded as "Resolve Matrix" for distribution by Parametrics exclusively; however, Parametrics has since privately labeled the product for exclusive distribution by Extremity Care, who now owns the brand and named the product "xenoPATCH." Resolve Matrix will remain in use. As such, we propose to:

Revise existing HCPCS Level II code A2024, “Resolve matrix, per square centimeter” to instead read “Resolve matrix or xenopatch, per square centimeter” to describe the rebranded product, xenoPATCH.

### Summary of Public Feedback

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

### CMS Final HCPCS Coding Decision

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

Revise existing HCPCS Level II code A2024, “Resolve matrix, per square centimeter” to instead read “Resolve matrix or xenopatch, per square centimeter” to describe the rebranded product, xenoPATCH.

## MatriDerm - HCP2312299XQ9C

### Topic/Issue

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

Applicant's suggested language: AXXXX, “MatriDerm, per square centimeter”

### Summary of Applicant's Submission

Access Pro Medical submitted a request to establish a new HCPCS Level II code to identify MatriDerm. MatriDerm received the Food and Drug Administration’s (FDA’s) 510(k) clearance on January 7, 2021. MatriDerm is a single-use three-dimensional acellular dermal matrix composed of bovine collagen fibers and bovine elastin. MatriDerm provides a moist wound healing environment and scaffold. MatriDerm is indicated for the management of wounds including full thickness and partial thickness wounds, chronic wounds (e.g. pressure ulcers, venous ulcers, diabetic ulcers, chronic ulcers), surgical wounds (donor sites/grafts, post-Moh’s surgery, post-laser surgery, podiatric, wound dehiscence), partial thickness burns, trauma wounds (abrasions, lacerations, skin tears) and draining wounds.

### CMS Preliminary HCPCS Coding Recommendation

Establish a new HCPCS Level II code AXXXX, “Matriderm, per square centimeter” to describe MatriDerm.

### Summary of Public Feedback

Access Pro Medical agreed with CMS’ published preliminary HCPCS coding recommendation to establish a new HCPCS Level II code.

### CMS Final HCPCS Coding Decision

We appreciate the written 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:

Establish a new HCPCS Level II code A2027, “Matriderm, per square centimeter” to describe MatriDerm.

## MicroMatrix® Flex - HCP231218YCJEE

### Topic/Issue

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

Applicant's suggested language: AXXXX, “MicroMatrix Flex, per cc”

### Summary of Applicant's Submission

Integra LifeSciences Corporation submitted a request to establish a new HCPCS Level II code to identify MicroMatrix® Flex. MicroMatrix® Flex received the Food and Drug Administration’s (FDA’s) 510(k) clearance on September 22, 2023. The MicroMatrix® Flex device is supplied as a dual-syringe system for the mixing and delivery of a MicroMatrix® paste for the management of wounds. The particulate component of the device is composed of porcine-derived extracellular matrix known as urinary bladder matrix. The MicroMatrix® particulate within the MicroMatrix® Flex device is lyophilized (freeze-dried) micronized particles of porcine urinary bladder extracellular matrix. MicroMatrix® Flex is intended for the management of wounds including partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds, trauma wounds and draining wounds.

### CMS Preliminary HCPCS Coding Recommendation

Establish a new HCPCS Level II code AXXXX, “Micromatrix flex, per mg” to describe MicroMatrix® Flex.

The weight of lyophilized MicroMatrix® Flex particulate component provided in a syringe is between 750-800 mg. In the preparation of the device, the particulate component is mixed with up to 8 mL of saline solution to form the paste.

### Summary of Public Feedback

Integra LifeSciences Corporation agreed with CMS’ published preliminary coding recommendation to establish a new HCPCS Level II code; however, they requested to revise a dose descriptor to say “per cc” instead of “per mg.” Integra LifeSciences Corporation provided the following reasons as their rationale: 1) to avoid coder confusion as all pertinent information of the products such as the product specification page and the product brochure, refers to cc as the unit of measure; 2) inability to determine the number of milligrams furnished as with a per cc base dose, providers would know the number of service units to bill since the MicroMatrix® Flex is provided in a syringe that is pre-filled with 5 cc’s of the product; 3) consistency with other products as there are more than 20 skin substitute product HCPCS Level II codes that have a unit of measure of cc.

### CMS Final HCPCS Coding Decision

We appreciate the written 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:

Establish a new HCPCS Level II code A2028, “Micromatrix flex, per mg” to describe MicroMatrix® Flex.

CMS uses the concentration of the drug components verses the amount of the drug in milliliters as a manufacturer could change packaging sizes in the future.

## MiroTract Wound Matrix - HCP240102AB73B

### Topic/Issue

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

Applicant's suggested language: AXXXX, “MiroTract Wound Matrix Sheet, per cm3”

### Summary of Applicant's Submission

Reprise Biomedical, Inc. submitted a request to establish a new HCPCS Level II code to identify MiroTract Wound Matrix. MiroTract Wound Matrix received the Food and Drug Administration’s (FDA’s) 510(k) clearance on December 13, 2023. MiroTract Wound Matrix consists of a segment of dry, decellularized porcine collagen that is radially compressed and provided on a guidewire. Once placed, the matrix can be wetted by the natural wound environment, or it can be hydrated with saline or Lactated Ringer’s Solution. This wetting process allows relaxation to a thick sheet-like form and expansion contact with the adjacent wound bed. MiroTract Wound Matrix is supplied sterile and is intended for one-time use in a single patient. MiroTract is available in four size configurations.

### CMS Preliminary HCPCS Coding Recommendation

Establish a new HCPCS Level II code AXXXX, “Mirotract wound matrix sheet, per cubic centimeter” to describe MiroTract Wound Matrix.

### 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 A2029, “Mirotract wound matrix sheet, per cubic centimeter” to describe MiroTract Wound Matrix.

## AceConnex Pre-Sutured Fascia Allograft - HCP231217FK5VQ

### Topic/Issue

Request to establish a new HCPCS Level II code to identify AceConnex pre-sutured fascia allograft.

Applicant's suggested language: AXXXX, “AceConnex Pre-Sutured Fascia, per millimeter”

### Summary of Applicant's Submission

AlloSource submitted a request to establish a new HCPCS Level II code to identify AceConnex pre-sutured fascia allograft. AceConnex pre-sutured fascia allograft received the Food and Drug Administration’s (FDA’s) 510(k) clearance on June 27, 2023. AceConnex pre-sutured fascia allograft is used as a component in soft tissue surgical procedures for reconstruction, replacement, or augmentation of the hip labrum. It is applied by using multiple hip labral anchors per surgeon preference. The product is provided in a sterile single unit in various package sizes.

### CMS Preliminary HCPCS Coding Recommendation

It is our understanding that AceConnex pre-sutured fascia allograft 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

AlloSource disagreed with CMS’ preliminary HCPCS Level II coding recommendation. The speaker stated that AceConnex pre-sutured fascia is a new, unique device for the treatment of hip labral damage. By its nature, the AceConnex pre-sutured fascia saves between 30 and 45 min in preparation time in the operating room. Since this is a new device, payers are not able to reflect the cost of the product when used in surgery. A HCPCS Level II code should be available for this device, so that providers can accurately describe the exact materials administered to the patient and their cost as required by HCPCS regulations. The speaker confirmed that even though the AceConnex pre-sutured fascia allograft is used during a procedure reported with a HCPCS Level I CPT® code, they have not approached the American Medical Association (AMA), because it is an extremely difficult process to get something like this approved by the CPT® Editorial Panel.

### 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. It is our understanding that AceConnex pre-sutured fascia allograft would generally be used in a procedure reported with a HCPCS Level I 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.

## Sparrow Ascent® - HCP231201M40EP

### Topic/Issue

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

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

### Summary of Applicant's Submission

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

### CMS Preliminary HCPCS Coding Recommendation

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

### Preliminary Medicare Benefit Category Determination

No determination.

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

1. Can withstand repeated use.

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

All five of these conditions must be met in order for equipment to be classified as DME. Our initial review found that the Sparrow Ascent® System may not meet these conditions as follows:

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

1. According to the definition of Mean Time Between Failures (MTBF), an MTBF of 19.2 years implies that, on average, the time between failures within the tested group is 19.2 years. However, MTBF alone doesn't indicate the device's service life. How was it determined that the device can endure repeated use for at least 3 years?

2. The sample size for the testing appears to be for one pulse generator. What is the rationale for the small sample size?

3. The report does not appear to include durability testing information related to the housing components of the device and seems to primarily include components of the circuit board. What was the testing criteria for the device housing?

**Preliminary Medicare Payment Determination**

No determination.

**Summary of Public Feedback**

Spark Biomedical disagreed with CMS' preliminary recommendation of no determination for the benefit category. The primary speaker was not aware of the preliminary HCPCS Level II coding recommendation; however, in the submitted written comments it was stated that the preliminary coding recommendation language does not accurately describe the proprietary mechanism of action, transcutaneous auricular neurostimulation (tAN®), and recommended that CMS use, “External cranial neurostimulator of the auriculotemporal nerve and auricular branch of the vagus nerve to relieve opioid withdrawal symptoms.” CMS’ questions were

also addressed by the speaker and stated that the MTBF analysis assumes constant load without standby time, ensuring reliable electronics for over 19 years. Sparrow Ascent® contains durable mechanical components, such as cable connectors rated for 5,000 cycles and tactile switches rated for 500,000 cycles, far exceeding expected use lifetime. Additionally, every PCBA board and housing undergo thorough inspection and testing, with 100% of assembled EPGs undergoing final functional testing, minimizing performance variation. Verification testing was conducted according to ISO standards. The Sparrow Ascent® device underwent rigorous reusability and cleaning testing, demonstrating full functionality after extensive simulated use, and separate durability testing per relevant standards. A detailed explanation of the design and testing processes employed to ensure the three-year minimum lifetime requirement of the Sparrow Ascent® device was also provided in the written 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 to:

Establish a new HCPCS Level II code E0721, "Transcutaneous electrical nerve stimulator for nerves in the auricular region" to describe Sparrow Ascent®.

The newly established code, E0721, accurately describes the Sparrow Ascent® device. We generally do not enumerate the device's indications in the HCPCS Level II code descriptor.

**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 Sparrow Ascent® was determined to meet the requirements to be classified as DME. Based on the submitted information, we believe this device has an expected life of at least 3 years.

**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 will 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

## Sparrow Ascent® Earpiece Kit - HCP231201AU2B3

### Topic/Issue

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

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

### Summary of Applicant's Submission

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

### CMS Preliminary HCPCS Coding Recommendation

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

### Preliminary Medicare Benefit Category Determination

No determination.

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

1. Can withstand repeated use.
2. Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.
3. Is primarily and customarily used to serve a medical purpose.

4. Generally is not useful to an individual in the absence of an illness or injury.
5. Is appropriate for use in the home.

All five of these conditions must be met in order for equipment to be classified as DME. Our initial review found that the Sparrow Ascent® System may not meet these conditions as follows:

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

1. According to the definition of Mean Time Between Failure (MBTF), an MBTF of 19.2 years implies that, on average, the time between failures within the tested group is 19.2 years. However, MBTF alone doesn't indicate the device's service life. How was it determined that the device could endure repeated use for at least 3 years?

2. The sample size for the testing appears to be for one pulse generator. What is the rationale for the small sample size?

3. The report does not appear to include durability testing information related to the housing components of the device and seems to primarily include components of the circuit board. What was the testing criteria for the device housing?

**Preliminary Medicare Payment Determination**

No determination.

**Summary of Public Feedback**

Spark Biomedical disagreed with CMS' preliminary recommendation of no determination for the benefit category. The primary speaker was not aware of the preliminary HCPCS Level II coding recommendation, however, in the submitted written comments it was stated that the preliminary coding recommendation language does not accurately describe the proprietary mechanism of action, transcutaneous auricular neurostimulation (tAN®) and recommended that CMS use, "Supplies and accessories for external cranial neurostimulator of the auriculotemporal nerve and auricular branch of the vagus nerve to relieve opioid withdrawal symptoms, per month". CMS' questions were also addressed by the speaker and stated that the MTBF analysis assumes constant load without standby time, ensuring reliable electronics for over 19 years. Sparrow Ascent® contains durable mechanical components, such as cable

connectors rated for 5,000 cycles and tactile switches rated for 500,000 cycles, far exceeding expected use lifetime. Additionally, every PCBA board and housing undergo thorough inspection and testing, with 100% of assembled EPGs undergoing final functional testing, minimizing performance variation. Verification testing was conducted according to ISO standards. The Sparrow Ascent® device underwent rigorous reusability and cleaning testing, demonstrating full functionality after extensive simulated use, and separate durability testing per relevant standards. A detailed explanation of the design and testing processes employed to ensure the three-year minimum lifetime requirement of the Sparrow Ascent® device was also provided in the written 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 to:

Establish a new HCPCS Level II code A4543, "Supplies for transcutaneous electrical nerve stimulator, for nerves in the auricular region, per month" to describe the Sparrow Ascent® supplies.

**Final Medicare Benefit Category Determination**

Durable Medical Equipment.

The Sparrow Ascent® earpieces serve as an essential accessory to the Sparrow Ascent® stimulator that has been modified and determined to meet the definition of DME. Chapter 15, Section 110.3 of the Medical Benefit Policy Manual (CMS Pub. 100-02) indicates that payment may be made for accessories that are necessary for the effective use of durable medical equipment. Because the earpieces are an essential accessory for HCPCS Level II code E0721 for an item of DME, the earpieces fall 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 the purchase of these non-durable accessories 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.

Pricing Indicator = 46

## iCare HOME2 Tonometer - HCP2312208153N

### Topic/Issue

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

Applicant's suggested language: XXXXX, “Tonometer, rebound, handheld”

### Summary of Applicant's Submission

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

### CMS Preliminary HCPCS Coding Recommendation

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

clinical monitoring of IOP. We have not identified a specific need for this iCare HOME2 Tonometer to be separately paid, since we believe that a particular payer may elect to pay for the service in which this system is used. For instance, Medicare would typically reflect the costs of the system in the payment for the physician service/procedure, if it is used, and as such it would not be separately payable.

**Summary of Public Feedback**

iCare Finland Oy disagreed with CMS' published preliminary recommendation. The speaker stated that glaucoma is a chronic, slowly progressive optic neuropathy that can result in irreversible vision loss and blindness. It is a leading cause of preventable and irreversible vision loss worldwide, affecting approximately 3 million people in the United States. Black, Hispanic, and Asian Americans experience a higher prevalence of glaucoma compared to non-Hispanic White Americans, and they have worse visual outcomes. Intraocular pressure (IOP) refers to the measurement of fluid pressure inside the eye. It is a leading risk factor for the development and progression of glaucoma, and more importantly, it is the only modifiable and treatable risk factor. All therapies, both medical and surgical, aim to reduce IOP to help prevent damage from glaucoma, as landmark studies have shown that lowering IOP reduces risk and progression. While an in-office IOP assessment is important in establishing a baseline, it provides only a single measurement at a single point in time. IOP is a dynamic fluctuating value that correlates with vision loss, and there is a need for more than just a single in-office value. Detecting and tracking patterns in IOP over periods of time is critical in managing glaucoma treatment and adjusting medications and therapies for these patients. It is not possible to obtain the IOP measurements required to appropriately manage these patients solely based on single measurements taken in a doctor's office. Thus, the iCare HOME2 Tonometer and Probe provide the means to detect and track IOP (including spikes and fluctuations, which are risk factors in their own right, as well as when the patient's IOP is stable), while the patient is in their home in various positions (lying down vs. sitting upright), after performing daily activities, and over periods of days, weeks and months. The iCare HOME2 Tonometer may also confirm when IOP is stable which could avoid costly and unnecessary interventions and office visits. These IOP measurements obtained outside of the office by the patient allow qualified healthcare professionals to effectively manage treatment of their patient's glaucoma and adjust therapies for their patients based on data collected from the devices used in the patients' homes, along with self-reported documentation provided by the patient regarding their activities prior to the time their IOP was measured. Patients use this device in the patient's home to measure IOP at various times of the day and night to facilitate and optimize glaucoma treatment management. The iCare HOME2 Tonometer is FDA-cleared exclusively for use in the patient's home.

**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 specific need for this iCare HOME2 Tonometer to be separately paid, since we believe that a particular payer may elect to pay for the service in which this system is used. For instance, Medicare would typically reflect the costs of the system in the payment for the physician service/procedure, if it is used, and as such it would not be separately payable.

## iCare HOME2 Tonometer Probe - HCP231220WWK6M

### Topic/Issue

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

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

### Summary of Applicant's Submission

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

### CMS Preliminary HCPCS Coding Recommendation

The iCare HOME2 Tonometer can measure IOP outside of the physician’s office and office hours, thereby enabling the physician to assess real-world IOP spikes and fluctuations over a 24-hour period for several days to weeks, as required to inform clinical decision making. Our understanding is that iCare HOME2 Tonometer is intended as an adjunct to the routine clinical monitoring of IOP. We have not identified a specific need for this iCare HOME2 Tonometer Probe to be separately paid, since we believe that a particular payer may elect to pay for the service in which this system is used. For instance, Medicare would typically

reflect the costs of the system in the payment for the physician service/procedure, if it is used, and as such it would not be separately payable.

**Summary of Public Feedback**

iCare Finland Oy disagreed with CMS' published preliminary recommendation. The speaker stated that glaucoma is a chronic, slowly progressive optic neuropathy that can result in irreversible vision loss and blindness. It is a leading cause of preventable and irreversible vision loss worldwide, affecting approximately 3 million people in the United States. Black, Hispanic, and Asian Americans experience a higher prevalence of glaucoma compared to non-Hispanic White Americans, and they have worse visual outcomes. Intraocular pressure (IOP) refers to the measurement of fluid pressure inside the eye. It is a leading risk factor for the development and progression of glaucoma, and more importantly, it is the only modifiable and treatable risk factor. All therapies, both medical and surgical, aim to reduce IOP to help prevent damage from glaucoma, as landmark studies have shown that lowering IOP reduces risk and progression. While an in-office IOP assessment is important in establishing a baseline, it provides only a single measurement at a single point in time. IOP is a dynamic fluctuating value that correlates with vision loss, and there is a need for more than just a single in-office value. Detecting and tracking patterns in IOP over periods of time is critical in managing glaucoma treatment and adjusting medications and therapies for these patients. It is not possible to obtain the IOP measurements required to appropriately manage these patients solely based on single measurements taken in a doctor's office. Thus, the iCare HOME2 Tonometer and Probe provide the means to detect and track IOP (including spikes and fluctuations, which are risk factors in their own right, as well as when the patient's IOP is stable), while the patient is in their home in various positions (lying down vs. sitting upright), after performing daily activities, and over periods of days, weeks and months. The iCare HOME2 Tonometer may also confirm when IOP is stable which could avoid costly and unnecessary interventions and office visits. These IOP measurements obtained outside of the office by the patient allow qualified healthcare professionals to effectively manage treatment of their patient's glaucoma and adjust therapies for their patients based on data collected from the devices used in the patients' homes, along with self-reported documentation provided by the patient regarding their activities prior to the time their IOP was measured. Patients use this device in the patient's home to measure IOP at various times of the day and night to facilitate and optimize glaucoma treatment management. The iCare HOME2 Tonometer is FDA-cleared exclusively for use in the patient's home.

**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. CMS has not identified a specific need for this iCare HOME2 Tonometer Probe to be separately paid, since we believe that a particular payer may elect to pay for the service in which this system is used. For instance, Medicare would typically reflect the costs of the system in the payment for the physician service/procedure, if it is used, and as such it would not be separately payable.

## MysteryVibe Crescendo 2 - HCP231231B8WQX

### Topic/Issue

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

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

### Summary of Applicant's Submission

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

### CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a program operating need for Medicare or other payers to establish a unique HCPCS Level II code to describe a pelvic floor genital vibrator to treat pelvic pain. We would like to understand how the MysteryVibe Crescendo 2 device achieves medical outcomes. It is evident from the manufacturer’s website[2] that this device has a broad range of uses for other indications, including “all-time best sex toy, and boost your sex life.” Also, this device is advertised for solving arousal, pain, and dryness issues. We welcome information from the applicant and other insurers who are currently paying for this product to demonstrate a claims processing need for a unique HCPCS Level II code to describe the MysteryVibe Crescendo 2.

### Summary of Public Feedback

MysteryVibe LLC disagreed with CMS’ preliminary HCPCS Level II coding recommendation. The speaker stated the Crescendo 2 is a medical device that meets the HCPCS application criteria and all the requirements as a durable medical device. The product is a non-implantable pelvic floor genital vibrator with an adjustable stimulator that stimulates the pelvic muscles with a customizable frequency, waveform, and intensity. The speaker stated Aetna classified the vibrator as a durable medical device (DME). However, the speaker

[2] https://mysteryvibe.com/

also indicated that Aetna's policy considers the vibrator as 'not primarily medical device' because it may be used in the absence of illness and injury. The speakers suggested that if CMS established a new HCPCS Level II code, insurers would be able to cover the device.

The pelvic floor muscle needs to be worked on and released both internally and externally. This is why clinicians recommend vibratory stimulation to promote proper function and pain reduction. The Crescendo 2 device is designed by doctors to mimic the fingers. It can be bent into 5 different shapes. It allows the right amount of stimulation at exact pain point to the pain. It can be used by a physical therapist during therapy or by the patient at home.

The main treatment option for pelvic pain is physical therapy provided by a physical therapist. Pelvic floor therapy is the coordinated control of the pelvic floor muscles to help reduce pelvic pain by improving the muscle tone, mobility, and strength. Where therapy is not effective, medications, injections, or surgical procedures can offer alternative solutions. According to the speaker, recent cost data indicate per patient cost for diagnostics is over $5,000 and treatment is approximately $9,000. The cost of the device is under $300, and the patient will only need two remote consultations at the beginning and end of treatment**.**

The speaker questioned if they could bill existing HCPCS Level II code E0740, "non-implanted pelvic floor electrical stimulator, complete system" to describe MysteryVibe Crescendo 2. The speaker explained that the same device is advertised on two websites, one as a medical device and the other non-medical. While the main purpose behind the product design was to address pelvic pain, Crescendo has proven effective in conditions like arousal disorder and anorgasmia. However, treating pelvic pain is fundamentally more important than arousal or orgasms. Following the publication of studies in the Journal of Sexual Medicine, MysteryVibe LLC started selling Crescendo 2 for pelvic pain. Over the past 2 years, 90% of our Crescendo 2 sales have been for pelvic pain and approximately 100,000 patients are using Crescendo 2 in the United States. According to the speaker, Crescendo 2 is recommended by healthcare practitioners at Mayo Clinic, Cedars Sinai, Rush, Northshore, etc.

**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 pelvic floor genital vibrator to treat pelvic pain and solving arousal issues. Crescendo 2 uses vibratory stimulation which is considered a massage modality and is ineligible for classification as DME within the Medicare program. While this device may be used to treat pelvic pain, it may be used in the absence of illness and injury. The manufacturer confirmed that the same device is advertised on two different websites with medical and no-medical indications. The study mentioned above was sponsored by MysteryVibe LLC, and out of the 21 subjects that enrolled, only 11 completed the study. Also, the effectiveness of the Crescendo pelvic therapy was not discussed during this study. 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.

## myPTM™, Personal Therapy Manager - HCP231221EK8Q5

### Topic/Issue

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

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

### Summary of Applicant's Submission

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

### CMS Preliminary HCPCS Coding Recommendation

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

### Preliminary Medicare Benefit Category Determination

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

**Preliminary Medicare Payment Determination**

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

Pricing Indicator = 46

**Summary of Public Feedback**

Medtronic disagreed with CMS' preliminary recommendations. The primary speaker stated that the response by the committee that the "relatively low volume of intrathecal drug delivery systems" does not warrant a code is not accurate. Looking at the last five years of CMS fee-for-service claims the volume of new IDDS implants ranged from 6,736 in 2022 to 9,482 in 2019. However, IDDS and the associated myPTM™ devices are not unique to Medicare patients, when accounting for total national volumes inclusive of all payers (calculation based on Inovalon commercial claims data) the total incident patient volume ranges from 17,942 to 22,655 per year. According to the speaker, HCPCS Level II coding decisions not only affect the ability to bill Medicare, but also the ability to bill commercial and other payers. As per the speaker, they do not believe procedure volume is a precursor to code designation. Moreover, the recommendation by CMS to use the miscellaneous code A9999 can cause significant issues in patient access for a replacement myPTM™ device, as many MACs and commercial carriers implement automatic manual review and approval of claims with this code causing additional time and expense for providers and payers. Very often, the commercial payers will deny a claim submitted with this code, with the patient then bearing the entire cost of a replacement device. Most implanted patients will require a myPTM™ device replacement given the average reasonable useful life is 5 years, shorter than the average useful life of the IDDS of 9 years. The myPTM™ is similar in nature to a handheld phone (it is used exclusively for managing the patient's IDDS therapy), where it is external to the body and undergoes natural wear/tear from everyday use. Another speaker explained the patient benefit of the myPTM™, which is the ability of the patient to deliver medication boluses throughout the day (within pre-set limits) due to the varying nature of pain intensity due to normal activities of daily living. This mitigates additional resources spent on patients having to come to the clinician's office for adjustment of medication dosage flow rates; which would still not deliver the same on-demand bolus of medication the myPTM™ can provide a patient real-time. Additionally, having a working myPTM™ device is important for patient safety as it allows them to show any clinician (for example during an ED visit) what medication(s), at what dose, and flow rate that are currently being delivered by their IDDS implant.

**CMS Final HCPCS Coding Decision**

We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments we received, CMS requires additional time to consider Medtronic's request to establish a new HCPCS Level II code to identify myPTM™. We are seeking clarification from the applicant what exactly they would like to be coded in a new HCPCS Level II code. In a request for information (RFI) sent to the applicant, the manufacturer explained that they would want a code specific to the patient programmer (i.e., the handset) and inclusive of the communicator, when required. However, within the HCPCS Level II application, there was no mention of the communicator, and the applicant's

suggested language only states the following: “Patient programmer (external) for use with implantable programmable infusion pump, replacement only.” Also, within the public meeting presentation, only the programmer was mentioned in relation to coding. In addition, CMS would like to request volume related to the replacement only for the year to date, and not necessarily all of the myPTM™ on the market. In the RFI, the applicant provided volume for peripheral replacements, but we would like the applicant to clarify if this information is just for the myPTM™, and if it is, what component(s) of the myPTM™ are included in the peripheral replacements. The use of miscellaneous codes helps avoid the inefficiency and administrative burden of assigning distinct codes for items or services that are rarely furnished or for which few claims are expected to be filed. As a result, CMS is deferring this application to a subsequent biannual coding cycle.

**Final Medicare Benefit Category Determination**

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

**Final Medicare Payment Determination**

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

## InTandem - HCP231229HB5QU

### Topic/Issue

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

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

### Summary of Applicant's Submission

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

### CMS Preliminary HCPCS Coding Recommendation

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

1. Could a patient use the auditory aspect without the clip attachment?

2. The applicant indicated that there are differences between InTandem music list and a commercial playlist. The studies provided compared InTandem to an active control, described as walking practice supervised by clinical investigators. Essentially, this

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

3. It seems that rhythmic auditory stimulation (RAS) methods, using only a metronome without music, may have similar effectiveness in gait training compared to this device. Therefore, the added significance of incorporating music does not appear to demonstrate greater efficacy in improving gait. Explain how InTandem differs from metronome for gait rehabilitation in patients post-stroke.

4. We would like to understand the distinctiveness of the music therapy for patients with a stroke compared to other types of music therapies for different diagnoses.

5. Are there other uses for the product besides this therapy? For instance, could it be used by patients that did not experience a stroke?

**Summary of Public Feedback**

MedRhythms Inc. addressed specific questions about InTandem. The speaker stated InTandem combines established rhythmic auditory stimulation **(**RAS) science, best practices in stroke rehabilitation, and technological innovation to improve outcomes for patients with chronic stroke. MedRhythms requested that CMS establish the unique HCPCS Level II code requested by the company and grant DME classification for InTandem to allow patients to maximize their recovery potential and achieve lasting health improvements.

InTandem is a gait modulating system that delivers a rehabilitation intervention designed with a scientific basis. InTandem uses pre-screened music to induce entrainment, with its control unit utilizing real-time gait sensing to automatically modify features of the music to personalize the rhythmic auditory stimulation. This autonomous modulation of the music, in turn, modulates the patient's gait towards a more desirable pattern and speed. According to the speaker, InTandem delivers a specific type of music-based intervention (RAS), which is a well-established neurologic rehabilitation technique and distinct from music therapy. While music therapy as a broad discipline can be applied to a wide range of conditions, including mental health disorders, developmental disabilities, and pain management, RAS is specifically designed to address the unique needs of individuals with neurologic motor conditions. RAS targets gait impairments by leveraging the strong connections between auditory and motor brain regions to facilitate the recovery of motor function. MedRhythms specifically analyzes, screens, and modifies music to only allow patients to select songs that meet the specific criteria to serve as an effective rhythm for InTandem's RAS-based intervention and are clinically optimized and modified for use by InTandem's hardware control unit and associated algorithms. The closed-loop algorithms used in InTandem's control unit deliver a multi-modal rhythmic stimulus that incorporates both music and a metronome feature to deliver an individualized, progressive, and challenging neurorehabilitation intervention. While the main rhythmic stimulus in this neurorehabilitation intervention is music-based, InTandem can overlay a rhythm-assist/metronome feature during a session to enhance the music's rhythmic structure, thus entraining the auditory-motor systems more strongly. The closed-loop algorithms are designed to automatically overlay and remove this rhythm-enhancing feature based on the gait parameters collected in real-time. InTandem's music-based approach, with the ability to overlay rhythm assist cues, represents an optimized method to maximize patient engagement, entrainment, and functional outcomes. MedRhythms has conducted initial feasibility studies exploring the potential of RAS-based

interventions in various populations, recognizing that InTandem's hardware and algorithms would need to be revised to address the specific gait impairments associated with each condition. The speaker reiterated that InTandem's RAS intervention is distinct from more general applications of music therapy due to its specific focus on gait rehabilitation in neurologic populations, its grounding in the neuroscience of rhythm and motor control, and its validation through clinical research in patients who experienced a stroke. While the foundational principles of RAS may extend to other neurologic conditions, InTandem in its current form is specifically designed and indicated for use in chronic stroke rehabilitation. InTandem requires shoe-worn sensor data with active gait data to activate the auditory stimulation. The system will not play music on a standalone basis without the gait data input from the sensors.

The speaker stated based on one of CMS' questions, that InTandem or the studies that have been published in relation to InTandem, should not be categorized as "no music and music." The study was designed in collaboration with the FDA to compare InTandem intervention to the standard of care (walking practice) in this chronic stroke population. According to the speaker, a study comparing InTandem to random music was not chosen for a variety of reasons. The underlying neuroscience supports that RAS, not just any music, is necessary to drive the desired neuromotor changes. InTandem's music is carefully selected and modified to deliver RAS, engaging specific neural pathways to induce targeted gait improvements. Generic music would not be expected to produce these effects. Moreover, MedRhythms' personnel and advisors have had experience delivering in-person RAS to many patients. This experience has consistently shown that commercial music alone does not yield meaningful gait changes. According to the speaker, there has been research in other patients with neurological gait impairments (Parkinson's Disease) suggesting random music could negatively impact gait parameters. Patients post stroke often suffer from similar cognitive and physical impairments as those with Parkinson's Disease, providing a further reason that commercial music played during walking is not comparable to InTandem intervention and will not achieve improved gait characteristics. In summary, while music is inherent to InTandem, the system is designed to produce meaningful, targeted gait improvements that go beyond any non-specific effects of music in general. The clinical evidence demonstrates InTandem's efficacy compared to standard walking practice, which is the most relevant comparison for this prescription device intended to improve gait speed and quality.

CMS received comments from stroke advocacy groups, patients recovering from stroke, and caregivers stating that many survivors face challenges accessing traditional physical therapy sessions for gait improvement, and many need more treatments than what their insurance will pay for. The comments indicated that InTandem gives patients recovering from stroke another option, filling a care gap for patients who otherwise must rely on clinic-based interventions for post-stroke gait impairments. Other speakers commented that in the field of neurorehabilitation for patients who experienced a stroke, effective interventions are primarily based on the concept of neuroplasticity. Well-recognized research demonstrates that neuroplastic effects are optimized when interventions are intensive, repetitious, challenging, and individualized, as interventions with these characteristics are best suited to help the stroke-damaged brain reorganize around the neural injury. A consistent barrier that is seen for patients with chronic stroke is a lack of access to rehabilitation once they have returned to the home. After discharge, many of the patients are unable to attend the clinic on regular basis. This is a highly undesirable outcome that negatively impacts their long-term recovery and health outcomes**.**

Other organizations commented on “lack of program operating need.” The speaker believes this denial reason is more commonly applied to digital technologies to identify an app-based product configuration, even if the item clearly demonstrates payor need, is evaluated in published studies, and otherwise meets the requirements of a DME hardware system. For example, InTandem meets Medicare’s DME criteria by providing a durable hardware controller to perform the medically necessary function and Point32 Health, a commercial insurance plan, submitting a letter demonstrating an operating need for new coding. MedRhythms consulted with the FDA and InTandem was granted Breakthrough Device Designation. As MedRhythms proceeded through the regulatory authorization process from 2020-2022, the FDA concluded that InTandem qualified as a Class II, 510(k)-exempt device. InTandem is a prescription-only product with specific indications for use in patients with chronic stroke with gait deficits. The software is deactivated at the end of the prescribed treatment period. MedRhythms does not have legal rights to the music content beyond this prescription use.

**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 E3200, “Gait modulation system, rhythmic auditory stimulation, including restricted therapy software, all components and accessories, prescription only” to describe InTandem.

InTandem is a gait modulating system that utilizes RAS, unlike a public commercial music playlist.

**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.

InTandem meets all five of the conditions that must be met in order for equipment to be classified as DME.

**Medicare Payment Determination**

No determination. CMS did not previously issue a preliminary payment determination for this device in this cycle. The payment determination for this item will be addressed at a

subsequent HCPCS Level II public meeting. MedRhythms Inc. has already submitted some payment-related information to CMS to assist in development of a payment determination; however, the applicant is welcome to provide any updated or new information during or prior to the public meeting.

At this time, the local fee schedule amounts for this item will 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 for Medicare payment determination for IpsiHand™ Upper Extremity Rehabilitation System.

### 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 HCPCS Coding Determination

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

### Medicare Benefit Category Determination

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

**Preliminary Medicare Payment Determination**

In accordance with Medicare regulations at 42 CFR § 414.238, fee schedule amounts for new HCPCS Level II codes for items and services without a fee schedule pricing history are established using existing fee schedule amounts for comparable items when items with existing fee schedule amounts are determined to be comparable to the new items and services based on a comparison of: physical components, mechanical components, electrical components, function and intended use, and additional attributes and features.

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

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

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

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

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

Pricing Indicator = 36

**Summary of Public Feedback**

CMS received a written comment that disagreed with CMS' published preliminary Medicare payment recommendation, believing that the proposed fee schedule amounts were not in line with the associated efficacy of the device.

**Final Medicare Payment Determination**

We are finalizing our preliminary payment determination to establish the Medicare payment amount in accordance with the "gap filling" methodology regulations at 42 CFR 414.238(c). We used commercial pricing of $30,000 for the IpsiHand™ Upper Extremity Rehabilitation System from the Federal Supply Schedule to gap-fill the fee schedule amount for HCPCS Level II code E0738. Annual deflation factors, specified in program instructions, are applied

and the deflated amount is increased by the update factors specified in section 1834(a)(14) of the Act for DME. The 2024 average non-rural capped rental fee schedule amount for HCPCS Level II code E0738 will be approximately $1,952.78 for months 1 through 3 and approximately $1,464.59 for months 4 through 13 for a total of $20,504.24 after 13 months of continuous use.

Pricing Indicator = 36

## Motus Hand and Motus Foot - HCP230314K8EQG

### Topic/Issue

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

### Summary of Applicant's Submission

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

### CMS Final HCPCS Coding Determination

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

### Medicare Benefit Category Determination

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

### Preliminary Medicare Payment Determination

In accordance with Medicare regulations at 42 CFR § 414.238, fee schedule amounts for new HCPCS Level II codes for items and services without a fee schedule pricing history are established using existing fee schedule amounts for comparable items when items with existing fee schedule amounts are determined to be comparable to the new items and services based on a comparison of: physical components, mechanical components, electrical components, function and intended use, and additional attributes and features. CMS identified the following HCPCS Level II codes to describe the Motus Hand and the Motus Foot: E1806 ("Static progressive stretch wrist device, flexion and/or extension, with or without range of motion adjustment, includes all components and accessories"), E1816 ("Static progressive stretch ankle device, flexion and/or extension, with or without range of motion adjustment, includes all components and accessories"), E0650 ("Pneumatic compressor, non-segmental home model") and E0655 ("Non-segmental pneumatic appliance for use with pneumatic compressor, half arm").

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

| | **E0650** | **E1806/E1816** | **E0655** | **Motus Hand and Motus Foot** |
|---|---|---|---|---|
| **Physical Components** | Pump or Control Unit<br><br>Wraps | Cuffs<br><br>Straps<br><br>Pads | Pump<br><br>Arm Wraps/Sleeves<br><br>Straps/Harness<br><br>Zippers | A Locked Touch Screen console<br><br>Pump<br><br>Hand or Foot Controller<br><br>Actuator |
| **Mechanical Components** | Pneumatic Pump | Wrist/Ankle Mechanical Joints | Pneumatic Pump<br><br>Segmental or Sequential Gradient Pressure<br><br>Non-Peristatic | Pneumatic Pump<br><br>Pneumatic Actuator |
| **Electrical Components** | Battery | | | Processors<br><br>Bio-feedback Sensors |
| **Function and Intended Use** | To provide timed periods of pressurized air to the affected area through a Single Outflow Port<br><br>Designed for the treatment of lymphedema or Chronic Venus | To provide static stretching with stress relaxation to elongate contracted tissue<br><br>Designed for the prevention and treatment of joint contractures with the goal to maintain or restore range of motion. | To provide gradient sequential or segmental gradient compression<br><br>Designed for the treatment of chronic venous statis ulcers and venous insufficiency | To deploy pneumatic artificial muscles for simulating dorsal muscle contraction and relaxation<br><br>Designed for patients who have had strokes or conditions that lead to upper limb movement disorders |

| | E0650 | E1806/E1816 | E0655 | Motus Hand and Motus Foot |
|---|---|---|---|---|
| | Insufficiency with venous stasis ulcers | | | including but not limited to: muscle tightness (tone), spasticity, weakness, or motor control deficits |
| **Additional Aspects and Features** | Pressure range 30-90 mm/Hg<br><br>Used by successive patients | Foam liner can be used.<br><br>Bidirectional to be used in flexion/extension (for wrist braces) and dorsiflexion/ plantarflexion (for ankle braces)<br><br>Used by successive patients | Pressure range 20-80 mm/Hg<br><br>Used by Single patients | Portable<br><br>Used by successive patients. |

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

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

Pricing Indicator = 36

**Summary of Public Feedback**

Motus Nova agreed with CMS' preliminary payment determination and the methodology used in the determination of the fee schedule. The speaker requested that CMS adds some additional information to the "Function and Intended Use" for the Motus Hand and Motus Foot, such as including lower limb and to read "...conditions that lead to upper limb or lower limb movement disorders…" The speaker recommended that the pricing indicator for HCPCS Level II code E0739 be classified as 32. The speaker mentioned that since April, a

broader base of supplier and commercial price lists has become available for HCPCS Level II code E0739. Price lists from Humana, Humana-Medicare, Aetna, Aetna-Medicare, Ambetter, Anthem, and Anthem Blue Cross Blue Shield were submitted as supplemental information for consideration. Another commenter disagreed with the preliminary payment determination expressing concerns that the fee schedule amounts are not in line with the associated efficacy of the device.

**Final Medicare Payment Determination**

We appreciate the comments provided in response to CMS' preliminary recommendations. Based on our conclusion that the Motus Hand and Motus Foot are not comparable to other items with an existing fee schedule, we are using the gap-fill methodology to establish the fee schedule amounts for HCPCS Level II code E0739. However, after consideration of the comments received and in accordance with regulations at 42 CFR 414.238(c), CMS is revising its preliminary payment recommendation and finalizing the establishment of fee schedule amounts using pricing submitted by Motus Nova during the public meeting process. To gap-fill the fee for HCPCS Level II code E0739, we used non-Medicare pricing sources for the Motus Hand and the Motus Foot that averaged to $22,745.44. The annual deflation factors as specified in program instructions were applied and the deflated amounts were then increased by the update factors specified in section 1834(a)(14) of the Act for DME. The 2024 average non-rural capped rental fee schedule amount for HCPCS Level II code E0739 will be approximately $1,529.65 for months 1 through 3 and approximately $1,147.24 for months 4 through 13 for a total of $16,061.35 after 13 months of continuous use.

We note that the Medicare definition of routinely purchased equipment under 42 CFR 414.220(a)(2) specifies that routinely purchased equipment means equipment that was acquired by purchase on a national basis at least 75 percent of the time during the period July 1986 through June 1987. Equipment that was not acquired by purchase on a national basis at least 75 percent of the time during the period July 1986 through June 1987 cannot be classified as routinely purchased equipment. HCPCS codes are classified as capped rental items if they do not fall under any of the other DME payment classes. Based on the information provided in the application, reclassification to a pricing indicator of 32 is not appropriate for the equipment described by HCPCS Level II code E0739.

Pricing Indicator = 36

## Vivally® System, Hardware Control Unit - HCP240102XXG03

### Topic/Issue

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

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

### Summary of Applicant's Submission

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

### CMS Preliminary HCPCS Coding Recommendation

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

**Preliminary Medicare Benefit Category Determination**

Durable Medical Equipment.

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

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

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

**Preliminary Medicare Payment Determination**

In accordance with regulations at § 414.238(b), fee schedule amounts for new HCPCS Level II codes for items and services without a fee schedule pricing history are established using existing fee schedule amounts for comparable items when items with existing fee schedule amounts are determined to be comparable to the new items and services based on a comparison of: Physical components, mechanical components, electrical components, function and intended use, and additional attributes and features. If there are no items with existing fee schedule amounts that are comparable to the items and services under the new code, the fee schedule amounts for the new code are established in accordance with paragraph (c) of this section.

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

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

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

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

Pricing Indicator = 36

**Summary of Public Feedback**

Avation Medical disagreed with CMS' preliminary recommendations. The speaker stated that Vivally® System is a revolutionary, closed-loop, wearable neuromodulation system to treat patients with chronic urge urinary incontinence and urinary urgency caused by OAB syndrome; it performs a significantly different function through its patented, FDA-recognized, closed-loop design. The speaker requested that CMS establish unique HCPCS Level II codes to describe both the hardware controller and garment, which are integral components to the Vivally® System's FDA-recognized, closed-loop operation. According to the speaker, this would be consistent with CMS' previous coding recognition of closed-loop

technologies. They also disagreed with the payment comparability determinations that CMS used to establish a preliminary payment amount for the Vivally® with hardware control and the Vivally® garment. They believe neither item is comparable to items described with existing codes, and CMS should use its gap-fill authority to establish fee schedules based on commercial pricing for these items. The speakers claimed that ZIDA and Vivally® should not be compared as one is an open-loop system and the other is a closed-loop system, as ZIDA's 510(k) does not reference closed-loop.

A speaker stated that the Vivally® System is the first and only closed-loop neuromodulation device for home use to treat symptoms of OAB syndrome. The Vivally® System's revolutionary closed-loop operation incorporates technological innovations that are significantly different from any other device to treat OAB, including advanced componentry, proprietary closed-loop control algorithms, embedded EMG sensors, and unique stimulation parameters. The Vivally® System continuously adjusts the stimulation output based on real-time EMG sensor data. A proprietary algorithm is implemented through a high-speed microprocessor, with broad data processing capabilities and a unique circuit board that can collect and interpret very low voltage EMG signals. The closed-loop algorithm ensures safety, usability, and efficacy for home use, as a self-adjusting system that needs no clinical supervision to achieve improved outcomes. Vivally® uses unique stimulation characteristics to maximize efficacy, safety and patient comfort. A fixed current amplitude of 20 mA is delivered with an internal feedback control circuit to ensure the same amount of charge is safely delivered to the patient, regardless of skin condition, body impedance, or other environmental factors. Unlike other devices, Vivally® modulates the pulse width of the stimulation, rather than the voltage or current, which avoids high current spikes for improved patient safety. Vivally® also generates a charge-balanced bi-phasic waveform that is more comfortable for patients, particularly at higher stimulation levels, than a monophasic waveform. This minimizes risk of tissue damage and pain, but this can only be achieved with Vivally®'s advanced electrical circuitry in the stimulator.

Another speaker stated that one of the most important innovations and trends they have witnessed has been the availability of true "closed-loop" neuromodulation systems to treat chronic conditions. True "closed-loop" systems can continue to adjust their stimulation over the course of therapy in response to changing input signals. Research shows that closed-loop systems can provide advantages over open-loop, fixed-output neuromodulation systems. The capability of closed-loop neuromodulation can be especially important for devices used outside of the clinical setting.

A speaker commented that in their clinical experience, they have treated thousands of patients with OAB. Standard in-office neuromodulation treatment for patients with OAB involves percutaneous tibial nerve stimulation (PTNS). PTNS requires weekly, in-office treatment sessions, typically for at least 12 weeks, during which a physician inserts a needle electrode through the skin. A non-invasive alternative treatment to PTNS is transcutaneous tibial nerve stimulation (TTNS). The Vivally® System's closed-loop operation objectively confirms activation of the nerve through the patient's EMG response, and automatically ensures that stimulation stays in a personalized, therapeutically optimal range. Because of this closed-loop functionality, a patient can self-administer therapy at home. According to the speaker, the Vivally® System is the only TTNS device they are aware of that has published data evaluating effectiveness beyond an initial 12-week period and has shown significant symptom reduction and life improvement out to 12 months.

## 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 E0736, "Transcutaneous tibial nerve stimulator" describes the controller kit component of the Vivally® System with hardware control unit.

It was confirmed that ZIDA Wearable Neuromodulation System is a closed-loop control system. As such, existing code E0736 describes Vivally® System with hardware control unit and ZIDA Wearable Neuromodulation System.

## Final Medicare Benefit Category Determination

Durable Medical Equipment.

As stated in our Preliminary Medicare Benefit Category Determination, during the benefit category determination process for multi-component devices, CMS has a longstanding policy of first determining which specific component provides the medically necessary function of rendering direct treatment (CMS-1577-F, November 10, 2011). That regulation explains that a multi-component device consisting of durable and non-durable components is considered non-durable if the component that performs the medically necessary function of the device is non-durable, even if other components of that device are durable. The Vivally® System components consist of a Hardware or Software Application Control Unit (in the case of this application, it's the Hardware Control Unit), a Garment, and Gel cushions. The Hardware Control Unit is comprised of a controller kit, including a rechargeable smart controller ("Controller") with proprietary closed-loop control algorithms, charging accessories, and a hardware control unit (a dedicated device to use the Vivally® System). According to the applicant, the Controller provides electrical stimulation through two transmission electrodes embedded in the Garment. The Controller also measures the EMG signal from the patient's foot via three additional EMG sensing electrodes embedded in the Garment. Of all the components making up the Vivally® System, the durable Controller component is the component that provides a medically necessary function because it is the component that delivers the electrical stimulation. The Controller meets all five of the conditions that must be met in order for equipment to be classified as DME.

## Final Medicare Payment Determination

We will be finalizing our preliminary Medicare payment determination. In accordance with regulations at § 414.238(b), fee schedule amounts for new HCPCS Level II codes for items and services without a fee schedule pricing history are established using existing fee schedule amounts for comparable items when items with existing fee schedule amounts are determined to be comparable to the new items and services based on a comparison of: Physical components, mechanical components, electrical components, function and intended use, and additional attributes and features. If there are no items with existing fee schedule amounts that are comparable to the items and services under the new code, the fee schedule amounts for the new code are established in accordance with paragraph (c) of this section.

We undertook a comparability analysis and still believe that the Vivally® Hardware Controller is comparable to HCPCS Level II code E0720. TENS units use two primary mechanisms. The first is the Gate Control Theory, which suggests that a neural mechanism in the spinal cord acts as a gate that controls the flow of pain signals to the brain. This gate can open or close based on signals from the brain, thereby altering the perception of pain. This mechanism is similar to how closed-loop neuromodulation devices aim to halt pain by delivering signals when pain is detected. The second mechanism is the Endorphin Release Theory, which proposes that electrical impulses from TENS units stimulate the production of endorphins and enkephalins in the body. These natural substances block pain messages from reaching the brain, functioning similarly to conventional drug therapy but without the risk of dependence or side effects. Only the Gate Control Theory aligns with the closed-loop concept.

In the research field, individuals have been applying stimuli to nerves that do not transmit pain signals with the aim of influencing those that do—a phenomenon termed neuromodulation. This mirrors the principles behind devices like transcutaneous electrical nerve stimulation (TENS) units or implanted spinal cord stimulators.[3] While many patients report significant relief from these interventions, the precise mechanisms driving their effectiveness are still not well understood. Neuromodulation refers to interventions that alter the strength of information transmission within neuronal circuits. It can be categorized into open or closed-loop systems. Closed-loop systems dynamically adjust electrical impulses and stimulation parameters based on continuous feedback from the patient's nervous system via a programmed algorithm, thus adapting to changes in the patient's condition. In contrast, open-loop systems operate on a fixed schedule regardless of the physiological state of the organ or system being modulated. Neuromodulation can regulate neural transmission through various physical forces such as mechanical, magnetic, and electrical pulses.[4] Electrical pulses, central to TENS units, can induce action potentials in excitable cells, eliciting predictable responses known as reflexes. This process is referred to as electrical stimulation. Additionally, neuromodulation devices can trigger responses in areas that previously exhibited none. Neuromodulation functions by actively stimulating nerves to induce natural biological responses or by delivering targeted pharmaceutical agents in minute doses directly to the site of action. [5] Furthermore, neurostimulation, which intricately influences nerves and represents an evolution from today's TENS systems, is a firmly established therapy for managing movement disorders. Neuromodulation involves applying stimuli to nerves that do not carry pain signals to influence those that do, an effect known as neuromodulation. Both the Vivally® System and the ZIDA Wearable Neuromodulation System employ the concept of neuromodulation.

We provide the below comparability analysis that details our comparison of the two codes.

[3] Sun, F. T., & Morrell, M. J. (2014). Closed-loop neurostimulation: The clinical experience. Neurotherapeutics, 11(3), 553–563. https://doi.org/10.1007/s13311-014-0280-3

[4] Sayenko, D. G., Bazo, H. a. C., Horner, P. J., & Taccola, G. (2022). Neuromodulation and restoration of motor responses after severe spinal cord injury. In Elsevier eBooks (pp. 51–63). https://doi.org/10.1016/b978-0-12-822427-4.00005-8

[5] Sayenko, D. G., Bazo, H. a. C., Horner, P. J., & Taccola, G. (2022)

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

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

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

Pricing Indicator = 36

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

### Topic/Issue

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

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

### Summary of Applicant's Submission

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

### CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a program operating need to establish a unique HCPCS Level II code to describe the Vivally® System configuration controlled by smartphone application. CMS’ determination is based on the device characteristics presented for review that rely on a smartphone. We welcome information from the applicant and other insurers who are currently paying for this product to demonstrate a claims processing need for a unique

HCPCS Level II code to describe the Vivally® System configuration controlled by the smartphone application.

**Summary of Public Feedback**

Avation Medical disagreed with CMS' preliminary recommendations. They requested CMS to establish a unique HCPCS Level II code for the Vivally's® app-enabled configuration, consistent with the prior decisions to establish unique codes for app-based solutions, including for different app-based and hardware-based configurations available for the same device. The speaker stated that based on their conversations to date with non-Medicare payors, unique coding is necessary to facilitate efficient claims processing for non-Medicare payors seeking to cover and assign different pricing for the hardware and app-based configurations. Moreover, establishing a unique code for the app-based configuration of the Vivally® System would further CMS' stated desire for the HCPCS process to "facilitate patient access to the advantages and benefits of innovative items or services by ensuring codes are available to providers and suppliers."

A speaker stated that Vivally® System is the first and only closed-loop neuromodulation device for home use to treat symptoms of OAB syndrome. The Vivally® System's revolutionary closed-loop operation incorporates technological innovations that are significantly different from any other device to treat OAB, including advanced componentry, proprietary closed-loop control algorithms, embedded EMG sensors, and unique stimulation parameters. The Vivally® System continuously adjusts the stimulation output based on real-time EMG sensor data. A proprietary algorithm is implemented through a high-speed microprocessor, with broad data processing capabilities and a unique circuit board that can collect and interpret very low voltage EMG signals. The closed-loop algorithm ensures safety, usability, and efficacy for home use, as a self-adjusting system that needs no clinical supervision to achieve improved outcomes. Vivally® uses unique stimulation characteristics to maximize efficacy, safety and patient comfort. A fixed current amplitude of 20 mA is delivered with an internal feedback control circuit to ensure the same amount of charge is safely delivered to the patient, regardless of skin condition, body impedance, or other environmental factors. Unlike other devices, Vivally® modulates the pulse width of the stimulation, rather than the voltage or current, which avoids high current spikes for improved patient safety. Vivally® also generates a charge-balanced bi-phasic waveform that is more comfortable for patients, particularly at higher stimulation levels, than a monophasic waveform. This minimizes risk of tissue damage and pain, but this can only be achieved with Vivally®'s advanced electrical circuitry in the stimulator.

Another speaker stated that one of the most important innovations and trends they have witnessed has been the availability of true "closed-loop" neuromodulation systems to treat chronic conditions. True "closed-loop" systems can continue to adjust their stimulation over the course of therapy in response to changing input signals. Research shows that closed-loop systems can provide advantages over open-loop, fixed-output neuromodulation systems. The capability of closed-loop neuromodulation can be especially important for devices used outside of the clinical setting.

A speaker commented that in their clinical experience, they have treated thousands of patients with OAB. Standard in-office neuromodulation treatment for patients with OAB involves percutaneous tibial nerve stimulation (PTNS). PTNS requires weekly, in-office treatment sessions, typically for at least 12 weeks, during which a physician inserts a needle electrode

through the skin. A non-invasive alternative treatment to PTNS is transcutaneous tibial nerve stimulation (TTNS). The Vivally® System's closed-loop operation objectively confirms activation of the nerve through the patient's EMG response, and automatically ensures that stimulation stays in a personalized, therapeutically optimal range. Because of this closed-loop functionality, a patient can self-administer therapy at home. According to the speaker, the Vivally® System is the only TTNS device they are aware of that has published data evaluating effectiveness beyond an initial 12-week period and has shown significant symptom reduction and life improvement out to 12 months.

**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, and consistent with our decision to establish new HCPCS Level II code E4545 to describe the accessories and supplies for the Vivaly® System, CMS is revising its preliminary recommendation and finalizing the decision to:

Establish a new HCPCS Level II code E0737, "Transcutaneous tibial nerve stimulator, controlled by phone application" to describe the Vivally® System that is controlled by a smartphone application.

**Final Medicare Benefit Category Determination**

No Medicare DMEPOS benefit category.

Durable medical equipment (DME) is defined in section 1861(n) of the Social Security Act and in Medicare regulations at title 42 Code of Federal Regulations (CFR) 414.202, and means equipment, furnished by a supplier or a home health agency that meets the following conditions:

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

During the benefit category determination process for multi-component devices, CMS has a longstanding policy of first determining which specific component provides the medically necessary function of rendering direct treatment (CMS-1577-F, November 10, 2011). That regulation explains that a multi-component device consisting of durable and non-durable components is considered non-durable if the component that performs the medically necessary function of the device is non-durable, even if other components of that device are durable. The Vivally® System components consist of a Hardware or Software Application Control Unit (in the case of this application, it's the Software Application Control Unit), a Garment, and Gel cushions. The Software Application Control Unit is comprised of a controller kit, including a rechargeable smart controller ("Controller") with proprietary closed-loop control algorithms, charging accessories, and a hardware control unit (a dedicated device with software to use the Vivally® System). According to the applicant, the

Controller provides electrical stimulation through two transmission electrodes embedded in the Garment. The Controller also measures the EMG signal from the patient's foot via three additional EMG sensing electrodes embedded in the Garment.

Of all the components making up the Vivally® System, the durable Controller component is the component that provides a medically necessary function because it is the component that delivers the electrical stimulation. The Controller meets all five of the conditions that must be met in order for equipment to be classified as DME. However, the Vivally® System with Software Application does not meet the definition of DME because it relies on a patient's smartphone and Vivally®'s app to function (e.g., turn on, turn off, and program settings). A personal smartphone device is useful to an individual in the absence of an illness or injury. We note that this is consistent with a prior benefit category decision for a multi-component device that similarly utilized a personal smartphone device and software application to initiate and manage therapy sessions.[6]

**Final Medicare Payment Category Determination**

No Medicare DMEPOS payment. Pricing = 00

[6] eXciteOSA® device. https://www.cms.gov/files/document/2023-hcpcs-application-summary-biannual-1-2023-non-drug-and-non-biological-items-and-services.pdf

## Vivally® System, Gel Cushion - HCP24010291273

### Topic/Issue

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

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

### Summary of Applicant's Submission

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

### CMS Preliminary HCPCS Coding Recommendation

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

### Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

During the benefit category determination process for multi-component devices, CMS has a longstanding policy of first determining which specific component provides the medically necessary function of rendering direct treatment. The Vivally® System components consist of a Controller, a Garment, and Gel cushions. Of the three components the Controller component is the sole component that provides a medically necessary function. The Vivally® System Gel Cushions meet the definition of DME because the Vivally® System Controller meets all of the conditions listed in Medicare regulations at title 42 Code of Federal Regulations (CFR) 414.202, and thus is DME.

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

**Preliminary Medicare Payment Determination**

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

Pricing Indicator = 34

**Summary of Public Feedback**

Avation Medical agreed with CMS' published preliminary HCPCS Level II coding recommendation that existing HCPCS Level II code A4595 describes the gel cushion component of the Vivally® System.

**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 A4545, "Supplies and accessories for external tibial nerve stimulator (e.g., socks, gel pads, electrodes, etc.), needed for one month" to describe the gel cushion component of the Vivally® System.

We believe a singular HCPCS Level II code is appropriate to describe all of the supplies and accessories that are needed for devices under HCPCS Level II codes E0736 and E0737 to function.

**Final Medicare Benefit Category Determination**

Durable Medical Equipment.

**Final Medicare Payment Determination**

As explained in more detail below, the monthly fee schedule amounts for HCPCS Level II code A4545 are based on the average of the monthly unadjusted fee schedule amounts for existing HCPCS Level II codes for items comparable to the accessories used with two versions of the equipment described by HCPCS Level II code E0736.

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 explained

in more detail below, one version of a device described by HCPCS Level II code E0736 works with supplies and accessories that are described by HCPCS Level II code A4595. This version does not use a conductive garment and all accessories for transcutaneous nerve stimulators other than a conductive garment fall under HCPCS Level II code A4595 and are paid using the monthly fee schedule amounts for this HCPCS Level II code. A second version of a device described by HCPCS Level II code E0736 works with a conductive garment described by HCPCS Level II code E0731 in lieu of the supplies and accessories described by HCPCS Level II code A4595. HCPCS Level II code E0731 is a non-durable accessory that is replaced once a year in accordance with Medicare claims data and is only paid for on a lump sum purchase basis. The final pricing methodology for new HCPCS Level II code A4545 is to use the average of the unadjusted fee schedule amounts for HCPCS Level II code A4595 and the unadjusted fee schedule amounts for HCPCS Level II code E0731 divided by 12 to convert the purchase fee schedule amounts for HCPCS code E0731 to monthly fee schedule amounts.

We concluded in our preliminary coding recommendation that existing HCPCS Level II code A4595, “Electrical stimulator supplies, 2 lead, per month, (e.g., tens, nmes)” describes the EMG-sensing garment of the Vivally® System as well as the gel cushion component of the Vivally® System. We also finalized in the B2 2023 coding cycle our decision to 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. We said that the ZIDA control sock uses nerve stimulation through transcutaneous electrical stimulation of the posterior tibial nerve near the ankle. We also said that 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.

Our data indicates that HCPCS Level II code E0731 typically has one unit of service per beneficiary per year. To calculate the 2024 monthly fee schedule amount for new HCPCS Level II code A4545, we first divide the 2024 unadjusted purchase new fee schedule amount for HCPCS Level II code E0731 by 12 to calculate the monthly fee schedule amount for the code. Then, we add the monthly unadjusted fee schedule amounts for HCPCS Level II code A4595 and divide by two to compute the monthly fee schedule amounts for supplies and accessories for the external tibial nerve stimulator. The average 2024 monthly fee schedule amount for HCPCS Level II code A4545 is $39.19.

In sum, HCPCS Level II code E0731 divided by twelve equals the monthly cost of the accessory that is used with the ZIDA transcutaneous tibial nerve stimulator (in this case a conductive garment). HCPCS Level II code A4595 equals the monthly cost of the accessories used with the Vivally® transcutaneous tibial nerve stimulator (in this case gel cushions and a garment). We then add both fees together and divide by two to come up with the average monthly cost of accessories for the transcutaneous tibial nerve stimulators described by HCPCS level II code E0736.

Pricing Indicator = 34

## Vivally® System, Garment - HCP2401029GHMA

### Topic/Issue

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

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

### Summary of Applicant's Submission

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

### CMS Preliminary HCPCS Coding Recommendation

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

### Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

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

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

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

**Preliminary Medicare Payment Determination**

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

Pricing Indicator = 34

**Summary of Public Feedback**

Avation Medical disagreed with CMS' preliminary recommendations. The speaker stated that Vivally® System is a revolutionary, closed-loop, wearable neuromodulation system to treat patients with chronic urge urinary incontinence and urinary urgency caused by OAB syndrome; it performs a significantly different function through its patented, FDA-recognized, closed-loop design. The speaker requested that CMS establish unique HCPCS Level II codes to describe both the hardware controller and garment, which are integral components to the Vivally® System's FDA-recognized, closed-loop operation. According to the speaker, this would be consistent with CMS' previous coding recognition of closed-loop technologies. They also disagreed with the payment comparability determinations that CMS used to establish a preliminary payment amount for the Vivally® with hardware control and the Vivally® garment. They believe neither item is comparable to items described with existing codes, and CMS should use its gap-fill authority to establish fee schedules based on commercial pricing for these items. The speakers claimed that ZIDA and Vivally® should not be compared as one is an open-loop system and the other is a closed-loop system, as ZIDA's 510(k) does not reference closed-loop. A speaker stated that the Vivally® garment is an integral component of the closed-loop operation, with embedded EMG-sensing and stimulation electrodes developed using a proprietary manufacturing process that achieves a wireless design. To develop the garment, Avation Medical conducted multiple clinical and human factors studies.

**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 A4545, "Supplies and accessories for external tibial nerve stimulator (e.g., socks, gel pads, electrodes, etc.), needed for one month" to describe the EMG-sensing garment of the Vivally® System.

We believe a singular HCPCS Level II code is appropriate to describe all of the supplies and accessories that are needed for devices under HCPCS Level II code E0736 and E0737 to function.

**Final Medicare Benefit Category Determination**

Durable Medical Equipment.

**Final Medicare Payment Determination**

As explained in more detail below, the monthly fee schedule amounts for HCPCS Level II code A4545 are based on the average of the monthly unadjusted fee schedule amounts for existing HCPCS Level II codes for items comparable to the accessories used with two versions of the equipment described by HCPCS Level II code E0736.

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 explained in more detail below, one version of a device described by HCPCS Level II code E0736 works with supplies and accessories that are described by HCPCS Level II code A4595. This version does not use a conductive garment and all accessories for transcutaneous nerve stimulators other than a conductive garment fall under HCPCS Level II code A4595 and are paid using the monthly fee schedule amounts for this HCPCS Level II code. A second version of a device described by HCPCS Level II code E0736 works with a conductive garment described by HCPCS Level II code E0731 in lieu of the supplies and accessories described by HCPCS Level II code A4595. HCPCS Level II code E0731 is a non-durable accessory that is replaced once a year in accordance with Medicare claims data and is only paid for on a lump sum purchase basis. The final pricing methodology for new HCPCS Level II code A4545 is to use the average of the existing unadjusted fee schedule amounts for HCPCS Level II code A4595 and the existing unadjusted fee schedule amounts for HCPCS Level II code E0731 divided by 12 to convert the purchase fee schedule amounts for HCPCS code E0731 to monthly fee schedule amounts.

We concluded in our preliminary coding recommendation that existing HCPCS Level II code A4595, “Electrical stimulator supplies, 2 lead, per month, (e.g., tens, nmes)” describes the EMG-sensing garment of the Vivally® System as well as the gel cushion component of the Vivally® System. We also finalized in the B2 2023 coding cycle our decision to 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. We said that the ZIDA control sock uses nerve stimulation through transcutaneous electrical stimulation of the posterior tibial nerve near the ankle. We also said that 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.

Our data indicates that HCPCS Level II code E0731 typically has one unit of service per beneficiary per year. To calculate one monthly amount for new HCPCS Level II code A4545, we first divide the 2024 purchase new unadjusted fee schedule amount for HCPCS Level II code E0731 by 12 to calculate the monthly fee schedule amount for the code. Then, we add the monthly unadjusted fee schedule amounts for HCPCS Level II code A4595 and divide by two to compute the monthly fee schedule amounts for supplies and accessories for the

external tibial nerve stimulator. The average 2024 monthly fee schedule amount for HCPCS Level II code A4545 is $39.19.

In sum, HCPCS Level II code E0731 divided by twelve equals the monthly cost of the accessory that is used with the ZIDA transcutaneous tibial nerve stimulator (in this case a conductive garment). HCPCS Level II code A4595 equals the monthly cost of the accessories used with the Vivally® transcutaneous tibial nerve stimulator (in this case gel cushions and a garment). We then add both fees together and divide by two to come up with the average monthly cost of accessories for the transcutaneous tibial nerve stimulators described by HCPCS level II code E0736.

Pricing Indicator = 34

## ZIDA Wearable Neuromodulation System - HCP230703TF2YL

### Topic/Issue

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

### Summary of Applicant's Submission

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

### CMS Final HCPCS Coding Determination

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

**Medicare Benefit Category Determination**

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

**Preliminary Medicare Payment Determination**

In the Second Biannual 2023 HCPCS Level II coding cycle, we deferred our payment determination for the ZIDA Wearable Neuromodulation control unit. With further analysis, we are now able to establish a preliminary payment determination. We establish fee schedule amounts for new HCPCS Level II codes for items and services without a fee schedule pricing history in accordance with regulations at 42 CFR § 414.238. For new HCPCS Level II codes for items and services without a fee schedule pricing history we use the existing fee schedule amounts for comparable items when these items are determined to be comparable to the new items and services based on a comparison of physical components, mechanical components, electrical components, function and intended use, and additional attributes and features.

With further analysis of the ZIDA Wearable Neuromodulation control unit, we have concluded that it is comparable to HCPCS Level II code E0720 (Transcutaneous electrical nerve stimulation (TENS) device, two lead, localized simulation) with respect to the physical and electrical components and the function (nerve stimulation through transcutaneous electrical stimulation). See below table. We note that although an application for a HCPCS Level II code, benefit category, and payment determination may be made by a specific company for a particular item, we must establish payment amounts based on pricing information available for all items that would be included in the Product Classification List (PCL).

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

CMS recognizes the new indications through our preliminary valuation to compare the technology to HCPCS Level II code E0720 devices prior to competitive bidding, when

devices to treat a range of conditions like insomnia, depression, anxiety, pain, and in this case, urinary incontinence, were not available to suppliers engaging in the competitive bidding program. As such, CMS would establish the fees for HCPCS Level II code E0736 using fees for HCPCS Level II code E0720 that were not adjusted using information from the DMEPOS Competitive Bidding Program.[7]

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

Pricing Indicator = 36

**Summary of Public Feedback**

Zida LLC disagreed with the Medicare preliminary payment determination for the ZIDA Wearable Neuromodulation control unit. The presenter requested CMS to pay an equitable reimbursement rate to ensure Medicare beneficiaries would have access to this form of treatment. The speaker also requested that CMS should base its payment determination on what commercial insurers are paying for this technology. The presenter also asserted that the ZIDA Wearable Neuromodulation System is a closed-loop system. In written comments, the applicant requested that CMS either price the ZIDA Wearable Neuromodulation control unit based on commercial pricing for the Vivally® System's Hardware Control Unit (HCP240102XXG03), or base pricing on the Cala Trio device that is coded under HCPCS Level II code E0734.

**Final Medicare Payment Determination**

We will be finalizing our preliminary Medicare payment determination. Per 42 CFR 414.238(c)(1), we only use commercial pricing (gap-filling) when we determine that new HCPCS codes are not comparable to items and services with existing fee schedule amounts. In this case, we believe that the ZIDA Wearable Neuromodulation control unit is comparable to HCPCS Level II code E0720 (Transcutaneous electrical nerve stimulation (TENS) device, two lead, localized simulation) with respect to the physical and electrical components and the function (nerve stimulation through transcutaneous electrical stimulation). See below table.

In the research field, individuals have been applying stimuli to nerves that do not transmit pain signals with the aim of influencing those that do—a phenomenon termed neuromodulation. This mirrors the principles behind devices like transcutaneous electrical nerve stimulation (TENS) units or implanted spinal cord stimulators.[8] While many patients

[7] CMS has similarly applied comparability using unadjusted fee schedule amounts for Alpha-Stim® Cranial Electrotherapy Stimulation, 19.117, the Monarch eTNS System®, 20.070, and the gammaCore Sapphire™, 20.173.

[8] Sun, F. T., & Morrell, M. J. (2014). Closed-loop neurostimulation: The clinical experience. Neurotherapeutics, 11(3), 553–563. https://doi.org/10.1007/s13311-014-0280-3

report significant relief from these interventions, the precise mechanisms driving their effectiveness are still not well understood. Neuromodulation refers to interventions that alter the strength of information transmission within neuronal circuits. It can be categorized into open or closed-loop systems. Closed-loop systems dynamically adjust electrical impulses and stimulation parameters based on continuous feedback from the patient's nervous system via a programmed algorithm, thus adapting to changes in the patient's condition. In contrast, open-loop systems operate on a fixed schedule regardless of the physiological state of the organ or system being modulated. Neuromodulation can regulate neural transmission through various physical forces such as mechanical, magnetic, and electrical pulses.[9] Electrical pulses, central to TENS units, can induce action potentials in excitable cells, eliciting predictable responses known as reflexes. This process is referred to as electrical stimulation. Additionally, neuromodulation devices can trigger responses in areas that previously exhibited none. Neuromodulation functions by actively stimulating nerves to induce natural biological responses or by delivering targeted pharmaceutical agents in minute doses directly to the site of action.[10] Furthermore, neurostimulation, which intricately influences nerves and represents an evolution from today's TENS systems, is a firmly established therapy for managing movement disorders. Therefore, we believe the underlying concept of TENS units is akin to neuromodulation. Neuromodulation involves applying stimuli to nerves that do not carry pain signals to influence those that do, an effect known as neuromodulation. Both the Vivally® System and the ZIDA Wearable Neuromodulation System employ the concept of neuromodulation.

We will be establishing 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(b). 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.

| | **E0720** | **Zida Control Unit** |
|---|---|---|
| **Physical Components** | Control Unit | Control Unit |
| **Mechanical Components** | - | - |
| **Electrical Components** | Battery<br><br>Biphasic waveforms | Battery<br><br>Monophasic square waves |
| **Function and Intended Use** | Nerve stimulation through transcutaneous electrical stimulation of peripheral nerves<br><br>To treat patients with acute and chronic injuries and pain | Nerve stimulation through transcutaneous electrical stimulation of the posterior tibial nerve (TTNS) near the ankle<br><br>To treat patients with an overactive bladder (OAB) and associated symptoms of urinary urgency, |

[9] Sayenko, D. G., Bazo, H. a. C., Horner, P. J., & Taccola, G. (2022). Neuromodulation and restoration of motor responses after severe spinal cord injury. In Elsevier eBooks (pp. 51–63). https://doi.org/10.1016/b978-0-12-822427-4.00005-8

[10] Sayenko, D. G., Bazo, H. a. C., Horner, P. J., & Taccola, G. (2022)

| | E0720 | Zida Control Unit |
|---|---|---|
| | | urinary frequency, and urge incontinence. |
| **Additional Aspects and Features** | Low frequency usually below 300HZ | Fixed pulse frequency of 20 Hz |

CMS recognizes the new indications through our preliminary valuation to compare the technology to HCPCS Level II code E0720 devices prior to competitive bidding, when devices to treat a range of conditions like insomnia, depression, anxiety, pain, and in this case, urinary incontinence, were not available to suppliers engaging in the competitive bidding program. As such, CMS would establish the fees for HCPCS Level II code E0736 using fees for HCPCS Level II code E0720 that were not adjusted using information from the DMEPOS Competitive Bidding Program.[11]

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

Pricing Indicator = 36

Regarding the control sock for the ZIDA Wearable Neuromodulation System, as indicated in the Final HCPCS Coding Decision for the Vivally® System, we will be establishing a new HCPCS Level II code A4545, “Supplies and accessories for external tibial nerve stimulator (e.g., socks, gel pads, electrodes, etc.), needed for one month”. Therefore, this code will now describe the control sock used with the ZIDA Wearable Neuromodulation System.

As explained in more detail below, the monthly fee schedule amounts for HCPCS level II code A4545 are based on the average of the monthly unadjusted fee schedule amounts for existing HCPCS level II codes for items comparable to the accessories used with two versions of the equipment described by HCPCS level II code E0736.

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 explained in more detail below, one version of a device described by HCPCS Level II code E0736 works with supplies and accessories that are described by HCPCS Level II code A4595. This version does not use a conductive garment and all accessories for transcutaneous nerve

[11] CMS has similarly applied comparability using unadjusted fee schedule amounts for Alpha-Stim® Cranial Electrotherapy Stimulation, 19.117, the Monarch eTNS System®, 20.070, and the gammaCore Sapphire™, 20.173.

stimulators other than a conductive garment fall under HCPCS Level II code A4595 and are paid using the monthly fee schedule amounts for this HCPCS Level II code. A second version of a device described by HCPCS Level II code E0736 works with a conductive garment described by HCPCS Level II code E0731 in lieu of the supplies and accessories described by HCPCS Level II code A4595. HCPCS Level II code E0731 is a non-durable accessory that is replaced once a year in accordance with Medicare claims data and is only paid for on a lump sum purchase basis. The final pricing methodology for new HCPCS Level II code A4545 is to use the average of the existing unadjusted fee schedule amounts for HCPCS Level II code A4595 and the existing unadjusted fee schedule amounts for HCPCS Level II code E0731 divided by 12 to convert the purchase fee schedule amounts for HCPCS code E0731 to monthly fee schedule amounts.

We concluded in our preliminary coding recommendation for the Vivally® System that existing HCPCS Level II code A4595, “Electrical stimulator supplies, 2 lead, per month, (e.g., tens, nmes)” describes the EMG-sensing garment of the Vivally® System as well as the gel cushion component of the Vivally® System. We also finalized in the B2 2023 coding cycle our decision to 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. We said that the ZIDA control sock uses nerve stimulation through transcutaneous electrical stimulation of the posterior tibial nerve near the ankle. We also said that 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.

Our data indicates that HCPCS Level II code E0731 typically has one unit of service per beneficiary per year. To calculate one monthly amount for new HCPCS Level II code A4545, we first divide the 2024 purchase new unadjusted fee schedule amount for HCPCS Level II code E0731 by 12 to calculate the monthly fee schedule amount for the code. Then, we add the monthly unadjusted fee schedule amounts for HCPCS Level II code A4595 and divide by two to compute the monthly fee schedule amounts for supplies and accessories for the external tibial nerve stimulator. The average 2024 monthly fee schedule amounts for HCPCS Level II code A4545 is $39.19..

In sum, HCPCS Level II code E0731 divided by twelve equals the monthly cost of the accessory that is used with the ZIDA transcutaneous tibial nerve stimulator (in this case a conductive garment). HCPCS Level II code A4595 equals the monthly cost of the accessories used with the Vivally® transcutaneous tibial nerve stimulator (in this case gel cushions and a garment). We then add both fees together and divide by two to come up with the average monthly cost of accessories for the transcutaneous tibial nerve stimulators described by HCPCS level II code E0736.

Pricing Indicator = 34

## Flyte® System Controller - HCP24010236LW3

### Topic/Issue

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

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

### Summary of Applicant's Submission

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

### CMS Preliminary HCPCS Coding Recommendation

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

### Preliminary Medicare Benefit Category Determination

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

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

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

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

**Preliminary Medicare Payment Determination**

No Medicare payment. Pricing Indicator = 00

**Summary of Public Feedback**

Pelvital USA, Inc. disagreed with CMS' preliminary HCPCS Level II coding recommendation. The speaker stated that the determination that the Wand performs the medically necessary function of the system is incorrect. Instead, the Flyte® System Controller performs the medically necessary function of the system. According to the speaker, the Controller initiates, controls, algorithmically generates, and manages the mechanotherapy that affects and strengthens the pelvic floor muscle. The strengthening of pelvic floor muscles is recognized by the American College of Physicians clinical practice guidelines as a first-line conservative treatment and creation of muscle memory aids in durability of treatment. The Controller initiates the therapy and enables the Wand to vibrate at a specific frequency and timing. In reference to the "vibrating motor" the motor does not vibrate and does not directly affect and strengthen the pelvic floor muscle. The Controller initiates and controls delivery of therapy by sending signals to a motor in the Wand, which in turn causes an eccentric weight to oscillate, creating vibration. Vibrations in that specific frequency range deliver transvaginal mechanotherapy, in a process called mechanotransduction.

According to the speaker, the Controller functions are very similar to other multi-component devices, where CMS determined that the Controller performs the medically necessary function of that system and thus should be assessed for durability under the definition of durable medical equipment. When considering other decisions involving multi-component systems that similarly involve the delivery of energy, only a determination that the Controller performs the medically necessary function of the Flyte System would be consistent with previous CMS decisions (e.g., Vivally, ZIDA, PoNS™).

Additionally, the speaker indicated that there is a program operating need to establish a new HCPCS Level II codes to describe the Flyte® System Controller and Wand. The speaker reiterated that existing HCPCS Level II code E0740, "non-implanted pelvic floor electrical stimulator, complete system" is not appropriate, as the Flyte System uses transvaginal mechanotherapy to treat stress urinary incontinence as opposed to electrical stimulation. Another speaker explained the importance of the Flyte System to women with stress urinary incontinence, as important conservative treatment option that can prevent patients from

undergoing an invasive surgical procedure. The speakers urge CMS to establish HCPCS Level II codes for both components of this system to fill a significant gap in conservative care for women with stress urinary incontinence.

**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 E0715, "Intravaginal device intended to strengthen pelvic floor muscles during kegel exercises" to describe the Flyte® System Controller.

Other payers identified a program operating need for a new HCPCS Level II code to describe the Flyte® System Controller.

**Final Medicare Benefit Category Determination[12]**

No Medicare DMEPOS benefit category.

As stated in Chapter 1, Part 1, Section 230.8 of the Medicare National Coverage Determinations Manual (CMS Pub. 100-03), Medicare may cover a non-implantable pelvic floor electrical stimulator that provides neuromuscular electrical stimulation through the pelvic floor. However, the Flyte® System does not provide neuromuscular electrical stimulation to the pelvic floor and does not align with the Medicare coverage requirement.

The Flyte® System strengthens the pelvic floor muscle by delivering mechanical vibrations during pelvic floor contractions. We do not agree that the durable Flyte® Controller is the component of the Flyte® System that delivers the mechanical vibrations. The Flyte® Controller is a hand-held external component that pilots the Flyte® Wand. The Flyte® Wand is the component that provides vibratory pulses to the pelvic floor muscles. Electrical nerve stimulators such as the Portable Neuromodulation Stimulator (PoNS™), the Vivally® System, and the ZIDA Wearable Neuromodulation System all produce the electrical stimulation that provides the medically necessary treatment for the patient and are durable equipment. In the Flyte® System, the non-durable Flyte® Wand component, rather than the durable Flyte® Controller component, provides the medically necessary vibrations and treatment for the patient.

**Final Medicare Payment Determination**

No Medicare payment. Pricing Indicator = 00

[12] Updated on October 7, 2024 for further clarification for Medicare's final benefit category determination.

## Flyte® System Wand - HCP240102C74P1

### Topic/Issue

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

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

### Summary of Applicant's Submission

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

### CMS Preliminary HCPCS Coding Recommendation

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

### Preliminary Medicare Benefit Category Determination

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

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

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

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

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

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

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

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

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

**Preliminary Medicare Payment Determination**

No Medicare payment. Pricing Indicator = 00

**Summary of Public Feedback**

Pelvital USA, Inc. disagreed with CMS' preliminary HCPCS Level II coding recommendation. The speaker stated that the determination that the Wand performs the medically necessary function of the system is incorrect. Instead, the Flyte® System Controller performs the medically necessary function of the system. According to the speaker, the Controller initiates, controls, algorithmically generates, and manages the mechanotherapy that affects and strengthens the pelvic floor muscle. The strengthening of pelvic floor muscles is recognized by the American College of Physicians clinical practice guidelines as a first-line conservative treatment and creation of muscle memory aids in durability of treatment. The Controller initiates the therapy and enables the Wand to vibrate at a specific frequency and timing. In reference to the "vibrating motor" the motor does not vibrate and does not directly affect and strengthen the pelvic floor muscle. The Controller initiates and controls delivery of therapy by sending signals to a motor in the Wand, which in turn causes an eccentric weight to oscillate, creating vibration. Vibrations in that specific frequency range deliver transvaginal mechanotherapy, in a process called mechanotransduction.

According to the speaker, the Controller functions are very similar to other multi-component devices, where CMS determined that the Controller performs the medically necessary function of that system and thus should be assessed for durability under the definition of durable medical equipment. When considering other decisions involving multi-component systems that similarly involve the delivery of energy, only a determination that the Controller performs the medically necessary function of the Flyte System would be consistent with previous CMS decisions (e.g., Vivally, ZIDA, PoNS™).

Additionally, the speaker indicated that there is a program operating need to establish a new HCPCS Level II codes to describe the Flyte® System Controller and Wand. The speaker reiterated that existing HCPCS Level II code E0740, "non-implanted pelvic floor electrical stimulator, complete system" is not appropriate, as the Flyte System uses transvaginal mechanotherapy to treat stress urinary incontinence as opposed to electrical stimulation. Another speaker explained the importance of the Flyte System to women with stress urinary incontinence, as important conservative treatment option that can prevent patients from undergoing an invasive surgical procedure. The speakers urge CMS to establish HCPCS Level II codes for both components of this system to fill a significant gap in conservative care for women with stress urinary incontinence.

**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 E0716 "Supplies and accessories for intravaginal device intended to strengthen pelvic floor muscles during kegel exercises" to describe the Flyte® System Wand.

Other payers identified a program operating need for a new HCPCS Level II code to describe the Flyte® System Wand.

**Final Medicare Benefit Category Determination**

No Medicare DMEPOS benefit category.

**Final Medicare Payment Determination**

No Medicare payment. Pricing Indicator = 00

## NTX-100 Tonic Motor Activation (TOMAC) System - HCP231231EPL6H

### Topic/Issue

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

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

### Summary of Applicant's Submission

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

### CMS Preliminary HCPCS Coding Recommendation

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

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

### Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

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

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

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

**Preliminary Medicare Payment Determination**

In accordance with regulations at 42 CFR 414.238(c), fee schedule amounts for items and services without a fee schedule pricing history described by new HCPCS Level II codes that are not comparable to items and services with existing fee schedule amounts may be established using supplier price lists, including catalogs and other retail price lists (such as internet retail prices) that provide information on commercial pricing for the item. If the purchase price used in calculating the fee schedule amounts is greater than $150, then payment would be made on a capped rental basis in accordance with our regulations at 42 CFR 414.229. If the only available price information is from a period other than the fee schedule base period (for supplies, the 12-month period of 1986/1987), deflation factors are applied against current pricing in order to approximate the base period price. The annual deflation factors are specified in Medicare Claims Processing Manual, Chapter 23, Section 60.3 and the deflated amounts are then increased by the update factors specified in section 1834(a)(14) of the Social Security Act for DME.

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

| | NTX-100 | E0720 | E0734 |
|---|---|---|---|
| **Physical Components** | Therapy control unit<br><br>Lower body garment/cuff<br><br>Charging accessories<br><br>Each unit configured for a single electrode | Therapy control unit<br><br>Electric wiring for electrodes<br><br>Common configurations provide for attaching two or four leads | Therapy control unit<br><br>Wrist garment<br><br>Configured for attaching three electrodes<br><br>Base station for charging |
| **Mechanical Components** | - | - | Gyroscope and accelerometer |
| **Electrical Components** | Battery<br><br>Electronics for control mechanism<br><br>Delivers 30 mA at 4000 Hz to electrodes | Battery<br><br>Electronics for control mechanism<br><br>Delivers pulses at varying frequency and current, typically 50-100 Hz | Battery<br><br>Electronics for control mechanism<br><br>Delivers pulses at 150 Hz, alternating between two electrodes through an accelerometer |
| **Function and Intended Use** | To treat restless legs syndrome by delivering high current, high frequency electrical stimulation to the peroneal nerve | To treat post-operative acute pain or certain types of chronic pain by delivering low-intensity electric stimulation | To treat hand tremors by delivering electrical stimulation to medial and radial nerves |
| **Additional Aspects and Features** | Provides 30-minute stimulation session, turning off upon completion | User controlled therapy length, typically up to 60 minutes | Provides 40-minute stimulation session, turning off upon completion |

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

We note that while the device is often supplied as a pair of two units, we have proposed to establish a code for a single unit, for the reasons noted above. In accordance with regulations at 42 CFR 414.238I, the median of 2023 prices, as demonstrated by example claims from a variety of third-party payers submitted by the applicant, $3,562.50, is deflated to the 1986 fee schedule base period using the percentage change in the consumer price index for all urban consumers (CPI-U) from the mid-point of the year the prices are in effect to the mid-point of the fee schedule base period. The price is then updated to the current year using the covered item update factors at section 1834(a)(14) of the Social Security Act. As the price used in

calculating the fee schedule amounts is greater than $150 in the base period, payment would be made on a capped rental basis in accordance with our regulations at 42 CFR 414.229. Our preliminary determination is that the capped rental fee schedule amount would be $231.88 for months 1 through 3, and $173.91 for months 4 through 13, resulting in a total capped payment of $2,434.74 should there be 13 months of continuous use.

Pricing Indicator = 36

**Summary of Public Feedback**

Noctrix Health agreed with CMS' preliminary coding recommendations to establish two new HCPCS Level II codes to identify the NTX-100 Tonic Motor Activation (TOMAC) System, supplies, the Medicare benefit category, and payment determinations. However, Noctrix Health requested CMS to revise the proposed code language for the NTX-100 Tonic Motor Activation (TOMAC) System to include "tonic motor activation" to align with the applicant's initial suggested language and to be consistent with Food and Drug Administration (FDA) description of the generic device category. Alternatively, CMS could include "FDA-authorized or cleared" to provide the additional certainty and safety assurance that only appropriately cleared devices could report this HCPCS Level II code or CMS could consider adding the specific nerve target and stimulation characteristics, such as "high-frequency peroneal nerve stimulator," to restrict the use of the HCPCS Level II code to devices capable of delivering this specific form of stimulation.

Additionally, the speaker requested that CMS further revise the proposed code language to remove "each" and replace it with "bilateral" to describe a bilateral pair of stimulators. The NTX-100 TOMAC System is authorized by the FDA and supplied to patients only as a bilateral system containing two Therapy Bands (stimulators). Moreover, the TOMAC System has only been studied as a bilateral system that treats both legs, supporting the FDA's recognition and Noctrix's practice of only supplying pairs of Therapy Bands, not a single band. Most patients with restless legs syndrome (RLS) present with symptoms in both legs, limiting the relevance of using a code to describe a single band rather than bilateral stimulators. Although CMS notes that "RLS may affect one limb," the speaker commented that they are not aware of any evidence that suggests a single Therapy Band or unilateral stimulation (rather than bilateral) would be effective in resolving unilateral RLS symptoms. Specifically, only bilateral peroneal nerve stimulation has been evaluated clinically and shown to provide RLS symptom relief. Noctrix always supplies patients with two new bands (a bilateral pair) if a band replacement is needed. The speaker is concerned that the option of coding a single band could create confusion among prescribers and lead to diminished outcomes for patients.

**CMS Final HCPCS Coding Decision[13]**

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:

[13] Updated on October 7, 2024 to further refine CMS' coding rational to remove any indication of what may be medically necessary.

Establish a new HCPCS Level II code E0743, “External lower extremity nerve stimulator for restless legs syndrome, each” to describe NTX-100 Tonic Motor Activation (TOMAC) System.

CMS continues to believe that while the device is often supplied as a pair, there may be an instance when one unit would needed (e.g., replacement). The request for a revision to the HCPCS Level II code to identify NTX-100 Tonic Motor Activation (TOMAC) System has not been approved because it does not improve the code descriptor. The HCPCS Level II codes describe categories of similar items. The code set is not intended to be an exhaustive listing of all products on the market. CMS believes that the descriptor, as established, describes the NTX-100 Tonic Motor Activation (TOMAC) System.

**Final Medicare Benefit Category Determination**

Durable Medical Equipment.

**Final Medicare Payment Determination**

The fee schedule amount will be established as discussed in the preliminary determination. For HCPCS Level II code E0743, the 2024 capped rental fee schedule amount will be $231.88 for months 1 through 3, and $173.91 for months 4 through 13, resulting in a total capped payment of $2,434.74 should there be 13 months of continuous use.

Pricing Indicator = 36

## NTX-100 Tonic Motor Activation Supplies - HCP231231JYTC8

### Topic/Issue

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

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

### Summary of Applicant's Submission

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

### CMS Preliminary HCPCS Coding Recommendation

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

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

**Preliminary Medicare Benefit Category Determination**

Supplies and Accessories Used with Durable Medical Equipment.

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

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

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

**Preliminary Medicare Payment Determination**

In accordance with regulations at 42 CFR 414.238(c), fee schedule amounts for items and services without a fee schedule pricing history described by new HCPCS Level II codes that are not comparable to items and services with existing fee schedule amounts may be established using supplier price lists, including catalogs and other retail price lists (such as internet retail prices) that provide information on commercial pricing for the item. If the purchase price used in calculating the fee schedule amounts is less than $150 in the base period, payment would be made on a purchase basis, as “inexpensive equipment” (42 CFR 414.220).

If the only available price information is from a period other than the fee schedule base period (for supplies, the 12-month period of 1986/1987), deflation factors are applied against current pricing in order to approximate the base period price. The annual deflation factors are specified in Medicare Claims Processing Manual, Chapter 23, Section 60.3 and the deflated amounts are then increased by the update factors specified in section 1834(a)(14) of the Social Security Act for DME.

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

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

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

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

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

Pricing Indicator = 34

**Summary of Public Feedback**

Noctrix Health agreed with CMS' preliminary coding recommendations to establish two new HCPCS Level II codes to identify the NTX-100 Tonic Motor Activation (TOMAC) System, supplies, the Medicare benefit category, and payment determinations. However, Noctrix Health requested CMS to revise the proposed code language for the NTX-100 Tonic Motor Activation (TOMAC) System to include "tonic motor activation" to align with the applicant's initial suggested language and to be consistent with Food and Drug Administration (FDA) description of the generic device category. Alternatively, CMS could include "FDA-authorized or cleared" to provide the additional certainty and safety assurance that only appropriately cleared devices could report this HCPCS Level II code or CMS could consider adding the specific nerve target and stimulation characteristics, such as "high-frequency peroneal nerve stimulator," to restrict the use of the HCPCS Level II code to devices capable of delivering this specific form of stimulation.

Additionally, the speaker requested that CMS further revise the proposed code language to remove "each" and replace it with "bilateral" to describe a bilateral pair of stimulators. The NTX-100 TOMAC System is authorized by the FDA and supplied to patients only as a bilateral system containing two Therapy Bands (stimulators). Moreover, the TOMAC System has only been studied as a bilateral system that treats both legs, supporting the FDA's recognition and Noctrix's practice of only supplying pairs of Therapy Bands, not a single band. Most patients with restless legs syndrome (RLS) present with symptoms in both legs, limiting the relevance of using a code to describe a single band rather than bilateral stimulators. Although CMS notes that "RLS may affect one limb," the speaker commented that they are not aware of any evidence that suggests a single Therapy Band or unilateral stimulation (rather than bilateral) would be effective in resolving unilateral RLS symptoms. Specifically, only bilateral peroneal nerve stimulation has been evaluated clinically and shown to provide RLS symptom relief. Noctrix always supplies patients with two new bands (a bilateral pair) if a band replacement is needed. The speaker is concerned that the option of coding a single band could create confusion among prescribers and lead to diminished outcomes for patients.

**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 A4544, "Electrode for external lower extremity nerve stimulator for restless legs syndrome" to describe NTX-100 Tonic Motor Activation supplies.

**Final Medicare Benefit Category Determination**

Supplies and Accessories used with Durable Medical Equipment.

**Final Medicare Payment Determination**

The fee schedule amount will be established as discussed in the preliminary determination. We note that we incorrectly implied in the preliminary determination that the purchase basis is due to the price of these supplies ("inexpensive equipment" as described by 42 CFR 414.220); instead, we should have referred to Section 110.3 of the Medical Benefit Policy Manual (CMS Pub. 100-03), which indicates that payment may be made for replacement of essential accessories that are necessary for the effective use of durable medical equipment when the beneficiary owns or is purchasing the equipment. As noted in the benefit category determination, use of the NTX-100 Tonic Motor Activation System requires the use of essential accessories as described by this new HCPCS Level II code, A4544. The calculation of the payment amount is unchanged: for A4544, the 2024 purchase fee schedule amount will be approximately $6.07.

Pricing Indicator = 34

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

### Topic/Issue

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

### Summary of Applicant's Submission

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

### CMS HCPCS Coding Determination

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

### Medicare Benefit Category Determination

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

### Preliminary Medicare Payment Determination

In accordance with regulations at 42 CFR 414.236(b), fee schedule amounts for new HCPCS Level II codes for items and services without a fee schedule pricing history are established using existing fee schedule amounts for comparable items when items with existing fee schedule amounts are determined to be comparable to the new items and services based on a comparison of: Physical components, mechanical components, electrical components, function and intended use, and additional attributes and features. In determining whether the PoNS™ Controller is comparable to items with existing codes, we undertook a detailed examination of its physical, mechanical, and electrical components, function and intended use, and any additional aspects and features, in comparison with HCPCS Level II code E0745, "Neuromuscular stimulator, electronic shock unit".

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

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

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

| | | |
|---|---|---|
| | Connects to the mouthpiece via an electrical cord<br><br>Three twenty-minute session treatments per day for 14 weeks | |

Per this preliminary determination, the 2024 fee schedule amounts for HCPCS Level II code A4593 would be based on the rental fee schedule amounts for HCPCS Level II code E0745. As the price for the Controller is greater than $150 in the base period, payment would be made on a capped rental basis in accordance with our regulations at 42 CFR 414.229. Our preliminary determination is that the capped rental fee schedule amount would be approximately $114.91 on average for months 1 through 3, and approximately $86.18 on average for months 4 through 13, resulting in a total capped payment of $1,206.53 should there be 13 months of continuous use.

Pricing Indicator = 36

**Summary of Public Feedback**

Helius Medical Inc. disagreed CMS' published preliminary payment determination and maintained that the Controller is not comparable to existing fee schedule items. The speaker said that the Controller generates and controls delivery of electrotactile stimulation to the trigeminal and facial nerve endings in the tongue, leading to neuromodulation in the brainstem, which triggers long-term neuroplastic changes that correlate with improvement in gait deficits. The speaker went on to say that the PoNS™ System does not stimulate muscles or nerve endings in muscles. The speaker also discussed a letter from the FDA dated on September 20, 2022 that corrected the FDA's previous classification order, dated March 25, 2021, to correct the regulation name to more accurately describe the target of the electrical stimulation provided by devices of this generic type. Per the letter, the "FDA identifies this generic type of device as: Electrical tongue nerve stimulator to treat motor deficits. An electrical tongue nerve stimulator to treat motor deficits is a prescription device that consists of a non-implantable apparatus to generate electrical pulses for stimulation of the nerves in the tongue to provide treatment of motor deficits." Thus, the FDA changed the regulation name for the PoNS™ from "Neuromuscular tongue stimulator to treat motor deficits" to "Electrical tongue nerve stimulator to treat motor deficits". The speaker also requested that CMS calculate the payment rate for the Controller based on gap-filling, using a starting price based on insurer claims and Veterans Administration (VA) fee schedule amounts of $16,499 - $16,554. The speaker stated that the $16,499 is from the VA fee schedule, and the $16,554 is from an insurer claim.

**Final Medicare Payment Determination**

No determination. More time is needed to evaluate this complex issue. The payment determination for this item will be addressed at a subsequent HCPCS public meeting.

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

### Topic/Issue

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

### 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 HCPCS Coding Determination

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

### Medicare Benefit Category Determination

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

### Preliminary Medicare Payment Determination

In accordance with regulations at 42 CFR 414.238(c), fee schedule amounts for items and services without a fee schedule pricing history described by new HCPCS Level II codes that are not comparable to items and services with existing fee schedule amounts may be established using supplier price lists, including catalogs and other retail price lists (such as internet retail prices) that provide information on commercial pricing for the item. If the purchase price used in calculating the fee schedule amounts is greater than $150, then payment would be made on a capped rental basis in accordance with our regulations at 42 CFR 414.229. If the only available price information is from a period other than the fee schedule base period (for supplies, the 12-month period of 1986/1987), deflation factors are

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

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

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

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

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

The PoNS™ device can currently be purchased online at the following website: https://www.getponstherapy.com/pons-access-information/. On this website are the "cash pay" prices, which are $14,500 for the PoNS™ System (includes Controller and Mouthpiece) and $4,500 for the PoNS™ Mouthpiece. These cash pay prices are also confirmed in a Form 8-K submission from 2023.[14] The applicant has noted that these cash pay prices reflect introductory pricing that has been used for a few customers only and are not representative of the prices that most customers will pay. The Form 8-K[15] also provides list prices for the PoNS™, and the applicant has requested that these list prices be used as the starting point for gap-fill: $17,800 for the PoNS™ Controller and $7,900 for the PoNS™ Mouthpiece. However, we have not seen invoices in which these list prices have been paid. We believe these list prices may be an MSRP, and as previously mentioned, an MSRP is not, by itself, an adequate source of commercial pricing. Only verifiable supplier or commercial pricing may be used for gap-filling purposes (84 FR 60648). We consider the cash pay price an internet retail price since it is a price on the internet available for and used by consumers to purchase, and we have used that $4,500 price for the Mouthpiece as our source for the preliminary payment determination. We welcome the applicant to provide other commercial transactions or claims showing allowable/paid amounts for our consideration.

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

Pricing Indicator = 36

**Summary of Public Feedback**

Helius Medical Inc. disagreed with CMS' published preliminary payment determination. The applicant requested that CMS should establish a rate for the PoNS™ Mouthpiece by gap-filling using a starting point of $7,345-7,347 that is paid on a purchase basis, as it is a supply necessary for the effective use of DME. The speaker said that the Mouthpiece is an example of an essential supply, as the Controller cannot be used without the Mouthpiece, and the Mouthpiece is put directly into the Controller to achieve a therapeutic outcome. The speaker stated that payment on a rental basis jeopardizes commercial viability, as the Mouthpiece only has a 14-week useful life, but CMS gap-filled a price paid on a rental basis that is only paid out after 13 months. The speaker mentioned that it was not possible for the Mouthpiece to receive the full reimbursement amount that CMS calculated if paid on a rental basis. The speaker also discussed a letter from the FDA dated September 20, 2022, that corrected the FDA's previous classification order, dated March 25, 2021, to correct the regulation name to more accurately describe the target of the electrical stimulation provided by devices of this generic type. Per the letter, the "FDA identifies this generic type of device as: Electrical

[14] Exhibit No. 99.2. "Corporate Presentation, dated January 2023." https://www.sec.gov/ix?doc=/Archives/edgar/data/1610853/000155837023000410/hsdt-20230123x8k.htm
[15] https://www.sec.gov/ix?doc=/Archives/edgar/data/1610853/000155837023000410/hsdt-20230123x8k.htm

tongue nerve stimulator to treat motor deficits. An electrical tongue nerve stimulator to treat motor deficits is a prescription device that consists of a non-implantable apparatus to generate electrical pulses for stimulation of the nerves in the tongue to provide treatment of motor deficits." Thus, the FDA changed the regulation name for the PoNS™ from "Neuromuscular tongue stimulator to treat motor deficits" to "Electrical tongue nerve stimulator to treat motor deficits".

**Final Medicare Payment Determination[16]**

After further review, we agree with the applicant that the PoNS™ Mouthpiece should not be paid on a capped rental basis. We believe it is an essential accessory, and the pricing indicator would now be 32 for inexpensive and routinely purchased DME. We will also be making a technical change to the pricing indicator for HCPCS Level II code E0491, the HCPCS Level II code that we compared the PoNS™ Mouthpiece to in its preliminary and in this final payment determination. To be consistent and accurate with this final payment determination, we will be changing the pricing indicator for HCPCS Level II code E0491 to 32, as it is also an essential accessory. In the CMS Final HCPCS Coding Decision for HCPCS Level II code E0491, which was published in the B1 2023 cycle under application HCP2301032FA3J, we noted that the product coded under HCPCS Level II code E0491 serves as a DME accessory. We also noted this in its Preliminary Medicare Benefit Category Determination, which we finalized. This pricing indicator change to 32 does not change payment.

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

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

| | PoNS™ Mouthpiece | E0491 |
|---|---|---|
| **Physical Components** | Paddle-shaped mouthpiece containing nickel, gold, and copper materials with embedded electrodes | Gel pads, cloth, carbon layered, pre-gelled, sealed pouch with built-in electrodes |
| **Mechanical Components** | NA | NA |
| **Electrical Components** | Electrical Pulse Stimulation | Electrical Pulse Stimulation |
| **Function and Intended Use** | Delivers electrical stimulation to the trigeminal and fascial nerves placed on the tongue | Delivers NMES therapy to genioglossus muscle through electrodes placed on the tongue |

[16] Updated on October 7, 2024 to reflect Medicare's final payment determination.

| | | |
|---|---|---|
| | For short-term treatment of gait deficit due to mild to moderate symptoms from multiple sclerosis (MS) | For the reduction of obstructive sleep apnea |
| **Additional Aspects and Features** | Non-implantable<br><br>Used as an adjunct to a supervised therapeutic exercise program<br><br>Three twenty-minute session treatments per day for 14 weeks | Non-implantable<br><br>Can include disposable and reusable parts<br><br>Latex free<br><br>One twenty-minute session per day for 6 weeks |

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

In the preliminary payment determination, we noted that the PoNS™ device could be purchased online at the following website: https://www.getponstherapy.com/pons-access-information/. At the time, this website displayed the "cash pay" prices, which were $14,500 for the PoNS™ System (includes Controller and Mouthpiece) and $4,500 for the PoNS™ Mouthpiece. These cash pay prices are also confirmed in a Form 8-K submission from 2023.[17] The applicant has noted that these cash pay prices reflect introductory pricing that has been used for a few customers only and are not representative of the prices that most customers will pay. The Form 8-K[18] also provides list prices for the PoNS™, and the applicant has requested that these list prices be used as the starting point for gap-fill: $17,800 for the PoNS™ Controller and $7,900 for the PoNS™ Mouthpiece.

The applicant has provided CMS with additional pricing information for the PoNS™ Mouthpiece since the posting of our preliminary payment determination. We have received from the applicant invoices that reflect direct cash pay sales by Helius Medical Inc.; invoices that were sold by a distributor; a Department of Defense (DoD) contract price; and a price of $7,344.97 on the Veterans Affairs (VA) Federal Supply Schedule Service (FSS) and General Services Administration (GSA) websites, as contracted by Government Contractor Lovell Government Services Inc.[19,20] Instead of gap-filling using the $4,500 internet retail price, as was done in our preliminary payment determination, we will instead be gap-filling using the median of these prices.[21] We believe the median of these prices is more representative of the array of prices on the market. The median of these prices is $4,550. Of note, we discussed in

[17] Exhibit No. 99.2. "Corporate Presentation, dated January 2023." https://www.sec.gov/ix?doc=/Archives/edgar/data/1610853/000155837023000410/hsdt-20230123x8k.htm

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

[19] https://www.vendorportal.ecms.va.gov/NAC/MedSurg/Details?lognumber=8879982&type=fss

[20] https://www.gsaadvantage.gov/advantage/ws/search/advantage_search?q=0:0Lovell%20Government%20Services&q=0:0Helius&s=0&searchType=1&c=25

[21] We take the median of the series (1 DoD price, 1 VA FSS/GSA price, X# of invoices from Helius Medical Inc. direct sales, Y# of invoices from distributor sales). This means every purchase price is factored into one median calculation.

our CY 2020 rule (84 FR 60736) that prices for a particular item or service can vary significantly depending on the source used. If the median price paid by one group of payers (for example, non-Medicare payers) is significantly higher than the median price paid by another group of payers (for example, MA plans), not using or factoring in the prices from the group of payers with the lower prices could result in grossly excessive fee schedule amounts that are then difficult to adjust using the inherent reasonableness authority, which requires numerous time consuming and resource-intensive steps.

In accordance with regulations at 42 CFR 414.238(c), the current pricing is deflated to the 1986 fee schedule base period using the percentage change in the consumer price index for all urban consumers (CPI-U) from the mid-point of the year the prices are in effect to the mid-point of the fee schedule base period. The price is then updated to the current year using the covered item update factors specified in program instructions (Medicare Claims Processing Manual, Chapter 23, Section 60.3). After applying the annual deflation and update factors, our final payment determination is that the 2024 payment amount would be $2,963.30.

We note that the effective date for this Final Medicare Payment Determination will be January 1, 2025.

Pricing Indicator = 32

## Venowave - HCP220922Q7MR0

### Topic/Issue

Request for reconsideration of prior benefit category determination.

### Applicant's Summary

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

### CMS Preliminary HCPCS Coding Recommendation

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

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

### Preliminary Medicare Benefit Category Determination

Durable Medical Equipment

When CMS published a final determination for Venowave on August 23, 2023, we originally stated that Venowave did not fall into a durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) benefit category because it was a single patient use item. DME is defined in Medicare regulations at title 42 Code of Federal Regulations (CFR) 414.202 as

equipment furnished by a supplier or a home health agency that meets five conditions, including that of being able to withstand repeated use. We have reconsidered this determination based on new evidence that the applicant has brought to our attention.

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

**Preliminary Medicare Payment Determination**

In accordance with regulations at 42 CFR 414.238(c), fee schedule amounts for items and services without a fee schedule pricing history described by new HCPCS Level II codes that are not comparable to items and services with existing fee schedule amounts may be established using supplier price lists, including catalogs and other retail price lists (such as internet retail prices) that provide information on commercial pricing for the item. If the purchase price used in calculating the fee schedule amounts is greater than $150, then payment would be made on a capped rental basis in accordance with our regulations at 42 CFR 414.229. If the only available price information is from a period other than the fee schedule base period (for supplies, the 12-month period of 1986/1987), deflation factors are applied against current pricing in order to approximate the base period price. The annual deflation factors are specified in the Medicare Claims Processing Manual, Chapter 23, Section 60.3 and the deflated amounts are then increased by the update factors specified in section 1834(a)(14) of the Social Security Act for DME.

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

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

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

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

gap-filling purposes (84 FR 60648). To that end, we have identified and are using a commercial price of $1,199[22] from an official distributor of Venowave in the United States.[23]

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

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

Pricing Indicator = 36

**Summary of Public Feedback**

Venowave Inc. agreed with CMS' published preliminary recommendations.

**CMS Final HCPCS Coding Decision**

We appreciate the written 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:

Establish a new HCPCS Level II code E0683, "Non-pneumatic, non-sequential, peristaltic wave compression pump" to describe Venowave VW5.

**Final Medicare Benefit Category Determination**

Durable Medical Equipment.

**Final Medicare Payment Determination**

We are finalizing our preliminary payment determination to establish the Medicare payment amount in accordance with the "gap filling" procedure outlined in 42 CFR 414.238(c). As stated in the preliminary payment determination, we have identified and are using a commercial price of $1,199[24] from an official distributor of Venowave in the United States.[25]

[22] https://herolifecare.com/products/venowave
[23] https://www.theglobeandmail.com/investing/markets/stocks/TBRIF/pressreleases/20221870/
[24] https://herolifecare.com/products/venowave
[25] https://www.theglobeandmail.com/investing/markets/stocks/TBRIF/pressreleases/20221870/

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

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

Pricing Indicator = 36

## 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 increases 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

Establish a new HCPCS Level II code LXXXX, "External lower extremity sensory prosthesis, cutaneous stimulation of planter mechanoreceptors, per leg" to describe Walkasins®.

### Final Medicare Benefit Category Determination

Prosthetic Device.

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. In the Second Biannual 2023 HCPCS Level II coding cycle CMS made a conditional benefit category determination that the Walkasins® receptor sole is a prosthetic device, pending

evidence that the device replaces the permanent inoperative/malfunctioning receptors caused by sensory peripheral neuropathy. In April 2024, the applicant furnished extensive and detailed information regarding the operation of the Walkasins® system. Specifically, it addresses partially replacing the permanent loss of the plantar mechanoreceptor function in individuals diagnosed with sensory peripheral neuropathy (SPN). This is achieved by delivering crucial sensory pressure information to the brain, essential for maintaining gait and balance, through stimulation of a different set of healthy mechanoreceptors above the ankle. Based on the newly provided information and evidence, CMS has concluded that Walkasins® functions as a prosthetic device replacing the part of function of permanently malfunctioning internal body organs, specifically the damaged plantar cutaneous mechanoreceptors within the peripheral nervous system, utilizing healthy mechanoreceptors above the ankle.

**Preliminary Medicare Payment Determination**

No determination. More time is needed to evaluate and determine how this item is priced under Medicare Part B. The payment determination for this item will be addressed at a subsequent HCPCS public meeting. RxFunction, Inc. has already submitted some payment-related information to CMS to assist in development of a payment determination; however, the applicant is welcome to provide any updated or new information during the public meeting.

**Summary of Public Feedback**

RxFunction agreed with CMS' preliminary coding recommendation and the final Medicare benefit category determination. However, the speaker disagreed with the proposed code descriptor to identify the Walkasins® system. The speaker requested to remove "plantar" from the descriptor to accurately reflect that Walkasins® stimulates new, healthy mechanoreceptors above the ankle, as the plantar mechanoreceptors are malfunctioning and can no longer detect plantar pressure. The speaker recommended a descriptor of, "External lower extremity sensory prosthesis, cutaneous stimulation of mechanoreceptors, per leg."

**CMS Final HCPCS Coding Decision[26]**

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 L8720, "External lower extremity sensory prosthetic device, cutaneous stimulation of mechanoreceptors proximal to the ankle, per leg" to describe Walkasins®.

We agreed with the applicant to remove the word "planter" from the code descriptor; however, we believe that adding "proximal to the ankle" best describes the Walkasins® system. The Walkasins® system is designed to measure plantar pressure information that neuropathic, nonfunctional plantar mechanoreceptors can no longer detect. This information

[26] Updated on October 7, 2024 to revise the long descriptor for HCPCS Level II code L8720 to remove "prosthesis" and to instead read "prosthetic device."

is then transmitted to functional mechanoreceptors above, or proximal to, the ankle. Therefore, including this detail in the language description is more appropriate.

**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. Payment on a local fee schedule basis would be made in accordance with our regulations at § 42 CRF 414.228

Pricing Indicator = 46

## 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 increases 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

Establish a new HCPCS Level II code LXXXX, “Receptor sole for use with LXXXX, replacement, each” to describe Walkasins® receptor sole.

### Final Medicare Benefit Category Determination

Prosthetic Device.

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.

In the Second Biannual 2023 HCPCS Level II coding cycle CMS made a conditional benefit category determination that the Walkasins® receptor sole is a prosthetic device, pending evidence that the device replaces the permanent inoperative/malfunctioning receptors caused by sensory peripheral neuropathy. In April 2024, the applicant furnished extensive and detailed information regarding the operation of the Walkasins® system. Specifically, it addresses partially replacing the permanent loss of the plantar mechanoreceptor function in individuals diagnosed with sensory peripheral neuropathy (SPN). This is achieved by delivering crucial sensory pressure information to the brain, essential for maintaining gait and balance, through stimulation of a different set of healthy mechanoreceptors above the ankle. Based on the newly provided information and evidence, CMS has concluded that Walkasins® functions as a prosthetic device replacing the part of function of permanently malfunctioning internal body organs, specifically the damaged plantar cutaneous mechanoreceptors within the peripheral nervous system, utilizing healthy mechanoreceptors above the ankle.

**Preliminary Medicare Payment Determination**

No determination. More time is needed to evaluate and determine how this item is priced under Medicare Part B. The payment determination for this item will be addressed at a subsequent HCPCS public meeting. RxFunction, Inc. has already submitted some payment-related information to CMS to assist in development of a payment determination; however, the applicant is welcome to provide any updated or new information.

**Summary of Public Feedback**

RxFunction agreed with CMS' preliminary coding recommendation and the final Medicare benefit category determination.

**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 L8721, "Receptor sole for use with l8720, replacement, each" to describe Walkasins® receptor sole.

**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. Payment on a local fee schedule basis would be made in accordance with our regulations at § 42 CRF 414.228.

Pricing Indicator = 46

## SurgiLock® Tray - HCP2401023N82N

### Topic/Issue

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

Applicant's suggested language: JXXXX, “Surgical Safety Tray; designed to clip onto a metal stand with articulation top and will hold surgical instruments in place during a surgical procedure.”

### Summary of Applicant's Submission

Medical Lock Corporation submitted a request to establish a new HCPCS Level II code to identify SurgiLock® Tray. SurgiLock® is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). SurgiLock® Tray is a single use, disposable polypropylene plastic tray with adhesive elastomer surface that is designed to clip onto a metal stand to hold sterile instruments in place during surgery. The ElasTak technology creates unprecedented cost savings to the hospitals/payers by providing new efficiencies. SurgiLock® Tray will eliminate several sharps related injuries, therefore needing a J code.

### CMS Preliminary HCPCS Coding Recommendation

CMS’ understanding is that SurgiLock® Tray 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 primary speaker stated that SurgiLock's articulating Mayo stand is changing the game in surgeries. According to the speaker, the SurgiLock Tray is constructed from polypropylene plastic and with an adhesive elastomer surface (identical material to the SurgiLock device). The tray is designed to clip onto a metal stand with an articulating top and will hold instruments in place during a surgical procedure. Additionally, the tray will be sold as a single use, disposable item. The tray will have a silicone coated PET release liner protecting the elastomer top prior to use and will be shipped sterile in a Tyvek®/poly pouch. It is designed to clip onto a metal stand to hold instruments in place during surgery and it can help with eliminating sharp drops/infections.

### CMS Final HCPCS Coding Decision

CMS has 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 and is bundled in the facility payment.

## SNOO Smart Sleeper - HCP2312290MNL5

### Topic/Issue

Request to establish a new HCPCS Level II code to identify the SNOO Smart Sleeper.

Applicant's suggested language: XXXXX, "Infant Supine Sleep System consisting of a powered bed with motion and sound functions that respond to crying and sleep disturbances, 360-degree side enclosures, mattress, attachable swaddle sacks to securely position babies on the back, and a mobile app for sleep analytics and feedback"

### Summary of Applicant's Submission

Happiest Baby submitted a request to establish a new HCPCS Level II code to identify the SNOO Smart Sleeper. The SNOO Smart Sleeper received the Food and Drug Administration's (FDA's) De Novo clearance on March 30, 2023. The SNOO Smart Sleeper is a class II medical device for home use by caregivers of infants from birth to 6 months of age, who are not yet able to roll over consistently during sleep. The SNOO Smart Sleeper's bassinet plus the SNOO Sleep Sack are jointly intended to facilitate a supine position during sleep. Infants who are placed in a supine sleep position are at lower risk of sudden infant death syndrome (SIDS) or sudden unexpected infant death (SUID). SNOO Smart Sleeper is used exclusively by infants as an innovative sleep system that provides responsive soothing and a safe sleep environment. The SNOO Smart Sleeper's womb-like sound and motion reduce fussing, excessive crying, and infant sleep disruptions. In response to fussing and sleep disruptions, SNOO deploys a unique algorithm to provide incrementally greater sound and motion to calm excessive crying and reduce sleep interruptions. Fussing and excessive crying lead to approximately 20% of pediatric consultations. In addition, many infants experience sleep disruptions in the first 6 months (65% of 3-month-olds wake one or more times per night and 9% wake three or more times per night; more than 50% of 6-month-olds wake one or more times per night, 21% wake three or more times per night). Approximately 3,400 healthy infants in the U.S. die suddenly every year from SIDS and SUID, with no reduction in the last 20 years. The Centers for Disease Control and Prevention (CDC), the National Institutes of Health, the FDA, and the American Academy of Pediatrics (AAP) all note that infants that sleep in a supine position are at lower risk of SIDS/SUID. The SNOO sleep sack has wings that attach to safety clips on the bed's platform to secure sleeping infants in the supine position, this offers the benefits of swaddling (reduced fussing, excessive crying and sleep disruptions) while reducing a baby's ability to roll to an unsafe position. The AAP notes that rolling over while swaddled is associated with a markedly increased risk of SIDS/SUID. SNOO's mobile app adjusts the bed's motion and sound to allow monitoring of crying and sleep and provide daily sleep reports to show progress in reducing crying and sleep disruptions.

### CMS Preliminary HCPCS Coding Recommendation

According to the FDA's website[27] as part of the SNOO's evaluation, "the FDA reviewed data comparing the incidence of reported SIDS/SUID in SNOO users to historical CDC SIDS/SUID data. Although this data comparison was not sufficient to determine whether the device could prevent SIDS/SUID, the data did demonstrate the device did not increase the

[27]"FDA Roundup: March 31, 2023," www.FDA.gov, U.S. Food and Drug Administration. 03/31/2024. https://www.fda.gov/news-events/press-announcements/fda-roundup-march-31-2023

risk of SIDS/SUID in the study population. Therefore, the device is not intended to prevent or reduce the risk of SIDS/SUID. At this time, we are not aware of any medical devices that are infant sleep systems or infant positioners authorized for marketing by the FDA to prevent or reduce the risk of SIDS/SUID."

While CMS has not identified a program operating need for Medicare or other payers for a new HCPCS Level II code to describe an infant supine sleep system, we welcome information from the applicant and other insurers who are currently paying for this product to demonstrate a claims processing need for a unique HCPCS Level II code.

**Summary of Public Feedback**

Happiest Baby disagreed with CMS' published preliminary determination. According to the speaker, during the first year of life, every time a healthy infant is put to sleep, there is a risk of that child rolling to an unsafe position and experiencing sudden death. This results into an average of 3,400 infant sleep deaths each year due to SIDS/SUID. The speaker elaborated that, despite all the medical advances in recent years, there has been no reduction in the incidence of these deaths in the U.S. in over 20 years. According to the speaker, all major public health authorities (including the National Institutes of Health (NIH), the CDC, and the AAP note that the most immediate way to prevent these deaths is by having infants sleep on their backs. Approximately two-thirds of SIDS deaths occur when the baby is not on their back. The SNOO Smart Sleeper provides specific sound and motion sensations to quickly improve sleep and facilitate compliance with medical advice on safe sleep positioning. It also responds to crying with increased levels of sensations, calming about 50% of fussing in under 3 minutes. The SNOO Smart Sleeper is the first FDA De Novo authorized Class II medical device for keeping babies safely positioned on their backs. According to the speaker, multiple payers reimburse families for this device (including the recent additions of coverage by Aetna, Anthem Blue Cross, Maven, etc.). According to the speaker, the demand for a new HCPCS Level II code is accelerating, including among Medicaid managed care programs and payers. For example, CareSource (the largest Medicaid provider in the state of Ohio) is distributing hundreds of SNOO Smart Sleepers as a mental wellness intervention in high-risk populations. The speaker added that CareSource in Indiana is also considering a program, and medical providers in Wisconsin will soon launch an initiative to distribute hundreds of these devices to Milwaukee families at increased risk for SIDS. Further medical demand has been shown as well, where the SNOO is used in over 160 leading U.S. hospitals (from Harvard to UC San Francisco). They are used to improve the care of high-risk infants. The SNOO Smart Sleeper is also used in approximately 100 medical centers to help reduce the need for caregiver-provided medication in these babies by increasing their sleep and by reducing crying. The speaker stated that providers, payers, and families seeking reimbursement require a specific unique HCPCS Level II code for proper processing of billing claims.

**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. CMS has not identified a program operating need for Medicare or other payers for a new HCPCS Level II code to describe an infant supine sleep system as we were not provided with evidence that other payers are receiving claims from suppliers or providers in which the payer is directly paying the supplier or provider. While insurers might

reimburse for the SNOO Smart Sleeper under a health savings account or provide the SNOO Smart Sleeper out of their own administrative funds, not as part of covered medical benefit, these scenarios do not equate to a claims processing need for a new HCPCS Level II code.

## Red Blood Cells, Leukocytes Reduced, Oxygen/Carbon Dioxide Reduced - HCP231002Y5WRL

### Topic/Issue

Request to establish a new HCPCS Level II code to identify red blood cells (RBCs), Leukocytes Reduced (LR), O2/CO2 reduced.

Applicant's suggested language: XXXXX, "Red Blood Cells, Leukocytes Reduced, Oxygen/Carbon Dioxide Reduced, Each Unit (RBCs LR, O2/CO2 Reduced, Each Unit)"

### Summary of Applicant's Submission

Hemanext Inc. submitted a request to establish a new HCPCS Level II code to identify red blood cells, leukocytes reduced, O2/CO2 reduced. Hemanext's red blood cells, leukocytes reduced, O2/CO2 reduced was approved by the Food and Drug Administration (FDA) under De Novo classification on September 15, 2023. Hemanext's red blood cells, leukocytes reduced, O2/CO2 reduced product is intended for transfusion. Hemanext's ONE® RBC processing and storage system is a standard leukocyte-reduced RBC (LR RBC) product unit processed to reduce oxygen in the RBC storage environment and is packaged in the FDA-authorized Hemanext's Storage Bag (HSB) to maintain RBCs in a hypoxic state over the entire storage period up to 42 days. The three-part HSB comprises an inner oxygen-permeable bag containing the RBCs, an iron-based O2 and CO2 sorbent material, and an outer O2- and CO2-impermeable outer bag. Reduction and strict maintenance of limited oxygen saturation of the RBC storage environment minimizes oxidative damage to the RBCs, known generally as the RBC storage lesion. Similarly to standard LR RBCs, RBCs LR, O2/CO2 reduced are intravenously transfused to restore and maintain oxygen delivery to body tissues and vital organs of any patient experiencing acute or chronic anemia who requires RBC transfusion in the judgment of the attending physician. The unit dosage of RBCs, LR, O2/CO2 reduced is based on the extent of the individual patient's acute or chronic anemia and clinical status.

### CMS Preliminary HCPCS Coding Recommendation

The applicant made a claim for clinical therapeutic distinction compared to standard leukocyte reduced RBCs, currently coded under HCPCS Level II code P9016, "Red blood cells, leukocytes reduced, each unit." The applicant submitted clinical studies designed to evaluate biochemical, morphological and functional oxidative damage as compared to standard LR RBCs in animals. CMS believes that the applicant did not provide adequate support for the claim of significant therapeutic distinction for the storage and processing of RBCs up to 42 days that would result in a unique HCPCS Level II code. Red blood cells, leukocytes reduced, O2/CO2 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**

Hemanext Inc. disagreed with CMS' preliminary HCPCS coding recommendation. The speaker stated that Hemanext's ONE® is a three-part system used solely by non-hospital blood establishments to manufacture the O2/CO2-reduced RBC component product, which in turn is supplied to hospitals for transfusion into patients. Hospitals receive only the final O2/CO2 reduced RBC product, which, as with all existing HCPCS Level II-coded blood component products, is billed separately from its associated outpatient transfusion procedure.

**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 determined this application request was for the leukocytes reduced, O2/CO2 reduced blood itself and not the storage container, as described in the FDA clearance. As such, CMS is revising its preliminary recommendation to:

Establish a new HCPCS Level II code to P9027, "Red blood cells, leukocytes reduced, oxygen/carbon dioxide reduced, each unit" to describe the RBCs, leukocytes reduced, O2/CO2 reduced blood.

## Steripath® Gen2 Blood Collection System - HCP24010208L4M

### Topic/Issue

Request to establish a new HCPCS Level II code to identify Steripath® Gen2 Blood Collection System.

Applicant's suggested language: PXXXX, “Specimen collection for blood culture using a pre-assembled, disposable, and integrated sterile device with active initial blood sample diversion and sequestration (>0.5mL), each collection site”

### Summary of Applicant's Submission

Magnolia Medical Technologies Inc. submitted a request to establish a new HCPCS Level II code to identify Steripath® Gen2 Blood Collection System. Steripath® Gen2 Blood Collection System was approved by the Food and Drug Administration (FDA) under the 510(k) pathway on February 28, 2020. Steripath® Gen2 Blood Collection System service includes a blood draw from a patient with signs or symptoms of a potential bloodstream infection that may progress to sepsis. The service also includes the use of a specialized device that is a blood collection system that diverts and sequesters an initial aliquot of the blood draw to ensure a clean subsequent blood sample is inoculated into the blood culture bottles. The system is intended to reduce the frequency of blood culture contamination when contaminants are present in the initial blood sample compared to blood cultures drawn with standard procedure without manual diversion. The devices include the Steripath® family of products (commercialized under the trade names Steripath® Gen2 Blood Collection System and Steripath® Micro Blood Collection System).

### CMS Preliminary HCPCS Coding Recommendation

The Steripath® Gen2 Blood Collection System is not suitable for inclusion in the HCPCS Level II code set because it is used during blood collection and certain items are considered bundled into the facility payment. We have not identified a specific need for this Steripath® Gen2 Blood Collection System 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

Magnolia Medical Technologies Inc. disagreed with CMS’ preliminary HCPCS coding recommendation that Steripath® Gen2 Blood Collection System is not suitable for inclusion in the HCPCS Level II code set because it is used during blood collection and certain items are considered bundled into the facility payment. The speaker stated a blood culture draw with the Steripath® Gen2 Blood Collection System is materially different from the traditional collection system based on the clinical and economic evidence from peer-reviewed published studies that have been provided to CMS. The speaker stated the current venipuncture procedure code does not adequately cover the cost of the device, which has been demonstrated to lead to quality outcomes as part of an evidence-based bundle that combines the device with compliance to best practice.

**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. The Steripath® Gen2 Blood Collection System is not suitable for inclusion in the HCPCS Level II code set because it is used during blood collection and certain items are considered bundled into the facility payment. We have not identified a specific need for this Steripath® Gen2 Blood Collection System 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.

## VasQ™ - HCP2312298HHUR

### Topic/Issue

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

Applicant's suggested language: CXXXX, “External support device for arteriovenous-fistula”

### Summary of Applicant's Submission

Laminate Medical Inc. submitted a request to establish a new HCPCS Level II code to identify VasQ™. VasQ™ was granted De Novo clearance as a class II device by the Food and Drug Administration (FDA) on September 26, 2023. VasQ™ is a permanently implanted device intended to provide extravascular support for upper extremity arteriovenous fistulas created for vascular access by means of vascular surgery. VasQ™ is supplied in a sterile package as a single-use device for surgical implantation in persons who need renal dialysis. Vascular surgeons have asked for a code that their facilities can use to identify arteriovenous fistula procedures when the VasQ™ device is implanted.

### CMS Preliminary HCPCS Coding Recommendation

VasQ™ can be utilized in various anatomic areas including cephalic, basilic and forearm vein arteriovenous anastomosis transpositions as described by HCPCS Level I, Current Procedural Terminology (CPT®) codes, including but not limited to, 36818, 36819, 36820, and Cimino-type brachial artery to cephalic vein arteriovenous anastomosis (CPT® code 36821). It is our understanding that VasQ™ is not suitable for coding in the HCPCS Level II code set because it is used in facility settings during procedures reported using HCPCS Level I CPT® codes. We have not identified a specific need for this device to be separately paid, since we believe that a particular payer may elect to pay for the service in which this device is used. For instance, Medicare would typically reflect the costs of the device in the payment for the procedure, if it is used, and as such it would not be separately payable.

### Summary of Public Feedback

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

### CMS Final HCPCS Coding Decision

Based on the information provided in the application to establish a new HCPCS Level II code and considering that no public comments were received, CMS is finalizing its preliminary recommendation that VasQ™ is not suitable for coding in the HCPCS Level II code set because it is used in facility settings during procedures reported using HCPCS Level I CPT® codes.

## Volara™ System - HCP231218VF0N3

### Topic/Issue

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

Applicant's suggested language: XXXXX, “Multi-function oscillation and lung expansion airway clearance device, performs functions of continuous positive expiratory pressure, continuous high frequency oscillation, and nebulization, and supports delivery of supplemental oxygen”

### Summary of Applicant's Submission

Baxter submitted a request to establish a new HCPCS Level II code to identify the Volara™ System. The Volara™ System received the Food and Drug Administration’s (FDA’s) 510(k) clearance for home use on January 20, 2020. The Volara™ System is a multi-function airway clearance device that provides oscillation and lung expansion (OLE) therapy, delivering three therapies, continuous positive expiratory pressure (CPEP), continuous high frequency oscillation (CHFO) and nebulization, in one integrated product. The CPEP function treats and helps prevent pulmonary atelectasis by delivering continuous positive pressure to help expand and hold the airways open. When delivering CPEP therapy, the device provides continuous positive pressure to the patient’s airway opening regions of the lung that are otherwise closed off during tidal volume breathing. In addition, CPEP helps mobilize peripheral lung secretions into the larger airways and contributes to resolving atelectasis by preventing airway collapse during expiration. The CHFO function delivers continuous pulses of positive pressure. These pulsations shear or break down the mucus, loosen the mucus from the walls of the peripheral airways, and use the airflow to mobilize the mucus toward the central airways. CHFO is a form of chest physiotherapy that provides oscillating airflow to the airways by mouthpiece or mask. Nebulizer function allows for delivery of medication and/or delivery of saline to provide humidification and facilitate airway clearance. The aerosol and nebulizer function can be delivered concurrently with CPEP and CHFO for treatment efficiency or deliver nebulized medication as a stand-alone function. The supplemental oxygen capability supports delivery of oxygen during OLE therapy for patients who dependent on the oxygen. The Volara™ System utilizes a platform from which both CPEP and CHFO can be administered during alternating periods in a single treatment session. The treatments are provided in cycles with alternating intervals of 2.5 minutes of CPEP to open the airways and 2.5 minutes of CHFO to create airflow within the lungs to move retained secretions. Caregivers have the option of adjusting the duration of each interval based on physician’s order.

### CMS Preliminary HCPCS Coding Recommendation

Establish a new HCPCS Level II code XXXXX, “Lung expansion airway clearance, continuous high frequency oscillation, and nebulization device” to describe the Volara™ System.

### 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 Volara™ device meets the requirements to be classified as DME.

**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 EXXXX is to use the existing fee schedule amounts for comparable items described by HCPCS Level II code E0483 (“High frequency chest wall oscillation system, with full anterior and/or posterior thoracic region receiving simultaneous external oscillation, includes all accessories and supplies, each”) for the continuous high frequency oscillation function, with additional amounts based on HCPCS Level II code E0482 ("Cough stimulating device, alternating positive and negative airway pressure") and HCPCS Level II code E0570 ("Nebulizer, with compressor") to account for the continuous positive expiratory pressure and nebulizer functions of the device.

CMS has compared the three HCPCS Level II codes to Volara™ as shown in the below comparability table. Volara™ provides three functions in one integrated device: continuous positive expiratory pressure, continuous high frequency oscillation, and nebulization. HCPCS Level II codes E0482, E0483, and E0570 describing the three separate functions of the integrated device are found to be comparable to the Volara™ with respect to physical, mechanical, and electrical components, and function and intended use.

| | **Volara™** | **E0482** | **E0483** | **E0570** |
|---|---|---|---|---|
| **Physical Components** | Control Unit<br><br>Three Therapy ports (Continuous Positive Expiratory Pressure (CPEP), | Control Unit<br><br>One therapy port: Continuous Positive Expiratory Pressure (CPEP) | Control Unit<br><br>One therapy port: High Frequency Chest Wall | Control Unit<br><br>One therapy port: Nebulizer |

| | Volara™ | E0482 | E0483 | E0570 |
|---|---|---|---|---|
| | Continuous High Frequency Oscillation (CHFO), and Nebulizer<br><br>Air Filter, Breathing Tube, Nebulizer kit, Mouthpiece, Face Mask | <br><br><br><br><br>Air Filter, Breathing Tube | Oscillation (HFCWO)<br><br><br><br><br>Valves, Pistons, Pads | <br><br><br><br><br>Air Filter, Tubing + Mouthpiece, Nebulizer Chamber |
| **Mechanical Components** | Utilizes Automatic Program | Utilizes Automatic and Manual Program | Utilizes Manual Program | Utilizes Automatic Program |
| **Electrical Components** | Replaceable Battery | AC Adapter | Rechargeable Battery | AC Adapter |
| **Function and Intended Use** | Triple therapy in one: secretion clearance, lung expansion, and nebulizer treatment.<br><br>It benefits cystic fibrosis, neuromuscular, and bronchiectasis patients. | Lung expansion Treatment<br><br><br><br>It benefits patients with muscle weakness in neurological conditions such as muscular dystrophies and spinal cord lesions | Secretion Clearance therapy<br><br><br><br>It benefits patients having difficulty with secretion clearance, or the presence of atelectasis caused by mucus plugging | Breaking the liquid medication into breathable mist or aerosol<br><br>It benefits patients where inhaled medicines are indicated such as asthma and Chronic Obstructive Pulmonary Disease (COPD) |
| **Additional Aspects and Features** | Single Patient Use<br><br>10 min therapy<br><br>Maximum of 90 treatment sessions<br><br>Features a WiFi module to export | Multiple Patient Use<br><br>Ranging from 6 to 1200 breaths per minute. | Multiple Patient Use Connected through Mobile App as an option | Multiple Patient Use<br><br>Can be Ultrasonic or Electronic |

| | Volara™ | E0482 | E0483 | E0570 |
|---|---|---|---|---|
| | system and therapy data | | | |

As described above, the preliminary payment determination is to use the pricing for HCPCS Level II code E0483 to account for the continuous high frequency oscillation function and additional amounts to recognize the device's continuous positive expiratory pressure and nebulizer functions using HCPCS Level II codes E0482 and E0570 respectively. We believe the additional cost of the continuous positive expiratory pressure function can be accounted for by dividing the rental fee of HCPCS Level II code E0482 ("Cough stimulating device, alternating positive and negative airway pressure") by two to recognize only the positive pressure since HCPCS Level II code E0482 devices provide both positive and negative pressure. Secondly, we would compute the purchase price of HCPCS Level II code E0482 by multiplying the rental amount by 10 and then dividing that amount by 60 in order to get the cost of the continuous positive expiratory pressure feature added to the device over the course of the five-year reasonable useful lifetime. Similarly, we believe the additional cost of the nebulizer function can be accounted for by calculating the purchase price of HCPCS Level II code E0570 ("Nebulizer, with compressor") by multiplying the rental amount by 10 and then dividing that amount by 60 to obtain the cost of the added function over the device's five-year reasonable useful lifetime.

Therefore, the preliminary payment determination for HCPCS Level II code EXXXX using comparable items is calculated using the following formula: EXXXX= E0483 + ((E0482/2)*10/60) + (E0570*10/60). The 2024 average non-rural capped rental fee schedule amount for HCPCS Level II code EXXXX would be approximately $1,505.16 for months 1 through 3 and approximately $1,128.90 for months 4 through 13.

Pricing Indicator = 36

**Summary of Public Feedback**

Baxter agreed with CMS' published preliminary HCPCS Level II coding, Medicare benefit category, and Medicare payment recommendations.

**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 E0469, "Lung expansion airway clearance, continuous high frequency oscillation, and nebulization device" to describe the Volara™ System.

**Final Medicare Benefit Category Determination**

Durable Medical Equipment.

**Final Medicare Payment Determination**

We are finalizing our preliminary payment determination to establish the Medicare payment amount using fee schedule amounts for comparable items in accordance with regulations at 42 CFR 414.238. The fee schedule amount will be established as discussed in the preliminary determination. The final payment determination for HCPCS Level II code E0469 is calculated using the following formula: E0469= E0483 + ((E0482/2) *10/60) + (E0570*10/60).

The 2024 average non-rural capped rental fee schedule amount for HCPCS Level II code E0469 will be approximately $1,505.16 for months 1 through 3 and approximately $1,128.90 for months 4 through 13.

Pricing Indicator = 36

# Volara™ System Supply Kit - HCP231218VBVAD

## Topic/Issue

Request to establish a new HCPCS Level II code to identify disposable supply kit for the Volara™ System.

Applicant's suggested language: XXXXX, “Disposable supply kit for multi-function oscillation and lung expansion airway clearance device, includes but not limited to handset, nebulizer kit, biofilter, adapters, and hose”

## Summary of Applicant's Submission

Baxter submitted a request to establish a new HCPCS Level II code to identify disposable supply kit used with the Volara™ System. Volara™ System received the Food and Drug Administration’s (FDA’s) 510(k) clearance for home use on January 20, 2020. The supply kit is an integral part of the system, required for the patient to receive the therapy. The components in the supply kit connect to the Volara™ System to deliver the oscillation and lung expansion therapy. It has the following components: biofilter, nebulizer kit, handset, hose, and adapters. Biofilter is used as a barrier between patient and device to reduce chance for bioburden contamination. This filter is used for 90 therapy sessions and automatically alerts the patient when a new filter and supply kit are required. Nebulizer kit including nebulizer cup and tubing, transfers pressurized air from device nebulizer port to the nebulizer cup for the nebulization process to occur. Handset serves as the central connection point for the supply kit components and is the ergonomic means for the patient or caregiver to administer therapy. Hose is conduit for therapy air from device therapy port to the patient handset. Adapters allow for different configurations or setups of the supply kit based on the individual patient’s clinical needs. The Volara™ System supply kit is configurable via various adapters to adjust to the patient’s clinical needs.

## CMS Preliminary HCPCS Coding Recommendation

Establish a new HCPCS Level II code XXXXX, “Supplies and accessories for lung expansion airway clearance, continuous high frequency oscillation, and nebulization device (e.g., handset, nebulizer kit, biofilter)” to describe the disposable supply kit for the Volara™ System.

## Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

The Volara™ supply kit serves as a DME accessory to the durable Volara™ device. The single patient use supply kit is intended for 30 days of treatment or a maximum of 90 treatment session. Section 110.3 of the Medical Benefit Policy Manual (CMS Pub. 100-03) indicates that payment may be made for supplies and accessories that are necessary for the effective use of durable medical equipment. Because the Volara™ supply kit is an accessory to an item of DME, the supply kit falls under the DME benefit category.

**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 AXXXX is to use the existing fee schedule amounts for comparable items described by HCPCS Level II code A7030 ("Full face mask used with positive airway pressure device, each"), HCPCS Level II code A7003 ("Administration set, with small volume nonfiltered pneumatic nebulizer, disposable"), HCPCS Level II code A7004 ("Small volume nonfiltered pneumatic nebulizer, disposable"), HCPCS Level II code A7037 ("Tubing used with positive airway pressure device") and HCPCS Level II code A7039 ("Filter, non disposable, used with positive airway pressure device") to describe the components of the Volara™ supply kit.

CMS has compared the five HCPCS Level II codes to the components of the Volara™ supply kit as shown in the below comparability tables. HCPCS Level II code A7030 describes the Volara™ mask and HCPCS Level II codes A7003 and A7004 recognize the Volara™ handset, mouthpiece, nebulizer cup and tubing. The Volara™ breathing tube and tracheostomy adaptor is described by comparable HCPCS Level II code A7037 and the Volara™ biofilter by HCPCS Level II code A7039. We believe HCPCS Level II codes A7030, A7003, A7004, A7037 and A7039 describe the components of the Volara™ supply kit and are comparable with respect to the physical and mechanical components, function and in the additional aspects and features.

| | **Volara™ Face Mask** | **A7030** |
|---|---|---|
| **Physical Components** | Mask | Mask |
| **Mechanical Components** | Contains Silicone | Contains Silicone |
| **Electrical Components** | NA | NA |
| **Function and Intended Use** | It covers the mouth and nose of the patient tightly.<br><br>Use is Optional in the Volara™ system | It covers the mouth and nose of the patient tightly.<br><br>It is used with CPAP ventilation system |
| **Additional Aspects and Features** | The narrow end of the mask is over the patient's nose<br><br>15mm Outer Diameter (OD) (infant) or 22mm of Internal Diameter (ID) (Adult)<br><br>Comes in regular or inflatable<br><br>Single Patient Use | The narrow end of the mask is over the patient's nose<br><br>15mm Outer Diameter (OD) (infant) or 22mm of Internal Diameter (ID) (Adult)<br><br>Comes in small, medium, and large<br><br>Reusable or Single Patient use |

| | Volara™ Nebulizer Kit | A7003 | A7004 |
|---|---|---|---|
| **Physical Components** | Nebulizer Cup<br><br>Nebulizer Tube | Nebulizer Cup<br><br>Nebulizer Tube | Nebulizer Cup |
| **Mechanical Components** | Capacity: 2-10 ml | Capacity: 0.2 ml | Capacity: 0.2 ml |
| **Electrical Components** | NA | NA | NA |
| **Function and Intended Use** | It is designed to aerosolize medication approved for nebulization and prescribed by a physician.<br><br>A fill volume of 2.5 ml of medication is expected to last 10 minutes of nebulization. | It is intended for use in the treatment of upper and lower respiratory tract illnesses where aerosolized medication is required.<br><br>A fill volume of 0.2 ml of medication is expected to last 1 minute of nebulization. | It is intended for use in the treatment of upper and lower respiratory tract illnesses where aerosolized medication is required.<br><br>A fill volume of 10 ml of medication is expected to last 6-8 minutes of nebulization. |
| **Additional Aspects and Features** | Single Use<br><br>Includes connection for in-line nebulization filter | Single Use (disposable) | Single Use (disposable) |

| | Volara™ Tubing | A7037 |
|---|---|---|
| **Physical Components** | Endotracheal tube or tracheostomy tube. | Endotracheal tube or tracheostomy tube. |
| **Mechanical Components** | 22 mm x 20 mm adapter | 22mm male fitting connectors |
| **Electrical Components** | NA | NA |
| **Function and Intended Use** | Used in Volara™ System | Used in CPAP system |
| **Additional Aspects and Features** | | |

| | Volara™ Bio-Filter | A7039 |
|---|---|---|
| **Physical Components** | Connector, Filter, Port | Connector, Filter, Port |
| **Mechanical Components** | Poly Propylene Housing Material | Poly Propylene Housing Material<br><br>Contains Foam |
| **Electrical Components** | NA | NA |

| | Volara™ Bio-Filter | A7039 |
|---|---|---|
| **Function and Intended Use** | Used in Volara™ System<br><br>Attached to the breathing hose | Used in CPAP or BIPAP system<br><br>Attached to the breathing hose |
| **Additional Aspects and Features** | The biofilter has a filtration efficiency of greater than 99% or penetration of less than 1% | The biofilter has a filtration efficiency of greater than 99% or penetration of less than 1% |

As described above, the preliminary payment determination is to use the pricing for HCPCS Level II codes A7030, A7003, A7004, A7037 and A7039 to describe the various components of the Volara™ supply kit. We believe that these codes represent the characteristics of the Volara™ supply kit and when the comparable code fees are summed, can be used to establish the fee schedule amounts for new supply HCPCS Level II code AXXXX. Payment for the supply kit would be established by summing the individual fee schedules for the following HCPCS Level II codes: A7030, A7003, A7004, A7037 and A7039.

Therefore, the preliminary payment determination for HCPCS Level II code AXXXX using comparable items is calculated using the following formula: AXXXX = A7030 + A7003 +A7004 +A7037+A7039. The average 2024 non-rural fee schedule amount for code AXXXX would be approximately $137.34.

Pricing Indicator = 34

**Summary of Public Feedback**

Baxter agreed with CMS' published preliminary HCPCS Level II coding, Medicare benefit category, and Medicare payment recommendations.

**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 A7021, "Supplies and accessories for lung expansion airway clearance, continuous high frequency oscillation, and nebulization device (e.g., handset, nebulizer kit, biofilter)" to describe the disposable supply kit for the Volara™ System.

**Final Medicare Benefit Category Determination**

Durable Medical Equipment.

**Final Medicare Payment Determination**

We are finalizing our preliminary payment determination with the fee schedule amounts established as discussed in the preliminary determination. Existing HCPCS level II codes

A7030, A7003, A7004, A7037 and A7039 describe the various components of the Volara™ supply kit and when the fees are summed, are used to establish the fee schedule amounts for new supply HCPCS Level II code A7021. The final payment determination for HCPCS Level II code A7021 is calculated using the following formula: A7021 = A7030 + A7003 + A7004 + A7037 + A7039. The average 2024 non-rural purchase fee schedule amount for new code A7021 will be approximately $137.34.

The preliminary determination incorrectly classified this accessory to an item of DME as a supply under pricing indicator 34. In the final determination we are revising the payment class to inexpensive and other routinely purchased items for this accessory, reflected by a pricing indicator of 32. Payment will be made on a purchase basis in accordance with section 1834(a)(2)(A) of the Social Security Act.

Pricing Indicator = 32

## TheraBionic® P1 - HCP240102U225T

### Topic/Issue

Request to establish a new HCPCS Level II Code to identify TheraBionic® P1.

Applicant's suggested language: EXXXX, “Systemic delivery of amplitude-modulated, radiofrequency electromagnetic field device, for cancer treatment”

### Summary of Applicant's Submission

TheraBionic, Inc. submitted a request to establish a new HCPCS Level II code to identify the TheraBionic® P1. The TheraBionic® P1 was granted humanitarian device exemption (HDE) as a humanitarian use device (HUD) by the Food and Drug Administration (FDA) on September 26, 2023. The TheraBionic® P1 is intended for use in adults with advanced hepatocellular cancer who have failed first and second-line therapy. The TheraBionic® P1 is a portable battery-driven generator coupled with a spoon shaped antenna placed in the patient’s mouth to deliver systemic low-level amplitude-modulated radiofrequency electromagnetic fields for tumor-specific treatment of advanced hepatocellular cancer. Each treatment episode lasts 28 days and consists of one-hour sessions three times per day at home by the patient until progression of malignancy is documented. The TheraBionic® P1 does not fit the existing HCPCS Level II code E0766 (“Electrical stimulation device used for cancer treatment, includes all accessories, any type”) because the code has been associated in clinical practice guidelines and payer policies with other home-use devices that deliver localized tumor treatment fields via electrodes applied to the skin (scalp or chest) for the treatment of glioblastoma or mesothelioma. The TheraBionic® P1 also does not fit HCPCS Level II code E0761 (“Non-thermal pulsed high frequency radiowaves, high peak power electromagnetic energy treatment device”) because the TheraBionic® P1 does not deliver high peak power or pulsed electromagnetic energy.

### CMS Preliminary HCPCS Coding Recommendation

Establish a new HCPCS Level II code EXXXX, “Intrabuccal, systemic delivery of amplitude-modulated, low-level radiofrequency electromagnetic field device, for cancer treatment, includes all accessories” to describe TheraBionic® P1.

### Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

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

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

The TheraBionic® P1 device meets all five of the conditions that must be met in order for equipment to be classified as DME.

**Preliminary Medicare Payment Determination**

No determination.

As this device is marketed under an HDE (Humanitarian Device Exemption), there are specific rules laid out in the Food and Drug Administration Amendments Act of 2007 that may impact the establishment of a national Medicare payment amount. Specifically, only certain devices with HDE approval may be sold at a profit, and that profit is limited to a certain quantity based on the Annual Distribution Number established by the FDA as part of the HDE process. Therefore, we are consulting with the Food and Drug Administration to determine whether this statute would impact a Medicare payment determination.

Pricing Indicator = 46

**Summary of Public Feedback**

TheraBionic, Inc. supported the preliminary HCPCS coding recommendation; however, they suggested that the payment category for the device should be "frequently serviced", as their card needs to be replaced monthly.

**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 modifying its preliminary coding recommendation by removing the phrase "low-level" to more closely reflect the applicant's suggested language, and finalizing the coding decision to:

Establish a new HCPCS Level II code E0767, "Intrabuccal, systemic delivery of amplitude-modulated, radiofrequency electromagnetic field device, for cancer treatment, includes all accessories" to describe TheraBionic® P1.

**Final Medicare Benefit Category Determination**

Durable Medical Equipment.

**Final Medicare Payment Determination**

We appreciate the comments regarding the refurbishment process for this device. While we understand that the chip card used to control access to the prescribed number of treatments must be periodically refreshed with additional authorized treatment sessions, we do not believe this process is sufficient to justify classifying this device as an item requiring frequent and substantial servicing. Overall, we believe that the servicing and refurbishment needs for this device are no different than what would be expected for any other item of durable medical equipment. As such, should the purchase price for this item exceed $150 in the base period, payment would be made on a capped rental basis in accordance with our regulations at 42 CFR 414.229. Should the purchase price for this item be less than $150 in the base

period, payment would be made on a rental or purchase basis in accordance with our regulations at 42 CFR 414.220. However, at this time, we do not have verifiable information from supplier invoices or non-Medicare payer data that would support the establishment of a national Medicare fee schedule amount. Payment amounts for this item will be established by the DME MACs.

Pricing Indicator = 46

## Medibottle® - HCP240102C0A2T

### Topic/Issue

Request for a new HCPCS Level II code to identify the medibottle®.

Applicant's suggested language: XXXXX, “Liquid Oral Medication Delivery Device”

### Summary of Applicant's Submission

The Medicine Bottle Company Inc. submitted a request is for a new HCPCS Level II code to identify the medibottle®. The medibottle®, Pediatric Medication Delivery System, is exempt from the Food and Drug Administration’s (FDA’s) review and classification. The medibottle® is designed and engineered to deliver an accurate dose of oral, liquid medication to the infant population. From the infant’s perspective, medibottle® appears to be a regular baby bottle. This is helpful because the process begins with something that they are familiar with and helps them get and stay comfortable throughout the administration of the dose. The bottle portion of the device is filled like a regular baby bottle and a preferred nipple is attached. The oral dispenser is filled with the prescribed medicine. The caregiver then inserts the oral dispenser into the sleeve, ready to begin the sip and squirt process. Incorporating fluid dynamic principles, the medicine is transported from the oral dispenser to the tip of the nipple without using any physical structure and remains essentially undiluted. The medibottle® utilizes the infant’s natural desire to take in the familiar liquid. Because the infant controls the flow, the medicine is delivered to the ideal position in the mouth for swallowing, also minimizing the residence time which in turn minimizes the chance for the infant to sense the medicine. The medibottle® is essentially a masking device–delivering the intended dose, undiluted and undetected. Peer-reviewed data state that compliance is a pediatrician’s most important concern and non-compliance to medication regimes directly and adversely affects the health of the infant population. Independent clinical trials conducted both inpatient and outpatient, have proven that the medibottle® device offers a significant therapeutic distinction. From an effectiveness standpoint, the medibottle® measured 93% or better versus the second-place oral dispensers failing 57%. This must be considered a significant therapeutic distinction, and it translates into higher quality and safer care for the infant population. If the infant cannot taste the medicine, then there is nothing to resist. Although not the objective, the infant’s acceptance level is also 329% greater than that of the oral dispenser. When implemented with a bad tasting medicine, the disparity between the oral dispenser and medibottle® widens further. Increasing compliance to equal or approaching 100% was the primary objective. Also, the device eliminates the trauma and upset that are often a part of the process for both infant and caregiver.

### 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 masking device intended to deliver an accurate dose of oral, liquid medication to an infant population. We welcome information from the applicant and other insurers who are currently paying for this product or any oral medication delivery products to demonstrate a claims processing need for a unique HCPCS Level II code.

**Summary of Public Feedback**

The Medicine Bottle Company Inc. disagreed with CMS' published preliminary determination. The medibottle® delivers an accurate dose of prescribed, oral liquid medication to the infant population, resulting in an increase of compliance. The Medicine Bottle Company Inc. submitted their first HCPCS Level II application to CMS 24 years ago. Currently, there are no payers for this product. An in-hospital study for medibottle® was conducted that used prednisolone, a bitter tasting medicine. According to the speaker, the study included 76 hospitalized infants and found medibottle® to be just over 85% more likely to deliver 100% of the prescribed liquid drug dose, than by using the industry's old "gold" standard oral syringe device delivery method. The medibottle® device has been mentioned in several nursing textbooks, including Wong's Essentials of Pediatric Nursing. The medibottle® can again help with infant patient compliance by delivering the prescribing clinician's intended dose.

**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. While the speaker noted that the medibottle® has been used by hospitals or clinics to assist in providing medication to infants, there is no indication that this item would be separately payable by Medicare or other payers. For this reason, CMS has not identified a program operating need for Medicare or other payers for a new HCPCS Level II code to describe a masking device intended to deliver an accurate dose of oral, liquid medication to an infant population.

## Sea-Long Medical Systems 5000 Series- HCP231025TT2K6

### Topic/Issue

Request to establish a new HCPCS Level II code to identify Sea-Long Medical Systems 5000 Series.

The applicant did not submit any suggested language.

### Summary of Applicant's Submission

Sea-Long Medical Systems LLC submitted a request to establish a new HCPCS Level II code to identify the 5000 Series Helmet and Neckseal Set that is to be used during hyperbaric treatments. The 5000 Series Helmet and Neckseal Set was approved by the Food and Drug Administration (FDA) on August 13, 1991. The sets are for single or multiple patient use. The helmet is connected to an oxygen line or tubing that will provide oxygen during treatments in a clinic or hospital setting. The closest HCPCS Level II code is A4620 ("Variable concentration mask") which is for a mask; however, the 5000 Series Helmet is classified as a helmet. The indications of use are based on the guidelines that the FDA has put into place under K010659 that the treatment hood is intended to be used in any place that a clinician normally uses a mask for medical purposes of supplying gas, oxygen, or air. The treatment hood is connected to gas, oxygen, or air supply. The 5000 Series Helmet and Neckseal Set is prescription use only. The dosage is one helmet per patient. The helmet is put onto the patient's head to receive treatment. The item is packaged into individual bags.

### CMS Preliminary HCPCS Coding Recommendation

CMS believes that Sea-Long Medical Systems 5000 Series is not suitable for coding in the HCPCS Level II code set as it is our understanding that the item is used by a clinician during a procedure that would be typically described by a HCPCS Level I Current Procedural Terminology (CPT®) code. CMS encourages the applicant to engage with the American Medical Association about potential HCPCS Level I CPT® coding.

### Summary of Public Feedback

Sea-Long Medical Systems LLC acknowledged CMS' preliminary recommendation.

### CMS Final HCPCS Coding Decision

Based on the information provided in the application and considering that no further comments were received, CMS is finalizing its preliminary recommendation. CMS believes that Sea-Long Medical Systems 5000 Series is not suitable for coding in the HCPCS Level II code set as it is our understanding that the item is used by a clinician during a procedure that would be typically described by a HCPCS Level I CPT® code. CMS encourages the applicant to engage with the American Medical Association about potential HCPCS Level I CPT® coding.

## 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 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/Final HCPCS Coding Decision

CMS established a new HCPCS Level II code A4271, “Integrated lancing and blood sample testing cartridges for home blood glucose monitor, per month” to describe POGO Automatic® Test Cartridges, effective April 1, 2024. However, CMS has been made aware of a claims processing need on behalf of Medicare to revise the current code language. The

descriptor language “per month” insinuates an allowance versus a set quantity. This language was causing providers to refer to our final coding determination in order to understand the code (i.e., descriptors should be stand-alone). As such, we recommend to:

Revise existing HCPCS Level II code A4271, “Integrated lancing and blood sample testing cartridges for home blood glucose monitor, per month” to instead read “Integrated lancing and blood sample testing cartridges for home blood glucose monitor, per 50 tests” to describe POGO Automatic® Test Cartridges.

**Final Benefit Category Determination**

CMS determined that the POGO Automatic® Test Cartridges are supplies used with Durable Medical Equipment, effective April 1, 2024.

**Final Medicare Payment Determination**

The fee schedule amounts for HCPCS Level II code A4271 went into effect on April 1, 2024, and were established based on supplies for 100 tests. They will therefore be revised so they are based on supplies for 50 tests. Two units of HCPCS Level II code A4271 would be used to bill for supplies for 100 tests.

**Summary of Public Feedback**

Intuity Medical supported the coding recommendation to revise the descriptor for HCPCS Level II code A4271 from “per month” to “per 50 tests” and to adjust the payment rate based on 50 tests instead of 100 tests.

**CMS Final HCPCS Coding Decision**

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

Revise existing HCPCS Level II code A4271, “Integrated lancing and blood sample testing cartridges for home blood glucose monitor, per month” to instead read “Integrated lancing and blood sample testing cartridges for home blood glucose monitor, per 50 tests” to describe POGO Automatic® Test Cartridges.

## Technegas® Aerosol - HCP230930XY3C1

### Topic/Issue

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

Applicant's suggested language: AXXXX, “Technetium Tc 99m-labeled carbon inhalation aerosol, diagnostic, per study dose, up to 27 mCi”

### Summary of Applicant's Submission

Cyclomedica Australia Pty. Ltd. submitted a request to establish a new HCPCS Level II code to identify Technegas® Aerosol. Technegas®, a drug/device combination kit for the preparation of Technegas® Aerosol, was approved by the Food and Drug Administration (FDA) under a 505(b)(2) New Drug Application (NDA) on September 29, 2023. Technegas® Aerosol is a diagnostic radiopharmaceutical drug composed of hydrophobic nanometer size particles of carbon labeled with Technetium-99m (Tc 99m) dispersed in high-purity argon gas as an aerosol for inhalation. Technegas® Aerosol is indicated for use in adults and pediatric patients aged six years or older for visualization of pulmonary ventilation and evaluation of pulmonary embolism when paired with perfusion imaging. Technegas® Aerosol is prepared using the TECHNEGAS® kit containing the Technegas® Crucible, a 1.25 gram single-use graphite carbon crucible. The Technegas® Plus System is an automated module used to prepare and administer Technegas® Aerosol in argon gas from the supplied Technegas® Crucible and the user supplied sodium pertechnetate Tc 99m injection, United States Pharmacopeia (USP). Upon addition of sodium pertechnetate Tc 99m injection, USP to the Technegas® Crucible, the Technegas® Plus System provides Technegas® Aerosol for oral inhalation. For adult patients, the recommended activity of sodium pertechnetate Tc 99m injection to be loaded in the Technegas® Crucible is 10.8 to 27 millicuries (mCi) to achieve a lung count rate between 1,500 and 2,500 counts per second (cps) at the end of the last respiration. For pediatric patients aged six years and older, a sufficient amount of Technegas® Aerosol should be inhaled to achieve between 500 cps and 1,000 cps at the end of the last respiration. Technegas® Aerosol should be administered as soon as possible following preparation, and inhalation should be completed within ten minutes of preparation. Technegas® Aerosol is administered to the patient by oral inhalation using the Technegas® Patient Administration Set, a single-use radionuclide rebreathing device for Technegas® Aerosol that connects directly to the Technegas® Plus System.

### CMS Final HCPCS Coding Determination

According to the FDA approved labelling, the Technegas® Aerosol kit includes five blister packs of ten single-use Technegas® Crucibles. According to the applicant, the 50 patient administration sets included in the kit are provided at no additional charge as necessary delivery devices for the drug product, and must be used for the inhalation of Technegas® Aerosol. The existing HCPCS Level II code A9512, “Technetium tc-99m pertechnetate, diagnostic, per millicurie” is not intended to be billed for Technegas® Aerosol. Instead, each single-use Technegas® Crucible and single-use Technegas® Patient Administration Set used in a lung ventilation imaging procedure is intended to be billed with the requested HCPCS Level II code for the Technegas® Aerosol. Therefore, CMS’ final coding decision is to:

Establish a new HCPCS Level II code A9506, “Graphite crucible for preparation of technetium tc 99m-labeled carbon aerosol, each” to describe Technegas® Aerosol.

Effective July 1, 2024.

We are requesting public comment on the language in the code descriptor for this new HCPCS Level II code.

**Summary of Public Feedback**

Cyclomedica agreed with the HCPCS Level II coding language for code A9506 to describe the single graphite crucible for preparation of technetium Tc 99-m labeled carbon aerosol. However, other speakers suggested that CMS clarify the meaning of the word “each” in the code descriptor by utilizing a different unit of measurement, such as “per millicurie” or “per study dose.” The speaker also suggested that we remove the phrase “for the preparation of” and add the word, “diagnostic” for the sake of consistency with other adjacent HCPCS Level II code descriptors.

**CMS Final HCPCS Coding Decision**

We appreciate the comments provided in response to CMS’ published HCPCS coding determination. Based on the information provided in the application and after consideration of the comments we received, CMS is revising its coding determination from:

HCPCS Level II code A9506, “Graphite crucible for preparation of technetium tc 99m-labeled carbon aerosol, each” to instead read, “Graphite crucible for preparation of technetium tc 99m-labeled carbon aerosol, one crucible” to describe Technegas® Aerosol.

We agree with revising the language in the code descriptor to clarify that each unit refers to one graphite crucible. However, we will maintain the phrase “for the preparation of” because it most closely reflects the language in the FDA approved label and will not include the word “diagnostic” because it does not accurately describe the crucible itself.

Effective July 1, 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.