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

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

Second Biannual (B2), 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' Second 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 April 1, 2025, unless otherwise indicated.

The HCPCS Level II coding decisions below will also be included in the April 2025 HCPCS Quarterly Update, pending publication by CMS in the coming weeks at: https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update. For inquiries regarding coverage, please contact the insurer(s) in whose jurisdiction(s) claim(s) would be filed. Specifically, contact the Medicaid agency in the state in which a Medicaid claim is filed, the individual private insurance entity, the Department of Veterans Affairs, or, for local Medicare coverage determinations, contact the Medicare contractor in the jurisdiction the claim would be filed. For detailed information describing CMS' national coverage determination process, refer to information published at https://www.cms.gov/Medicare/Coverage/DeterminationProcess and https://www.cms.gov/Center/Special-Topic/Medicare-Coverage-Center.

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Final coding, Medicare benefit category, and Medicare payment determinations from the HCPCS Level II Virtual Public Meeting on November 6, 2024 to November 8, 2024.

Chemo Mouthpiece™ - HCP240627CH4KV

Topic/Issue

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

Applicant's suggested language: XXXXX, "Intra-oral cryotherapy device for patients who receive stomatotoxic chemotherapy administration, kit of 6 plus accessories"

Summary of Applicant's Submission

ChemoMouthpiece, LLC submitted a request to establish a new HCPCS Level II code to identify Chemo Mouthpiece™. Chemo Mouthpiece™ received the Food and Drug Administration's (FDA's) 510(k) clearance on January 23, 2024. Chemo Mouthpiece™ is a medical device that is intended for use in adult individuals to cool the oral mucosa, causing vasoconstriction that decreases the flow of chemotherapy, thus reducing the incidence and severity of chemotherapy-induced oral mucositis. The device is indicated for use in the clinical and home settings in adult individuals who are receiving chemotherapy. The Chemo Mouthpiece™ device is a single individual, multiple-use item that is supplied in a kit containing six identical devices (intended for the same individual). The devices are placed in a freezer six hours prior to the individual being administered chemotherapy. Ten minutes prior to chemotherapy, the individual is instructed to use the device, which will remain in the individual's mouth for the duration of the chemotherapy administration. Each device maintains a temperature of 31.8 degrees to 35.5 degrees Fahrenheit for 30 minutes and the individual is instructed to switch to another frozen device every 30 minutes for the duration of chemotherapy infusion. Individuals are instructed to use the device at home (post-administration of chemotherapy) a minimum of two times per day for the following five days to keep the oral cavity cool to reduce the incidence and severity of chemotherapy-induced mucositis.

CMS Preliminary HCPCS Coding Recommendation

The Chemo Mouthpiece™ is not suitable for coding in HCPCS Level II for Medicare purposes because this product, if covered, would be expected to be included within the payment for the professional service. 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

ChemoMouthpiece, LLC disagreed with CMS' HCPCS preliminary recommendation that the Chemo Mouthpiece™ would be expected to be included within the payment for the professional service and therefore would not be suitable for HCPCS Level II coding. The speaker described oral mucositis, an adverse reaction of cytotoxic chemotherapy, as the painful atrophy, erythema and ulceration of the oral mucosa, which lasts at least a week to 10 days post-each chemotherapy administration and if not mitigated well, gets worse during subsequent chemotherapy cycles. The speaker stated that oral mucositis occurs in 40% of individuals receiving chemotherapy, is a common adverse event associated with the most prescribed chemotherapy regimens, and once it has occurred the likelihood of recurrence is higher which puts individuals at risk of infection and dose alteration. The speaker commented

that the treatment options for oral mucositis are sparse and typically involve cryotherapy in the form of ice chips. The speaker stated that the issues with ice chips included the logistics of constantly replenishing them, the coolness derived from ice chips is unevenly distributed in the mouth, they caused drooling and difficulty swallowing and were not easily continued outside the clinic. The speaker referenced that in a multi-institutional, randomized Phase 3b trial[1], the Chemo Mouthpiece® device demonstrated its efficacy in significantly mitigating mucosal pain and the use of analgesics. The speaker also stated that by using the Chemo Mouthpiece® cryotherapy may be applied in a more even, efficacious, and convenient manner, thus reducing healthcare resource costs by approximately $1,900 per individual per cycle of treatment according to a study they performed. Finally, the speaker commented that the device would be dispensed to the individual at their first chemotherapy encounter. Other commenters reiterated the devices impact on individuals, allowing them to continue chemotherapy uninterrupted, decreasing their use of analgesics including opioids, and how a reliable replacement for ice chips was needed.

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. It is our understanding that as the product is provided to the individual at the time of their first chemotherapy encounter and, for Medicare purposes, if this product were covered, it would be included within the payment for the professional service.

[1] 2023/9/18, A Trial Assessing Chemo Mouthpiece Device with Best Supportive Care for Symptoms of Chemotherapy-Induced Oral Mucositis, Clinicaltrials.gov, https://clinicaltrials.gov/study/NCT04595838

Flexi-Q DV Auto-Injector - HCP240701MKHXP

Topic/Issue

Request to establish a new HCPCS Level II code to describe the Flexi-Q DV Auto-Injector.

Applicant's suggested language: XXXXX, “Prefilled syringes and vials, featuring reusable for chronic disease that require frequent injection”

Summary of Applicant's Submission

Vanguard Health Management LLC submitted a request to establish a new HCPCS Level II code to describe the Flexi-Q DV Auto-Injector. The Flexi-Q DV Auto-Injector received the Food and Drug Administration’s (FDA’s) 510(k) clearance on February 9, 2012. The Flexi-Q DV Auto-Injector is a multi-use auto-injector with a reusable driving unit and cost-effective needle protection disposable cassette for use with standard pre-filled syringes and vials. The Flexi-Q DV Auto-Injector is intended for use in chronic diseases that require frequent injections, and its partially reusable design lowers the cost per injection and reduces the volume for storage and disposal. The Flexi-Q DV Auto-Injector offers automatic needle insertion with customizable preset needle penetration depths, preset injection speeds, and fixed delivery volumes. The Flexi-Q DV Auto-Injector has windows for visual inspection of the syringe content along the full length of the barrel. Drug reconstitution and mixing from a vial can be performed using Flexi-Q’s optional vial adaptor or dual-chamber prefilled syringe which permit reconstitution of hard-to-dissolve drugs by allowing swirling and time delays followed by user inspection prior to injection.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code A4211, “Supplies for self-administered injections” describes the Flexi-Q DV Auto-Injector. Flexi-Q DV Auto-Injector is similar to other devices in HCPCS Level II code A4211.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

The current Medicare policy and prior established benefit category determination for HCPCS Level II code A4211 applies to this item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code A4211 apply to this product. Items or services described by HCPCS Level II code A4211 are not covered under the Medicare Part B DMEPOS benefit.

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 A4211, “Supplies for self-administered injections” to describe the Flexi-Q DV Auto-Injector. Flexi-Q DV Auto-Injector is similar to other devices in HCPCS Level II code A4211.

Final Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

Final Medicare Payment Determination

No Medicare Payment. Pricing Indicator = 00

iHealth® COVID-19/Flu A&B Rapid Test - HCP240530Q0P9A

Topic/Issue

Request to establish a new HCPCS Level II code to identify iHealth® COVID-19/Flu A&B Rapid Test.

The applicant did not submit any suggested language.

Summary of Applicant's Submission

iHealth Labs, Inc submitted a request to establish a new HCPCS Level II code to identify iHealth® COVID-19/Flu A&B Rapid Test. iHealth® non-prescription home use self-collected COVID-19/Flu A&B Rapid Test received the Food and Drug Administration's (FDA's) Emergency Use Authorization (EUA) on May 7, 2024. The iHealth® COVID-19/Flu A&B Rapid Test is a non-prescription, self-collected, nasal swab for individuals aged 14 years or older, or with adult-collected nasal swab specimen from individuals 2 to 14 years old. This test is only authorized for individuals with signs and symptoms of respiratory infection consistent with COVID-19 within the first four days of symptom onset when tested at least twice over three days, with at least 48 hours between tests.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a program operating need for Medicare or other payers to establish a new HCPCS Level II code to describe iHealth® COVID-19/Flu A&B Rapid Test. iHealth® COVID-19/Flu A&B Rapid Test would not be payable by Medicare as there is no Medicare Benefit Category for at-home COVID-19/Flu A&B Rapid tests. CMS is not aware of other insurers potentially paying for this non-prescription home use self-collected COVID-19/Flu A&B Rapid tests. Please contact non-Medicare payers for coding and payment guidance. If information regarding payers who are currently paying for these COVID-19/Flu A&B Rapid tests becomes available to describe a claims processing need for a unique HCPCS Level II code, the applicant is welcome to submit a new application.

Summary of Public Feedback

No verbal or written comments were provided in response to CMS' published preliminary 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. CMS has not identified a program operating need for Medicare or other payers to establish a new HCPCS Level II code to describe iHealth® COVID-19/Flu A&B Rapid Test. iHealth® COVID-19/Flu A&B Rapid Test would not be payable by Medicare as there is no Medicare Benefit Category for at-home COVID-19/Flu A&B Rapid tests. CMS is not aware of other insurers potentially paying for this non-prescription home use self-collected COVID-19/Flu A&B Rapid tests. Please contact non-Medicare payers for coding and payment guidance. If information regarding payers who are currently paying for these COVID-19/Flu A&B Rapid tests

becomes available to describe a claims processing need for a unique HCPCS Level II code, the applicant is welcome to submit a new application.

Missing and Murdered Indigenous Persons (MMIP) and Historical Trauma (HT) - IHC240819DMW1D

Topic/Issue

Request to establish two new HCPCS Level II codes to identify Missing and Murdered Indigenous Persons (MMIP) and Historical Trauma (HT) services.

Applicant's suggested language:

1. XXXXX, “Missing and murdered indigenous persons (MMIP) mental health and clinical care”

2. XXXXX, “Historical Trauma (HT) mental health and clinical care”

Summary of Applicant's Submission

The Not Invisible Act Commission recommended the Department of Health & Human Services establish two HCPCS Level II codes to describe Missing and Murdered Indigenous Persons (MMIP) and Historical Trauma (HT) services. These new codes could be used for American Indian and Alaska Native Tribal members and other ethnicities to receive and bill for services rendered for MMIP and HT related conditions. The types of services that could be included under these codes may be related to behavioral health services for individuals affected by an unacknowledged death or missing indigenous or other person and for care related to HT for American Indians and Alaska Natives.

CMS Final HCPCS Coding Determination

1. Establish a new HCPCS Level II code H0052, “Missing and murdered indigenous persons (mmip) mental health and clinical care”

2. Establish a new HCPCS Level II code H0053, “Historical trauma (ht) mental health and clinical care for indigenous persons”

Effective January 1, 2025

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

Summary of Public Feedback

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

1. Establish a new HCPCS Level II code H0052, “Missing and murdered indigenous persons (mmip) mental health and clinical care”

2. Establish a new HCPCS Level II code H0053, “Historical trauma (ht) mental health and clinical care for indigenous persons”

   Effective January 1, 2025

S3 Uplifter Toilet Chair - HCP240701719RN

Topic/Issue

Request to establish a new HCPCS Level II code to identify S3 Uplifter Toilet Chair.

Applicant's suggested language: EXXXX, “Sit to stand feature with weight activated hydraulic dual control lever system”

Summary of Applicant's Submission

S3 Secure Sit to Stand, LLC submitted a request for a new HCPCS Level II code to identify the S3 Uplifter Toilet Chair. The S3 Uplifter Toilet Chair is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The Secure Sit to Stand patented technology has been incorporated into a toilet/showering chair to assist the individual with sitting and standing while toileting or showering. The S3 Uplifter Toilet Chair operates by a two-way hydraulic dual lever system and weight activated arm paddles to allow one to sit down with appropriate resistance and stand with hydraulic lever assisted lift mechanism. This feature allows the individual to softly descend when sitting and stand up with safety and support, decreasing the likelihood of a fall. As one prepares to sit, the individual applies a force on the seat base as they lower themselves into the chair. During this time, one may continue to apply a desired amount of downward force on the front ends of the arms to counteract the force of their weight on the seat base. Since the seat base is tilted upwardly in the extended position, the distance an individual must lower themselves before contacting the chair is significantly decreased relative to a traditional toilet chair. There are also safety locks on the left and right side under the handles that allow you to lock the seat into place while cleaning yourself by simply pushing the left and right knob. As one prepares to stand, they can pull out the safety knob allowing the lever mechanisms to re-engage. Then they can apply a downward force on the front ends of the arms as they apply an upward force on the seat base that activates the hydraulic lever system to tilt the seat base upwardly from a depressed position to an extended position. As the individual begins to stand, the seat base will continue moving upwardly to assist the individual to stand up from a seated position. These features offer a solution for individuals with cognitive impairments and frailty who may otherwise be unable to use existing toileting solutions. Similar technology has been used in the Uplifter Chairs for the dining and living room which has been shown to improve safety and independence with ‘sit-to-stand’ activities for adults with conditions such as amyotrophic lateral sclerosis, multiple sclerosis, and lower extremity amputations.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code E0172, “Seat lift mechanism placed over or on top of toilet, any type” describes the S3 Uplifter Toilet Chair. The S3 Uplifter Toilet Chair is similar in nature to other devices in HCPCS Level II code E0172.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

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

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

All five of these conditions must be met in order for equipment to be classified as DME. The S3 Uplifter Toilet Chair does not meet one condition as follows:

- **Not primarily and customarily used to serve a medical purpose** – The S3 Uplifter Toilet Chair is a seat lift device that is placed over on or on top of a toilet. It does not provide treatment for a medical condition.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Summary of Public Feedback

S3 Secure Sit to Stand, LLC disagreed with CMS' published preliminary recommendations. The speaker enumerated in both their presentation and written comment that 1 in 3 people over the age of 65 fall annually, with 80% of those falls occurring in the bathroom, that more than 50% of injuries in adults over the age of 85 occur during bathroom activities, highlighting how bathrooms present particular challenges with their confined space and slippery surfaces and the economic impact of fall related injuries in older populations. The speaker stated that the S3 Uplifter Toilet Chair is uniquely designed to address these risks and provide a safer alternative to current bathroom durable medical equipment and assistive devices. The speaker commented that the S3 Uplifter Toilet Chair has differentiating factors that separate their product from those classified under HCPCS Level II code E0172. Those factors mentioned were that the S3 Uplifter Toilet Chair has shower compatibility as it has no electronic components, features a weight-assisted paddle control system to support safe and natural sit-to-stand and stand-to-sit assistance that provides enhanced safety for transfers and has an antimicrobial coating. The speaker disagreed with the preliminary determination of "No Medicare DMEPOS benefit category" and believes this device should be classified as DME. They suggested that the S3 Uplifter Toilet Chair serves a medical purpose because it was designed to be used on top of a toilet as well as in a shower to prevent the risk of falling. Also, the speaker stated that the device is antimicrobial, waterproof, and mechanical, while another speaker stated that this item enhances an individual's independence.

CMS Final HCPCS Coding Decision

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

Existing HCPCS Level II code E0172, “Seat lift mechanism placed over or on top of toilet, any type” to describe the S3 Uplifter Toilet Chair.

The main purpose of the S3 Uplifter Toilet Chair is to assist in sitting and standing over a toilet. Even though the S3 Uplifter Toilet Chair is hydraulic, and not electric, HCPCS Level II code E0172 states any type of seat lift mechanism placed over or on top of a toilet. As such, HCPCS Level II code E0172 describes the S3 Uplifter Toilet Chair.

Final Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

The existing Medicare benefit category determination for HCPCS Level II code E0172 applies to this item.

Final Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

IndeeLift® - HCP2311125H5TT

Topic/Issue

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

Applicant's suggested language: XXXXX, “Multipositional patient transfer system, with integrated lift, patient accessible controls, transfer and/or lift in a seated position from floor to sit or to stand, <400 pounds”

Summary of Applicant's Submission

IndeeLift Inc. submitted a request for a new HCPCS Level II code to identify the IndeeLift®. IndeeLift® is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). IndeeLift® human floor lifts are multipositional electric patient seat lifts intended for lifting an individual who has fallen, who is either ambulatory or non-ambulatory, weighing up to 400 pounds, from the ground to a seated height, 21 inches, to enable them to either stand up or to transfer to a chair/wheelchair (Models PPU and HFL-400-D), or to a standing height, 30 inches, for those individuals who are not able to rise-up from a seated position but can walk with or without an assistive device once they are in a standing position (Model PPU-S and FTS-400). IndeeLift® devices are self-operational or can be used with the aid of a single caregiver depending on the mobility level of the individual. Existing HCPCS Level II codes that partially, but not adequately, describe the IndeeLift® are E0630, E0635, and E0636; however, the lifts described under these codes require at least one assistant to operate the device and assist in maneuvering an individual, and may require supine positioning of the individual. IndeeLift® is designed to be self-operated by the individual, who may or may not be ambulatory, so these requirements would not apply. IndeeLift® helps mitigate deterioration of the neuromuscular condition of an individual with a diagnosis such as severe arthritis of the hips or knees, or a neuromuscular disease, so they are not bed confined.

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 the IndeeLift®. CMS believes the IndeeLift® is precautionary in nature and does not replace a capacity that an individual previously had.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

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

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

5. Is appropriate for use in the home.

All five of these conditions must be met in order for equipment to be classified as DME. The IndeeLift® does not meet one condition as follows:

- **Is primarily and customarily used to serve a medical purpose** – In accordance with section 110.1.B.2 of chapter 15 of the Medicare Benefit Policy Manual, equipment that is precautionary-type equipment is considered nonmedical. The IndeeLift® is used as standby or precautionary equipment in the event of a fall and therefore is considered nonmedical. Thus, the preliminary BCD for this item would be no DMEPOS benefit category.

In addition, we have questions regarding whether the IndeeLift® meets two other conditions:

- **Generally is not useful to an individual in the absence of an illness or injury** - The applicant stated that the IndeeLift® may be used as a patient transfer system as well as an independent fall recovery system after an individual has fallen. This device also appears to be useful to an individual in the absence of an illness or injury to move heavy items such as boxes, small pieces of furniture, and small appliances in the same manner that a dolly would be used for non-medical residential and business purposes.

- **Is appropriate for use in the home** – If an individual falls and needs to be lifted off the floor, it may not be appropriate to use equipment such as the IndeeLift® in the home because the individual or caregiver may be unaware that the individual was injured in the fall and using the equipment may create further harm or injury to the individual. We are requesting more information to ascertain how the risk of use of IndeeLift® if the individual has been injured has an impact on the use of IndeeLift® in the home.

Preliminary Medicare Payment Determination

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. CMS has not identified a program operating need for Medicare or other payers for a new HCPCS Level II code to describe the IndeeLift®. CMS believes the IndeeLift® is precautionary in nature and does not replace a capacity that an individual previously had.

Final Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

Final Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

munevo DRIVE - HCP240628F7PWV

Topic/Issue

Request to establish a new HCPCS Level II code to identify munevo DRIVE.

Applicant's suggested language: EXXXX, “Power wheelchair accessory, wearable smart glass based, integrated sensors, proportional, specialty control interface”

Summary of Applicant's Submission

Munevo Inc. submitted a request for a new HCPCS Level II code to identify the munevo DRIVE. The munevo DRIVE is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The munevo DRIVE uses integrated sensors to calibrate head gestures which allow an individual who uses a wheelchair to navigate their power wheelchair. The device is intended for individuals who cannot use a joystick but are able to slightly tilt and turn their head (5 degrees). This alternative input technology, also referred to as an interface control, provides a means for independent operation of complex rehab technology (CRT) power wheelchairs. This device can be used for an individual with, but not limited to, amyotrophic lateral sclerosis, high level spinal cord injuries (C1-C4/5), and progressive diseases such as: multiple sclerosis, muscular atrophy, muscular dystrophy and cerebral palsy. Individuals who use power wheelchairs are often unable to use their hands to operate a joystick or other alternative input device. These individuals may also require adjustment or programming of the device’s performance and sensitivity to the user's movement based on the user's needs, physical condition, setting, time of day, and physical condition of the user. These adjustments may need to be made multiple times each day. Non-wearable, mechanical devices require third-party or external support by a CRT supplier, caregiver, or therapist. In contrast, the user can calibrate the munevo DRIVE at any time and within 15 seconds. The munevo DRIVE consists of two hardware components; a smart glass that can be worn like eyeglasses, and an adapter box which integrates with the power wheelchair electronics. For individuals who require simultaneous use of eyeglasses to correct vision impairment, special frames are available. There is specialized software inside the hardware that allows for safe and secure navigation of the wheelchair, power seating systems, and allows connectivity to other devices. Many individuals who use power wheelchairs requiring this type of input device use it to operate additional power seating systems. Frequent repositioning of the body and head can result in the user losing contact with the input device when they use non-wearable input devices. This creates a risk of the user being in a position where they cannot reach/access the input device or separate button/switch needed to activate a power seating function. This is not a concern with the munevo DRIVE, as it is a wearable input device.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code E2328, “Power wheelchair accessory, head control or extremity control interface, electronic, proportional, including all related electronics and fixed mounting hardware” describes the munevo DRIVE wheelchair accessory. We believe the munevo DRIVE is a technological refinement of a proportional head control interface, which allows the user to move the wheelchair in any direction and is similar to other devices coded within HCPCS Level II code E2328.

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 information submitted by the applicant was reviewed and was determined to meet the requirements to be classified as DME.

The current Medicare policy and prior established benefit category determination of DME for HCPCS Level II code E2328, "Power wheelchair accessory, head control or extremity control interface, electronic, proportional, including all related electronics and fixed mounting hardware" apply to the munevo DRIVE wheelchair accessory.

Note that the applicant has confirmed for CMS that while the munevo DRIVE wheelchair accessory includes add-on functions using Bluetooth® technology to permit wheelchair users to perform non-mobility-related functions, such as to operate a computer and smartphone, these add-on functions are disabled at initial issue of the wheelchair accessory and can be purchased separately by the individual. As these add-ons are not primarily and customarily used to serve a medical purpose, they would not be payable under a DMEPOS benefit category.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code E2328 apply to this product, if covered. Payment for existing HCPCS Level II code E2328 is made on a capped rental basis. Therefore, the monthly capped rental fee schedule amount would be approximately $582.27 on average for months 1 through 3, and approximately $436.70 on average for months 4 through 13, resulting in a total capped payment of $6,113.81 should there be 13 months of continuous use. Fee schedules are updated annually.

The HCPCS modifier KU can be included when billing certain wheelchair accessories furnished in connection with Group 3 power wheelchairs for complex rehabilitative individuals to receive the unadjusted fee schedule amount. The munevo DRIVE wheelchair accessory is applicable.

Pricing Indicator = 36

Summary of Public Feedback

Munevo Inc. disagreed with CMS' preliminary recommendations. The speaker stated that the head control devices listed under HCPCS Level II code E2328 were head arrays and worked differently than the munevo DRIVE's wearable smart glasses technology, which consists of software and an adapter box. The speaker commented the wearable glasses allows the user to control their wheelchair with only slight head movements, so it could be used by those individuals with progressive diseases where the mobility of the individual overtime is not guaranteed, helps reduce fatigue from applying pressure to the sensors in a head array, and eliminates the need for a caregiver to help recalibrate when an individual's position changes in the wheelchair throughout the day. The speaker also stated that the technology differences were that head arrays in HCPCS Level II code E2328 use sensors that measure pressure applied by the user and the munevo DRIVE uses gyroscope and accelerometer sensors that track head motion and that these differences in technology meant the munevo DRIVE required its own unique code. Other commenters also disagreed with CMS' preliminary decision that the munevo DRIVE was a technological refinement of a proportional head control interface and required its own code.

CMS Final HCPCS Coding Decision

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

Existing HCPCS Level II code E2328, "Power wheelchair accessory, head control or extremity control interface, electronic, proportional, including all related electronics and fixed mounting hardware" to describe the munevo DRIVE.

The sensors mounted in munevo DRIVE smart glasses, as opposed to on the wheelchair itself, is a technological refinement that allows the users to control their wheelchair using head movements to move in any direction. Therefore, the munevo DRIVE is a head control interface described by existing HCPCS Level II code E2328.

Final Medicare Benefit Category Determination

Durable Medical Equipment.

Final Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code E2328 apply to this product. Payment for existing HCPCS Level II code E2328 is made on a capped rental basis. Therefore, the 2025 monthly capped rental fee schedule amount would be approximately $596.73 on average for months 1 through 3, and approximately $447.55 on average for months 4 through 13, resulting in a total capped payment of $6,265.69 should there be 13 months of continuous use. The average fee schedule amount is the average of the 2025 fee schedule amounts for the code for each of the 50 states, Washington D.C., and the Virgin Islands.

In Puerto Rico, the 2025 monthly capped rental fee schedule amount would be approximately $659.42 on average for months 1 through 3, and approximately $494.57 on average for months 4 through 13, resulting in a total capped payment of $6,923.91 should there be 13 months of continuous use.

Fee schedules are updated annually.

The HCPCS modifier KU can be included when billing certain wheelchair accessories furnished in connection with Group 3 power wheelchairs for complex rehabilitative individuals to receive the unadjusted fee schedule amount. The munevo DRIVE wheelchair accessory is applicable.

Pricing Indicator = 36

Complex Rehabilitative Power Seat Elevation System - HCP2407015PF60

Topic/Issue

Request to revise existing HCPCS Level II code E2298, “Complex rehabilitative power wheelchair accessory, power seat elevation system, any type” to include complex rehabilitative power seat elevation.

Applicant's suggested language: E2298, “Complex Rehabilitative Power Wheelchair Accessory, Power Seating System, Complex Rehab Seat Elevation, any type”

Summary of Applicant's Submission

The National Coalition for Assistive and Rehab Technology (NCART), on behalf of its member manufacturers of power seat elevation systems, submitted a request to revise existing HCPCS Level II code E2298 to identify the advanced technology of complex rehabilitative technology (CRT) power seat elevation (PSE) systems and to re-calculate its fee schedule amount. The current code description for HCPCS Level II code E2298, “Complex rehabilitative power wheelchair accessory, power seat elevation system, any type” does not differentiate CRT PSE systems from a basic PSE accessory and will have long-term unintended consequences if it is not changed. The language "complex rehabilitative power wheelchair accessory" does not define HCPCS Level II code E2298, it merely dictates what base codes a “power seat elevation system, any type” may be billed on. In NCART's prior HCPCS Level II code application from the second biannual 2023 coding cycle, it was requested CMS adopt characteristics to define CRT PSE that included at least 10" of elevation, being capable of elevating/descending while the power wheelchair (PWC) moves and of moving on a horizontal surface while fully elevated, and compatible with other power seating options (power tilt and/or power recline). If CMS’ objective is to preclude billing of a CRT PSE system with non-CRT base codes, such as E2300, NCART recommends revising the code description to differentiate clinically relevant CRT PSE characteristics from a basic PSE accessory used on a non-CRT PWC. Use of "power seating system" in the code description for HCPCS Level II code E2298, instead of “power seat elevation system”, would be consistent with all other HCPCS codes listed under Group 6, Power Seating Systems in the Wheelchair Options/Accessories Local Coverage Determination (L33792). NCART contends this because the basic physical components of a$ stand-alone CRT PSE system are the same as the components of a stand-alone power tilt or power recline system. Lastly, a revision to the code description for HCPCS Level II code E2298 will accurately define the scope of CRT PSE products and should serve as the basis for a re-calculation of the fee schedule, considering the three available pricing methodologies, and publicly available pricing information. CMS has three ways to calculate a reimbursement rate when a HCPCS Level II code is added. CMS can use an existing fee schedule amount for comparable items, previous fee schedule amounts for the old code mapped to the new code to ensure continuity of pricing, or gap filling methodology. NCART contends, firstly, that CRT PSE is comparable to a power tilt system, second that a reimbursement rate has already been established for the HCPCS Level II code E2300, “Wheelchair accessory, power seat elevation system, any type” based on thousands of claims paid from May 16, 2023 through March 31, 2024 and finally, that CMS is not mandated to use gap filling as a payment methodology.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code E2298, "Complex rehabilitative power wheelchair accessory, power seat elevation system, any type" describes power seat elevation that may be covered for use on a complex rehabilitative power-driven wheelchair in accordance with the Medicare national coverage determination (NCD) for power wheelchair seat elevation equipment.

The request to add specifications for the code (e.g., capable of elevating at least 10 inches) was addressed during the NCD process and is outside the scope of the HCPCS Level II coding process.

Summary of Public Feedback

No verbal or written comments were provided in response to CMS' published preliminary 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. Existing HCPCS Level II code E2298, "Complex rehabilitative power wheelchair accessory, power seat elevation system, any type" describes power seat elevation that may be covered for use on a complex rehabilitative power-driven wheelchair in accordance with the Medicare national coverage determination for power wheelchair seat elevation equipment.

Wheelchair Mounting Hardware - HCP240131PLFW5

Topic/Issue

Request to establish three new codes and revise an existing HCPCS Level II code E1028, “Wheelchair accessory, manual swingaway, retractable or removable mounting hardware for joystick, other control interface or positioning accessory” to further describe wheelchair mounting hardware.

Applicant's suggested language:

1. E1028, “Wheelchair accessory, manual swingaway, retractable or removable mounting hardware, other”

2. EXXX1, “Wheelchair accessory, manual swingaway, retractable or removable mounting hardware used with remote joysticks or touchpads”

3. EXXX2, “Wheelchair accessory, manual swingaway, retractable or removable mounting hardware for headrest, cushioned, any type”

4. EXXX3, “Wheelchair accessory, manual swingaway, retractable or removable mounting hardware for lateral trunk or hip support, any type”

Summary of Applicant's Submission

Palmetto GBA submitted a request to revise HCPCS Level II code E1028 and establish three new HCPCS Level II codes to further identify wheelchair mounting hardware accessories. Palmetto GBA further requested HCPCS Level II code E1028 be revised to account for any type of mounting hardware that does not fall into the three requested new HCPCS Level II codes. Mounting hardware for a wheelchair is used to attach additional accessories to the wheelchair to assist the beneficiary in which these types of accessories can range from electronic controls to assist in movement to cushions and support. The mounting hardware, itself, usually consists of a metal bracket and some screws, or similar devices to hold the accessory in place. The mounting hardware allows the correct placement of the accessories to support the individual, access controls and/or move accessories out of the way when getting in and out of the wheelchair. An individual will often need multiple accessories to be mounted, and this will require multiple billings of E1028, each needing a narrative description to identify the type of accessory being mounted. E1028 is in the capped rental pricing category so it is billed for up to 13 months of rental. In addition, there is a Medically Unlikely Edit (MUE) edit for E1028. Creation of the new codes will help with multiple billings of E1028, and the need to review the narrative description, manual tracking of the rental months, and correction when MUE edits are applied.

CMS Preliminary HCPCS Coding Recommendation

We believe there is a claims processing need on behalf of Medicare to address issues related to multiple billings of existing HCPCS Level II code E1028, such as review the narrative description, manual tracking of the rental months, and correction of inappropriate MUE edits. As such, CMS is proposing to:

1. Revise existing HCPCS Level II code E1028, “Wheelchair accessory, manual swingaway, retractable or removable mounting hardware for joystick, other control interface or positioning accessory” to instead read “Wheelchair accessory, manual swingaway, retractable or removable mounting hardware, other”

2. Establish a new HCPCS Level II code EXXX1, “Wheelchair accessory, manual swingaway, retractable or removable mounting hardware used with remote joysticks or touchpads”

3. Establish a new HCPCS Level II code EXXX2, “Wheelchair accessory, manual swingaway, retractable or removable mounting hardware for headrest, cushioned, any type”

4. Establish a new HCPCS Level II code EXXX3, “Wheelchair accessory, manual swingaway, retractable or removable mounting hardware for lateral trunk or hip support, any type”

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

CMS established HCPCS Level II code E1028, “Wheelchair accessory, manual swingaway, retractable or removable mounting hardware for joystick, other control interface or positioning accessory” effective January 1, 2004, and assigned it to the Durable Medical Equipment Medicare benefit category. The current Medicare policy and prior established benefit category determination of DME for HCPCS Level II code E1028 apply when the HCPCS Level II code is revised and new HCPCS Level II codes EXXX1, EXXX2, and EXXX3 are established to more specifically identify mounting hardware: joysticks/touchpads, headrests, and lateral trunk/hip support. Mounting hardware for a wheelchair is used to attach additional accessories to the wheelchair in order to assist the individual.

Preliminary Medicare Payment Determination

For HCPCS Level II codes EXXX1, EXXX2, and EXXX3, in accordance with regulations at 42 CFR 414.236(a) if a new HCPCS Level II code is added for a DMEPOS item, CMS and/or DME MACs make efforts to determine whether the item has a pricing history. If there is a pricing history, the previous payment amounts for the previous code(s) are mapped to the new code(s) to ensure continuity of pricing. In this case, new codes have a pricing history based on HCPCS Level II code E1028. Thus, the preliminary payment determination for new HCPCS Level II codes EXXX1, EXXX2, and EXXX3 is to map the fee schedule amounts for HCPCS Level II code E1028 to each of the new HCPCS Level II codes EXXX1, EXXX2, and EXXX3.

The 2024 average capped rental fee schedule amount for HCPCS Level II codes EXXX1, EXXX2, and EXXX3 would be approximately $15.99 for months 1 through 3 and approximately $11.99 for months 4 through 13, for a total of $167.87 after 13 months of continuous use. Fee schedules are updated annually.

For items furnished in a former Competitive Bidding Area (CBA), the 2024 average capped rental fee schedule amount for HCPCS Level II codes EXXX1, EXXX2, and EXXX3 across all CBAs would be approximately $15.59 for months 1 through 3 and approximately $11.69 for months 4 through 13, for a total of $163.67 after 13 months of continuous use. Fee schedules are updated annually.

Pricing Indicator = 36

Summary of Public Feedback

Written comments mostly agree with CMS' published preliminary determinations with only minor changes. One commenter agreed with the revision to existing HCPCS Level II code E1028 and establishing the three additional codes. However, the pricing indicator of capped rental payment category should be updated based on Chapter 5 section 5 of the Supplier Manual, "complex rehabilitative power wheelchairs (HCPCS codes K0835-K0843 and K0848-K0864) and options/ accessories furnished for use with a complex rehabilitative power wheelchair can be either rented or purchased."

Another commenter agreed with the revision of the code description for E1028 and the addition of new HCPCS Level II codes for manual swingaway, retractable or removable mounting hardware. The commenter stated that this change will reduce provider burden by minimizing or eliminating the need for a narrative description currently required on every claim line to identify the type of accessory being mounted when billing E1028. However, the commenter asked for minor changes to CMS' proposed coding language, such as, removing the term "remote" and "touchpad" and adding "other drive control interface." CMS' proposed code description for EXXX1 is too prescriptive, will cause confusion, and may lead to inaccurate billing. The commenter proposed EXXX1, "Wheelchair accessory, manual swingaway, retractable or removable mounting hardware used with joystick or other drive control interface." Allowing EXXX1 to be used in conjunction with any type of joystick is consistent with how E1028 has been utilized historically. In addition, expanding the description to include other drive input devices is consistent with how E1028 has been utilized historically, is inclusive of a touchpad, will reduce provider confusion when determining which manual swingaway, retractable or removable mounting hardware HCPCS Level II code to submit (EXXX1 or E1028), and supports the provider's ability to file a clean claim. In addition, the commenter proposed the addition of another new HCPCS Level II code EXXX4, "Wheelchair accessory, manual swingaway, retractable or removable mounting hardware for lateral thigh or knee support, any type." The commenter explained that there is a claims processing needed for a dedicated HCPCS Level II code for use with a lateral thigh and/or knee support (E0953) to further identify wheelchair mounting hardware accessories used in conjunction with this dedicated HCPCS Level II code. The commenter agrees with CMS' preliminary payment determination to map the reimbursement rate from the E1028 code to the new HCPCS Level II codes. The commenter contends the new fee schedules for EXXX1, EXXX2, EXXX3 and hopefully EXXX4 should not be the average of the capped rental rates, they should be equal to the rural and/or non-rural rates established for each state, DC, Puerto Rico, and the Virgin Islands.

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:

1. Revise existing HCPCS Level II code E1028, “Wheelchair accessory, manual swingaway, retractable or removable mounting hardware for joystick, other control interface or positioning accessory” to instead read “Wheelchair accessory, manual swingaway, retractable or removable mounting hardware, other”

2. Establish a new HCPCS Level II code E1032, “Wheelchair accessory, manual swingaway, retractable or removable mounting hardware used with joystick or other drive control interface.”

3. Establish a new HCPCS Level II code E1033, “Wheelchair accessory, manual swingaway, retractable or removable mounting hardware for headrest, cushioned, any type”

4. Establish a new HCPCS Level II code E1034, “Wheelchair accessory, manual swingaway, retractable or removable mounting hardware for lateral trunk or hip support, any type”

CMS determined that HCPCS Level II code E0953, “Wheelchair accessory, lateral thigh or knee support, any type including fixed mounting hardware, each” includes fixed mounting hardware as described in the applicant’s proposed HCPCS Level II code EXXX4, “Wheelchair accessory, manual swingaway, retractable or removable mounting hardware for lateral thigh or knee support, any type.” The HCPCS modifier KU can be included when billing certain wheelchair accessories furnished in connection with Group 3 power wheelchairs for complex rehabilitative individuals to receive the unadjusted fee schedule amount. Also, the HCPCS modifier BP can be included when certain CRT wheelchairs are purchased in the first month. The wheelchair mounting hardware items of this application are applicable.

Final Medicare Benefit Category Determination

Durable Medical Equipment.

Final Medicare Payment Determination

For HCPCS Level II codes E1032, E1033, and E1034, in accordance with regulations at 42 CFR 414.236(a) if a new HCPCS Level II code is added for a DMEPOS item, CMS and/or DME MACs make efforts to determine whether the item has a pricing history. If there is a pricing history, the previous payment amounts for the previous code(s) are mapped to the new code(s) to ensure continuity of pricing. In this case, new codes have a pricing history based on HCPCS Level II code E1028. Thus, the final payment determination for new HCPCS Level II codes E1032, E1033, and E1034 is to map the fee schedule amounts for HCPCS Level II code E1028 to each of the new HCPCS Level II codes E1032, E1033, and E1034.

In accordance with our regulations, mapped fee schedule amounts will vary depending on Medicare beneficiary location; different payment amounts will apply in former Competitive

Bidding Areas (CBAs), and in areas where payment amounts are adjusted based on information from the competitive bidding programs (as detailed in 42 CFR 414.210(g)).

In areas fully adjusted based on competitive bidding, the 2025 average capped rental fee schedule amount for HCPCS Level II codes E1032, E1033, and E1034 would be approximately $16.47 for months 1 through 3 and approximately $12.35 for months 4 through 13, for a total of $172.91 after 13 months of continuous use.

For items furnished in a former CBA, the 2025 average capped rental fee schedule amount for HCPCS Level II codes E1032, E1033, and E1034 across all CBAs would be approximately $16.04 for months 1 through 3 and approximately $12.03 for months 4 through 13, for a total of $168.45 after 13 months of continuous use.

The average fee schedule amount is the average of the 2025 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.

In response to comments regarding the average of the fee schedule amounts for existing HCPCS Level II code E1028, the use of the average fee schedule amounts was intended for illustration purposes only. We never recommended or suggested that we would use the average of the fee schedule amounts for existing HCPCS Level II code E1028 to establish the fee schedule amounts for the proposed new codes. As indicated in the preliminary and final payment determinations, the statewide fee schedule amounts for existing HCPCS Level II code E1028 will be mapped directly to the proposed new codes.

Pricing Indicator = 36

Wheelchair Transit Accessories - HCP220624G4XCH

Topic/Issue

Request to establish two new HCPCS Level II codes to identify wheelchair transit accessories.

Applicant's suggested language:

1. XXXXX, “Transportation tie down system used in a motor vehicle during transportation”

2. XXXXX, “Dot approved occupant wheelchair restraint system”

Summary of Applicant's Submission

Palmetto GBA submitted a request to establish two HCPCS Level II codes to identify wheelchair transit accessories. The best practice for individuals in wheelchairs when traveling is to use occupant restraint systems. These securement methods are collectively known as wheelchair tiedown and occupant restraint systems (WTORS). Currently, transportation tie down straps and wheelchair restraint systems are billed under existing HCPCS Level II code K0108, “Wheelchair component or accessory, not otherwise specified.” Hundreds of claim lines are billed to Medicare each quarter, which require manual adjudication. For Medicare, these items are statutorily excluded and always denied. Defined codes would automate the process.

CMS Preliminary HCPCS Coding Recommendation

We believe there is a claims processing need on behalf of Medicare to help reduce the manual adjudication process for existing HCPCS Level II code K0108 for wheelchair tiedowns and occupant restraint systems. As such, CMS is proposing to:

1. Establish a new HCPCS Level II code EXXXX, “Wheelchair transportation securement system, includes all components and accessories”

2. Establish a new HCPCS Level II code EXXXX, “Department of transportation approved wheelchair transit securement system, includes all components and accessories”

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

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

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

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

All five of these conditions must be met in order for equipment to be classified as DME. The wheelchair transit accessory does not meet three of the conditions that must be met for equipment to be classified as DME:

Is primarily and customarily used to serve a medical purpose – The wheelchair transit accessory is a personal safety item for use during vehicle transport and is not intended to treat a medical condition. Therefore, it is not primarily serving a medical purpose.

Generally is not useful to an individual in the absence of an illness or injury - The wheelchair transit accessory is a personal safety item for use during vehicle transport and is not intended to treat an illness or injury. Therefore, it is useful to an individual in the absence of an illness or injury.

Is appropriate for use in the home – As stated in the application, the setting of use for the wheelchair transit accessory is 100% outside the home. It is intended for use during vehicle transport.

Therefore, the wheelchair transit accessory cannot be defined as durable medical equipment.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Summary of Public Feedback

A written comment disagreed with CMS's published preliminary recommendations and requested that CMS not proceed with establishing either proposed HCPCS Level II codes. The commenter agrees that there may be a claims processing need for Medicare to reduce the manual adjudication of HCPCS Level II code K0108 for unoccupied transit loops, occupied transit options, and occupant restraint systems used with a manual or power wheelchair dispensed at initial issue. However, neither the requested code descriptions nor CMS' preliminary code descriptions describe these wheelchair components; therefore, they do not see a Medicare claims processing need for either of the requested codes. The commenter explained that neither code clearly defines the wheelchair accessories necessary for the safe transportation of individuals with disabilities who use a medically necessary wheelchair and seating system in a motor vehicle. The commenter believes that further work is needed to differentiate the requirements for unoccupied and occupied transit and the defined component(s) necessary for the wheelchair and the wheelchair seating systems before meaningful codes can be established.

In addition, according to information found on the University of Michigan's Wheelchair Transportation Safety website[2], the federal safety standards administered by the National Highway Traffic Safety Administration (NHTSA) of the U.S. Department of Transportation generally only apply to the original vehicle manufacturer. The commenter stated that most

[2] https://wc-transportation-safety.umtri.umich.edu/faq-a2/

passenger vehicles modified for use by wheelchair users are exempt from federal safety requirements to allow greater independence. Because wheelchairs are considered medical devices regulated by the Federal Drug Administration, NHTSA does not have standards for addressing wheelchairs used as vehicle seating. Therefore, the commenter is unclear why there is a reference to the Department of Transportation (DOT) in the code description as the DOT does not approve any wheelchair accessories used for transit securement purposes for beneficiary-owned wheelchairs.

CMS Final HCPCS Coding Decision

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

1. Establish a new HCPCS Level II code E1022, "Wheelchair transportation securement system, any type includes all components and accessories"

2. Establish a new HCPCS Level II code E1023, "Wheelchair transit securement system, includes all components and accessories"

CMS has determined that there is a claims processing need on behalf of Medicare to help reduce the manual adjudication process for existing HCPCS Level II code K0108 for wheelchair tiedowns and occupant restraint systems. CMS agrees with the commenter that the reference to the Department of Transportation in the code description may be misleading, therefore, the Department of Transportation was removed to allow for more accurate billing. CMS welcomes information from other insurers currently paying for these products to demonstrate a claims processing need for additional HCPCS Level II codes.

Final Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

Final Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Rollz Motion - HCP240628PHWKW

Topic/Issue

Request to establish a new HCPCS Level II code to describe Rollz Motion.

Applicant's suggested language: XXXXX, “Walker, transport chair, folding, wheeled, adjustable or fixed height, convertible from walker to wheelchair and back”

Summary of Applicant's Submission

Rollz Mobility US Inc. submitted a request to establish a new HCPCS Level II Code to describe Rollz Motion. The Rollz Motion is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The Rollz Motion is a rollator and wheelchair combination. It has four large wheels, is heavy duty, foldable, has adjustable handlebars and a solid seat. As a wheelchair, this product has an adjustable solid back in addition to the previous mentioned features. This allows users to stay as active as possible using the Rollz Motion as a rollator and they can transform it into a wheelchair whenever they need more support. This benefits rehabilitation and achieving a more active lifestyle. Over 8.5 million people in the United States of all ages with diseases like Multiple Sclerosis, Parkinson's or Amytrophic Lateral Sclerosis, or those simply having serious mobility issues may benefit greatly from a combination product like the Rollz Motion. The Rollz Motion provides the user with a product for well over five years up to ten years, which they can use in multiple stages of mobility.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code E0143, “Walker, folding, wheeled, adjustable or fixed height” along with E0156, “Seat attachment, walker” describes the Rollz Motion when used as a walker. However, when used as a transport chair, existing HCPCS Level II code E1038, “Transport chair, adult size, patient weight capacity up to and including 300 pounds” describes the Rollz Motion.

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

The current Medicare policy and prior established benefit category determination of DME for HCPCS Level II codes E0143 (“Walker, folding, wheeled, adjustable or fixed height”) and E0156 (“Seat attachment, walker”) apply to the Rollz Motion, when used as a walker. Also, the current Medicare policy and prior established benefit category determination of DME for HCPCS Level II code E1038 (“Transport chair, adult size, patient weight capacity up to and including 300 pounds”) apply to Rollz Motion when used as a transport chair.

Preliminary Medicare Payment Determination

Note that based on the requirements for Medicare, suppliers must not bill both HCPCS Level II code E0143 and HCPCS Level II code E1038 for the same Medicare beneficiary for Rollz Motion.

For HCPCS Level II code E0143 along with HCPCS Level II code E0156:

The payment rules and pricing associated with existing HCPCS Level II codes E1043 and E0156 apply to this product, if covered. The current average 2024 rural fee schedule amount for HCPCS Level II codes E1043 + E0156 in the contiguous United States is $123.76. The current average 2024 non-rural fee schedule amount in the contiguous United States is $74.15.

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 = 32

For HCPCS Level II code E1038:

The payment rules and pricing associated with existing HCPCS Level II codes E1038 apply to this product, if covered. Payment for existing HCPCS Level II code E1038 is made on a capped rental basis. Therefore, the monthly capped rental fee schedule amount would be approximately $19.41 on average for months 1 through 3, and approximately $14.56 on average for months 4 through 13, resulting in a total capped payment of $203.83 should there be 13 months of continuous use. Fee schedules are updated annually.

Pricing Indicator = 36

Summary of Public Feedback

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

CMS Final HCPCS Coding Decision

This application is being deferred for additional consideration in a subsequent biannual coding cycle. Based on careful consideration of the information provided in the application and additional research regarding the intended use and purpose of the equipment, CMS requires additional time to consider the request to establish a new HCPCS Level II code to identify Rollz Motion. As a result, CMS is deferring this application to a subsequent biannual coding cycle.

Final Medicare Benefit Category Determination

No determination.

Final Medicare Payment Determination

No determination.

NYRC Brace™ - HCP2407013T365

Topic/Issue

Request to establish a new HCPCS Level II code to describe the NYRC Brace™.

Applicant's suggested language: LXXXX, “Tension based scoliosis orthosis with integrated Smart Brace technology for recording and transmitting proper wear and patient compliance monitoring, custom fabricated”

Summary of Applicant's Submission

Secured Ortho Manufacturing of America, LLC submitted a request to establish a new HCPCS Level II code to identify the NYRC Brace™. The NYRC Brace™ is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The NYRC Brace™ is a custom fabricated rigid shell Rigo-Cheneau style tension-based spinal orthosis with integrated smart technology for the treatment of individuals with adolescent idiopathic scoliosis. The custom-made NYRC Brace™ achieves a more intimate fit with three-dimensional corrective forces to prevent scoliosis progression and axial rotation of the spine. Proper fitting is achieved by affixing X-ray and palpation-guided anatomical markers to the individual’s body prior to 3D surface scanning. Individual-specific pelvic parameters and scoliosis classification system of the 3D curve pattern influence the design and custom fabrication. The pre-fabrication process includes a clinician consultation with NYRC Brace™ biomedical engineers to determine the brace design and strap placement configuration. Proprietary algorithm design software helps create an individualized brace. The NYRC Brace™ is differentiated from other scoliosis braces by the integrated smart device technology and connectivity via a mobile app. The smart device technology guides the fitting of the brace and the education to the individual of the proper use as well as captures usage data of the individual’s adherence to proper/adequate strap tensioning (brace tightness), daily hours of proper and improper brace use, and balance patterns when wearing the brace. The mobile app generates real-time (live) and look-back (week, month, year) analytics in easily understood visual formats to educate and benefit the individual while assisting medical providers in more effective management of the individual’s treatment plan. The NYRC Brace™ is custom fabricated and made for a specific individual using their own body geometry. The NYRC Brace™ requires intensive individual evaluation and precise body scanning imagery to support the custom fabrication, strap locations and fitting refinements. The NYRC Brace™ also has an anterior trim that overlaps when the straps are tightened with purposeful relief voids built into the shell to allow for adequate tension and comfortable application of corrective forces. Smart hardware and customized setup of the individual protocols, including mobile app-based individual education and self-guided practice sessions, enhance the individual experience and create opportunities for improved compliance and outcomes.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code L1300, “Other scoliosis procedure, body jacket molded to patient model” describes the NYRC Brace™ and existing HCPCS Level II code A9279, “Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified” describes the integrated monitoring smart device technology.

The NYRC Brace™ uses a computer-aided design - computer-aided manufacturing (CAD-CAM) technique to custom fabricate the brace. Appendix C of the DMEPOS Quality Standards[3] indicates that CAD-CAM is one of the techniques used to make a molded to individual model brace. HCPCS Level II code L1300, therefore, includes braces, such as the NYRC Brace™, that are custom fabricated using the CAD-CAM technique.

Preliminary Medicare Benefit Category Determination

Back Brace.

The NYRC Brace™ meets 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. This definition is also in Medicare regulations at 42 CFR 410.2. The NYRC Brace™ is a rigid device that is used to treat scoliosis in adolescents.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code L1300 apply to this product. Payment is made on a lump sum purchase basis. The average of the 2024 fee schedule amounts for HCPCS Level II code L1300 is $2,104.12.

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

Secured Ortho Manufacturing of America, LLC disagreed with CMS' published preliminary recommendations. The speaker noted the NYRC Brace™ is a dynamic tension-based orthosis with tension monitoring for proper wear and integrated data collection capabilities, unlike other static body jacket type braces or compression garments with reinforced panels that are assigned to HCPCS Level II code L1300. The speaker suggested that NYRC Brace™ is more comparable to the tension-based orthosis items assigned to HCPCS Level II code L1005, "Tension based scoliosis orthosis and accessory pads, includes fitting and adjustment." However, the speaker noted that HCPCS Level II code L1005 is not appropriate to bill because the NYRC Brace™ is a custom fabricated orthosis. The speaker mentioned that many commercial payers have processed claims for NYRC Brace™ when billed via HCPCS Level II code L1499, "Spinal orthosis, not otherwise specified", and reiterated that a unique code could help streamline insurance authorizations. The applicant's updated suggested language for the requested new HCPCS Level II code is LXXXX, "Tension-based scoliosis orthosis with integrated sensors for monitoring proper strap tensioning and compliance, custom fabricated."

[3] https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/DMEPOSQuality/DMEPOSQualBooklet-905709.html.

A commenter also stated that clinical studies reported that, when compared to other types of braces, the Rigo-Cheneau style custom thoracic lumbar sacral orthosis can hold the spine in the most anatomically correct position, and that the integrated monitoring technology can inform providers regarding individual compliance as well as inform both the provider and individual regarding how the brace fits, which correlates with brace correction and balance.

CMS Final HCPCS Coding Decision

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

Existing HCPCS Level II code L1300, "Other scoliosis procedure, body jacket molded to patient model" to describe the NYRC Brace™ and existing HCPCS Level II code A9279, "Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified" to describe the integrated monitoring smart device technology.

We do not see a claims processing need to establish a separate HCPCS Level II code for the NYRC Brace™. Our understanding is that there are numerous tension-based braces assigned to HCPCS Level II code L1300, which are similar to the NYRC Brace™. For instance, custom-fabricated Rigo-Cheneau style braces for scoliosis are specifically designed to apply corrective forces through strategic pressure points and these braces utilize tension across the body to gently guide the spine into alignment. Since the NYRC Brace™ operates on the same tension-based principles as these other Rigo-Cheneau style braces, we find no significant difference between the NYRC Brace™ and other devices assigned to HCPCS Level II code L1300 or similar tension-based codes.

The NYRC Brace™ is custom designed using Computer Aided Design-Computer Aided Manufacturing (CAD-CAM) technology, which is a recognized method for creating molded-to-patient-model braces, as specified in Appendix C of the DMEPOS Quality Standards. HCPCS Level II code L1300 therefore includes tension-based braces such as the NYRC Brace™ that are custom fabricated using the CAD-CAM technique.

The NYRC Brace™ is appropriately described using the combination of HCPCS Level II codes L1300 and A9279. The codes used in combination sufficiently identify the features and functionality of the NYRC Brace™ as both a custom-fabricated, tension-based device made using the CAD-CAM method, as well as a device that incorporates integrated smart monitoring technology. HCPCS Level II code L1300 accurately represents the tension-based mechanics of the brace, while HCPCS Level II code A9279, properly recognizes the integrated smart monitoring system included in the NYRC Brace™.

Final Medicare Benefit Category Determination

Back Brace.

Final Medicare Payment Determination

We are finalizing our preliminary determination that the payment rules and pricing associated with the existing HCPCS Level II code L1300 apply to this product. Payment is made on a lump sum purchase basis. The average of the 2025 fee schedule amounts for HCPCS Level II code L1300 is $2,154.62.

The average fee schedule amount is the average of the 2025 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

ExoBand - HCP240701FNQJ2

Topic/Issue

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

Applicant's suggested language: KXXXX, “Hip orthosis, including abduction orthosis consisting of a belt, two leg loops and two tensioners which together with a toothed guide join all these elements”

Summary of Applicant's Submission

Moveo SRL submitted a request to establish a new HCPCS Level II code to identify ExoBand. ExoBand is a class I device, exempt from the premarket notification procedures by the Food and Drug Administration (FDA). ExoBand is a hip orthosis including abduction orthosis device which is designed to support human walking for individuals with motor impairments caused by disabling diseases and health conditions including those with neurodegenerative diseases such as Parkinson’s disease and multiple sclerosis or those who experienced acute events like stroke, or spinal cord injury. ExoBand is a walking device consisting of a belt and two leg loops. These three independent elements are connected to each other by a mechanism that stores energy generated in the first phase of the gait cycle to return it in the second phase, enhancing the thrust of the hip flexors and leading to functional improvement in walking.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code A4467, “Belt, strap, sleeve, garment, or covering, any type” describes ExoBand. ExoBand is primarily made of elastic material and is similar to other devices in existing HCPCS Level II code A4467.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

Section 130 of Chapter 15 of the Medicare Benefit Policy Manual (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. This definition is also in Medicare regulations at 42 CFR 410.2. Elastic stockings, garter belts, and similar devices do not come within the scope of the definition of a brace. Based in this definition, the preliminary determination is that the ExoBand is not a brace. There is no indication that this product uses rigid or semi-rigid materials that would qualify it as a brace.

Preliminary Medicare Payment Determination

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 A4467, "Belt, strap, sleeve, garment, or covering, any type" to describe ExoBand. ExoBand is primarily made of elastic material and is similar to other devices in existing HCPCS Level II code A4467.

Final Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

Final Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

WalkOn - HCP240630DETBH

Topic/Issue

Request to establish a new HCPCS Level II code to describe the WalkOn ankle foot orthosis.

Applicant's suggested language: LXXXX, “Ankle foot orthosis (AFO), spiral, (institute of rehabilitative medicine type), plastic or other material, prefabricated, off-the-shelf”

Summary of Applicant's Submission

Ottobock submitted a request to establish a new HCPCS Level II code to describe the WalkOn ankle foot orthosis (AFO). The WalkOn is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The WalkOn is an off the shelf, posterior leaf design, ankle foot orthosis made from prepreg carbon graphite composite material. The WalkOn allows for compression of the heel at heel strike, dynamic response, floor reaction forces, and energy storage from mid-stance to toe off. The WalkOn and similar designs assist in the control of knee hyperextension and provide dorsiflexion assist to clear the foot/toe during the swing phase of gait. The design of the WalkOn ankle foot orthosis does not allow for much bending or molding. Substantial modification could include adding a supination correction strap, grinding or trimming the footplate, or adding a custom foot orthosis which all should be performed by a certified Orthotist or certified Fitter. The WalkOn is the predicate device for the HCPCS Level II code L1951, “Ankle foot orthosis, spiral, (institute of rehabilitative medicine type), plastic or other material, prefabricated, includes fitting and adjustment,” which was established January 1, 2004. At that time, there was not a distinction between prefabricated, custom fit with substantial modification versus prefabricated, off-the-shelf with minimal modifications. Since that time, HCPCS Level II code L1951 has been categorized as a prefabricated, custom fitted item requiring substantial modifications and customized to fit a specific patient by an individual with expertise that includes fitting and adjustment. Most individuals fitted with a L1951 device will not require substantial modifications. In the absence of a unique code, HCPCS Level II code L2999, “Lower extremity orthoses, not otherwise specified” has been the most appropriate code for billing prefabricated, off-the-shelf, minimal self-adjustment AFOs.

CMS Preliminary HCPCS Coding Recommendation

CMS believes a revision to the existing HCPCS Level II code L1951 and the establishment of a new HCPCS Level II code for the prefabricated, off-the-shelf, requiring minimal self-adjustment leg brace is necessary for claims processing. As such, CMS is proposing the following coding actions:

1. Revise existing HCPCS Level II code L1951, “Ankle foot orthosis, spiral, (institute of rehabilitative medicine type), plastic or other material, prefabricated, includes fitting and adjustment” to instead read “Ankle foot orthosis, spiral, (institute of rehabilitative medicine type), plastic or other material, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise.”

2. Establish new HCPCS Level II code LXXXX, “Ankle foot orthosis, spiral, (institute of rehabilitative medicine type), plastic or other material, prefabricated, off-the-shelf” to describe WalkOn.

Preliminary Medicare Benefit Category Determination

Leg Brace.

Preliminary Medicare Payment Determination

For new HCPCS Level II code LXXXX, 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 code LXXXX has a pricing history. For HCPCS Level II code LXXXX, the pricing history is based on HCPCS Level II code L1951. 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, 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 code LXXXX is to establish the fee schedule amount by mapping the existing fee schedule amount for the related item described by HCPCS Level II code L1951. The average 2024 purchase fee schedule amount for HCPCS Level II codes L1951 and LXXXX is $983.23. 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

Ottobock agreed with CMS’ preliminary coding recommendation to revise existing HCPCS Level II code, L1951, “Ankle foot orthosis, spiral, (institute of rehabilitative medicine type), plastic or other material, prefabricated, includes fitting and adjustment” to instead read “Ankle foot orthosis, spiral, (institute of rehabilitative medicine type), plastic or other material, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise.”

Ottobock also agreed with CMS’ preliminary coding recommendation to establish a new HCPCS Level II code, LXXXX, “Ankle foot orthosis, spiral, (institute of rehabilitative medicine type), plastic or other material, prefabricated, off-the-shelf” but suggested revising the specific phrase “off-the-shelf” to instead read “selected and fit by an individual with expertise.” The speaker explained that the phrase “off-the-shelf” implies that the device will fit and function out of the box, but while their devices would fit an individual, only a person with expertise will be able to determine which device will provide the appropriate functional outcomes for the individual.

CMS Final HCPCS Coding Decision

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

1. Revise existing HCPCS Level II code L1951, "Ankle foot orthosis, spiral, (institute of rehabilitative medicine type), plastic or other material, prefabricated, includes fitting and adjustment" to instead read "Ankle foot orthosis, spiral, (institute of rehabilitative medicine type), plastic or other material, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise."

2. Establish new HCPCS Level II code L1952, "Ankle foot orthosis, spiral, (institute of rehabilitative medicine type), plastic or other material, prefabricated, off-the-shelf" to describe WalkOn.

Our understanding is that WalkOn is considered an off-the-shelf orthotic or brace because it is prefabricated and requires only minimal self-adjustment[4] or no adjustments. In accordance with section 1847(a)(2)(C) of the Social Security Act, an off-the-shelf orthotic is an orthotic which requires minimal self-adjustment for appropriate use and does not require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual. As such, we identified a claims processing need to revise the existing HCPCS Level II code L1951 for braces that are customized to fit a specific patient by an individual with expertise and establish a new unique HCPCS Level II code for prefabricated braces furnished off-the-shelf with minimal self-adjustment or no adjustment.

Final Medicare Benefit Category Determination

Leg Brace.

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 new HCPCS Level II code L1952, 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 code L1952 has a pricing history. For HCPCS Level II code L1952, the pricing history is based on HCPCS Level II code L1951. 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, 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 code L1952 is to establish

[4] The term "minimal self-adjustment" is defined at 42 CFR §414.402 as an adjustment the beneficiary, caretaker for the beneficiary, or supplier of the device can perform and that does not require the services of a certified orthotist. https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-414/subpart-F/section-414.402

the fee schedule amount by mapping the existing fee schedule amount for the related item described by HCPCS Level II code L1951.

The average 2025 purchase fee schedule amount for HCPCS Level II codes L1951 and L1952 is $1,006.83. The average fee schedule amount is the average of the 2025 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

WalkOn Reaction - HCP240630953Y7

Topic/Issue

Request to establish a new HCPCS Level II code to describe the WalkOn Reaction.

Applicant's suggested language: LXXXX, “Ankle foot orthosis (AFO), rigid anterior tibial section, total carbon fiber or equal material, prefabricated, off-the-shelf”

Summary of Applicant's Submission

Ottobock submitted a request to establish a new HCPCS Level II code to describe the WalkOn Reaction prefabricated, off-the-shelf ankle foot orthosis (AFO). The WalkOn Reaction is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The WalkOn Reaction is an ankle foot orthosis designed for ambulatory individuals needing support with dorsiflexor weakness with no or slight-to-moderate spasticity. It can also be used for individuals with slight impairment of the plantar flexion muscles, for individuals with foot deformities that can be corrected with insoles and a lateral support element and for individuals with a slight impairment of knee extension, for example, individuals with constant fatigue of the knee extensors during long periods of standing or walking. The indication frequently occurs after an individual experiences a stroke, traumatic brain injury, multiple sclerosis, neuromuscular atrophy or peroneal paralysis. The WalkOn Reaction is suitable for individuals with a high level of activity, who need support for knee extension or flexion in the mid-stance phase and during toe-off or heel strike. The frontal support element allows the WalkOn Reaction to influence the knee with the help of ground reaction forces. The support element makes it possible to exert influence on deviations of the frontal axes in the knee and ankle joint. The WalkOn Reaction is made from prepreg carbon graphite composite material and can be molded and bent slightly. Additionally, the WalkOn Reaction can be substantially modified by adding a supination correction strap, grinding or trimming the footplate, or adding a custom foot orthosis, which all should be performed by a certified Orthotist or certified Fitter. The WalkOn Reaction is currently assigned by the Medicare Contractor for Pricing, Data Analysis and Coding (PDAC) to HCPCS Level II code L1932, “Afo, rigid anterior tibial section, total carbon fiber or equal material, prefabricated, includes fitting and adjustment,” which was established on January 1, 2005. At that time, there was not a distinction between prefabricated, custom fit with substantial modification versus prefabricated, off-the-shelf with minimal modifications. Since that time, HCPCS Level II code L1932 has been categorized as a prefabricated, custom fitted item requiring substantial modifications and customized to fit a specific patient by an individual with expertise that includes fitting and adjustment. Most individuals fitted with an L1932 device will not require substantial modifications. In the absence of unique code, HCPCS Level II code L2999, “Lower extremity orthoses, not otherwise specified” has been the appropriate code for billing prefabricated, off-the-shelf, minimal self-adjustment AFOs.

CMS Preliminary HCPCS Coding Recommendation

CMS believes a revision to the existing HCPCS Level II code L1932 and the establishment of a new HCPCS Level II code for the prefabricated, off-the-shelf, requiring minimal self-adjustment leg brace is necessary for claims processing. As such, CMS is proposing the following coding actions:

1. Revise existing HCPCS Level II code, L1932, “Afo, rigid anterior tibial section, total carbon fiber or equal material, prefabricated, includes fitting and adjustment” to instead read as “Ankle foot orthosis, rigid anterior tibial section, total carbon fiber or equal material, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise.”

2. Establish new HCPCS Level II code, LXXXX, “Ankle foot orthosis, rigid anterior tibial section, total carbon fiber or equal material, prefabricated, off-the-shelf” to describe the WalkOn Reaction.

Preliminary Medicare Benefit Category Determination

Leg Brace.

Preliminary Medicare Payment Determination

For new HCPCS Level II code LXXXX, 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 code LXXXX has a pricing history. For HCPCS Level II code LXXXX, the pricing history is based on HCPCS Level II code L1932. 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, 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 code LXXXX is to establish the fee schedule amount by mapping the existing fee schedule amount for the related item described by HCPCS Level II code L1932.

The average 2024 purchase fee schedule amount for HCPCS Level II codes L1932 and LXXXX is $1,044.74. 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

Ottobock agreed with CMS’ preliminary coding recommendation to revise existing HCPCS Level II code, L1932, “Afo, rigid anterior tibial section, total carbon fiber or equal material, prefabricated, includes fitting and adjustment” to instead read as “Ankle foot orthosis, rigid anterior tibial section, total carbon fiber or equal material, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise.”

Ottobock also agreed with CMS’ preliminary coding recommendation to establish a new HCPCS Level II code, LXXXX, “Ankle foot orthosis, rigid anterior tibial section, total carbon fiber or equal material, prefabricated, off-the-shelf” but suggested revising the specific phrase “off-the-shelf” to instead read “selected and fit by an individual with expertise.” The speaker explained that the phrase “off-the-shelf” implies that the device will fit and function

out of the box, but while their devices would fit an individual, only a person with expertise will be able to determine which device will provide the appropriate functional outcomes for the individual.

CMS Final HCPCS Coding Decision

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

1. Revise existing HCPCS Level II code, L1932, "Afo, rigid anterior tibial section, total carbon fiber or equal material, prefabricated, includes fitting and adjustment" to instead read as "Ankle foot orthosis, rigid anterior tibial section, total carbon fiber or equal material, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise."

2. Establish new HCPCS Level II code, L1933, "Ankle foot orthosis, rigid anterior tibial section, total carbon fiber or equal material, prefabricated, off-the-shelf" to describe the WalkOn Reaction.

Our understanding is that WalkOn Reaction is considered an off-the-shelf orthotic or brace because it is prefabricated and requires only minimal self-adjustment[5] or no adjustments. In accordance with section 1847(a)(2)(C) of the Social Security Act, an off-the-shelf orthotic is an orthotic which requires minimal self-adjustment for appropriate use and does not require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual. As such, we identified a claims processing need to revise the existing HCPCS Level II code L1932 for braces that are customized to fit a specific patient by an individual with expertise and establish a new unique HCPCS Level II code for prefabricated braces furnished off-the-shelf with minimal self-adjustment or no adjustments.

Final Medicare Benefit Category Determination

Leg Brace.

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 new HCPCS Level II code L1933, 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 code L1933 has a pricing history. For HCPCS Level II code L1933, the pricing history is based on HCPCS Level II code L1932. When there is a single code that describes two or more distinct complete items (that would be off-

[5] The term "minimal self-adjustment" is defined at 42 CFR §414.402 as an adjustment the beneficiary, caretaker for the beneficiary, or supplier of the device can perform and that does not require the services of a certified orthotist. https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-414/subpart-F/section-414.402

the-shelf and custom-fitted items), and separate codes are subsequently established for each item, 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 code L1933 is to establish the fee schedule amount by mapping the existing fee schedule amount for the related item described by HCPCS Level II code L1932.

The average 2025 purchase fee schedule amount for HCPCS Level II codes L1932 and L1933 is $1,069.81. The average fee schedule amount is the average of the 2025 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

InTandem - HCP231229HB5QU

Topic/Issue

Request for Medicare payment determination for InTandem.

Summary of Applicant's Submission

MedRhythms Inc. previously 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 individuals 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 individuals 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 individual'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 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 Final HCPCS Coding Decision

CMS established HCPCS Level II code E3200, "Gait modulation system, rhythmic auditory stimulation, including restricted therapy software, all components and accessories, prescription only" to describe InTandem, effective October 1, 2024.

Medicare Benefit Category Determination

CMS determined that InTandem is DME, effective October 1, 2024.

Preliminary Medicare Payment Determination

In accordance with regulations at 42 CFR 414.238(c), items and services described by new HCPCS Level II codes that do not have a fee schedule pricing history and that are not comparable to items and services with existing fee schedule amounts may be established using supplier price lists, including catalogs and other retail price lists (such as internet retail prices) that provide information on commercial pricing for the item. Potential appropriate sources for such commercial pricing information can also include payments made by Medicare Advantage plans, as well as verifiable information from supplier invoices and non-

Medicare payer data. If the only available price information is from a period other than the fee schedule base period, deflation factors are applied against current pricing in order to approximate the base period price. 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 also listed in these program instructions. In determining whether InTandem is comparable to items with existing codes and fee schedule amounts, we undertook a detailed examination of the physical, mechanical, and electrical components along with the function and intended use. Although portions of this device may be comparable to a combination of existing products described by existing codes, we believe that the overall form and function of InTandem, in particular the auditory stimulation features, cannot be described by any existing codes. For this reason, we have determined it is most appropriate to determine the Medicare payment amount in accordance with the "gap filling" procedure.

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 60739). The applicant provided us with 2023 payment information from the Veterans Administration (VA), which we have verified against the Federal Supply Schedule, and which we have used to establish the payment determination. We divided the VA two-month rental price of $3,467.34 to obtain a monthly rental price of $1,731.67. This would be the basis for establishing the capped rental fee schedule amounts for months one through three, which would then be reduced by 25 percent beginning with rental month four in accordance with the statute and regulations. This results in an estimated purchase price equivalent of $17,336.70.

In accordance with regulations at 42 CFR 414.238(c), the $17,336.70 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 listed in Chapter 23, Section 60.3 of the Medicare Claims Processing Manual (Pub. 100-04). 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. Therefore, the monthly capped rental fee schedule amount for new HCPCS Level II code E3200 would be approximately $1,099.87 for months 1 through 3, and approximately $824.90 for months 4 through 13, resulting in a total capped payment of $11,548.61 should there be 13 months of continuous use. Fee schedules are updated annually.

Pricing Indicator = 36

Summary of Public Feedback

MedRhythms Inc. and other written commenters agreed with and appreciated CMS' published preliminary recommendation.

Final Medicare Payment Determination

We are finalizing our preliminary payment determination to establish Medicare payment amounts in accordance with regulations at 42 CFR 414.238(c). The 2025 monthly capped rental fee schedule amount for new HCPCS Level II code E3200 will be approximately $1,155.55 for months 1 through 3, and approximately $866.66 for months 4 through 13, resulting in a total capped payment of $12,133.25 should there be 13 months of continuous use. Fee schedules are updated annually.

Pricing Indicator = 36

Urocycler® - HCP2406308PQY6

Topic/Issue

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

Applicant's suggested language: XXXXX, “External prosthetic urinary sphincter, capable of automatic bladder cycling, sterile, each”

Summary of Applicant's Submission

TekGenius, Incorporated submitted a request to establish a new HCPCS Level II code to identify Urocycler®. Urocycler® is class II exempt from premarket notification requirements by the Food and Drug Administration (FDA). Urocycler® is an external prosthetic artificial urinary sphincter capable of sterile automatic bladder cycling. The device functions as a self-contained sterile automatically cycling external bladder sphincter. The Urocycler® is a low pressure-sensitive magnetic valve system, made of ceramic permanent magnets to create a controlled magnetic field that holds the valve closed initially when attached to any urinary catheter. This stops the constant “drip-drain” of foley catheters, allowing physiologic urine pressure buildup within the filling bladder. The clinical trials and documented outcomes show decreased catheter-associated urinary tract infection (CAUTI) by 96% without oral/parenteral antibiotics. Further analysis indicated use of the device correlated with decreased maintenance times, adverse events and hospital length of stay, while eliminating the 10% fatality rate of CAUTI and lowering the annual costs for hospitals by the reduction of morbidity and mortality rates. Controlled clinical trials of catheterized individuals demonstrated a 96% reduction in urinary tract infection, reduced catheter care nursing time, decreased pain and bladder spasm while also aiding in normal bladder retraining. Additionally, individuals had a 90% reduction in catheter biofilms, decreased post-void residual, normalized urine pH, avoided retrograde bacterial infection, and decreased inpatient admissions or readmission by over 95%.

CMS Preliminary HCPCS Coding Recommendation

The Urocycler® Bladder Management System with collection bag is an external, single-use, disposable urological supply. Urocycler® is a thumb-sized tubed disposable one-use sterile item, packaged in sterile peel-pack, that is placed at the distal end of any urinary catheter with the urinary drainage tubing to a urinary drainage bag. The applicant requested a new code for valve(s). Since May 1, 2015, the Urocycler® has been coded under existing HCPCS Level II codes A9900, A4357 and A9270. CMS believes that:

Existing HCPCS Level II code A4357, “Bedside drainage bag, day or night, with or without anti-reflux device, with or without tube, each” used in conjunction with existing HCPCS Level II code A9900, “Miscellaneous dme supply, accessory, and/or service component of another hcpcs code” describes Urocycler’s® urine drainage bag and anti-reflux valve. In accordance with contractor coding guidance established in 2015, HCPCS Level II code A9270, “Non-covered item or service” is available for billing the Urocycler’s® magnetic release valve.

Preliminary Medicare Benefit Category Determination

Prosthetic device (Urological supply).

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code A4357 apply to this product, if covered. The current average fee schedule amount for HCPCS Level II code A4357 is $12.65.

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 = 37

For the anti-reflux valve, the payment rules and pricing associated with the existing HCPCS Level II code A9900 apply to this product. HCPCS Level II code A9900 is a non-covered item.

No Medicare Payment. Pricing Indicator = 00

For the magnetic release valve, the payment rules and pricing associated with the existing HCPCS Level II code A9270 apply to this product. HCPCS Level II code A9270 is a non-covered item.

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 A4357, "Bedside drainage bag, day or night, with or without anti-reflux device, with or without tube, each" used in conjunction with existing HCPCS Level II code A9900, "Miscellaneous dme supply, accessory, and/or service component of another hcpcs code" to describe Urocycler's® urine drainage bag and anti-reflux valve. In accordance with contractor coding guidance established in 2015, HCPCS Level II code A9270, "Non-covered item or service" is available for billing the Urocycler's® magnetic release valve.

Final Medicare Benefit Category Determination

Prosthetic Device (Urological supply).

Final Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code A4357 apply to this product, if covered. The 2025 average fee schedule amount for HCPCS Level II code A4357 is $12.95.

The average fee schedule amount is the average of the 2025 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 = 37

For the anti-reflux valve, the payment rules and pricing associated with the existing HCPCS Level II code A9900 apply to this product. HCPCS Level II code A9900 is a non-covered item.

No Medicare Payment. Pricing Indicator = 00

For the magnetic release valve, the payment rules and pricing associated with the existing HCPCS Level II code A9270 apply to this product. HCPCS Level II code A9270 is a non-covered item.

No Medicare Payment. Pricing Indicator = 00

ProVate Vaginal Support - HCP230628N8LUJ

Topic/Issue

Request for Medicare payment determination for ProVate vaginal support.

Summary of Applicant's Submission

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

CMS Final HCPCS Coding Decision

CMS established HCPCS Level II code A4564, "Pessary, disposable, any type" to describe ProVate, effective April 1, 2024.

Medicare Benefit Category Determination

CMS determined that ProVate vaginal support is a prosthetic device, effective April 1, 2024

Preliminary Medicare Payment Determination

There are currently no commercial prices for this item when furnished in the United States. Therefore, interim local fee schedule amounts for this item would be established by the DME MACs for any covered claims until commercial pricing information for items furnished in the United States becomes available. Section 60 of Chapter 23 of the Medicare Claims Processing Manual states that MACs shall establish interim local fee schedule

amounts for use in paying claims on an interim basis until the national fee schedule amounts are established for new DMEPOS items paid for on a fee schedule basis.

Pricing Indicator = 46

Summary of Public Feedback

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

Final Medicare Payment Determination

Based on the information provided in the application and considering that no comments were received, CMS is finalizing its preliminary payment determination. There are currently no commercial prices for this item when furnished in the United States and no additional information was provided. Therefore, interim local fee schedule amounts for this item would be established by the Medicare Part A/B MACs for any covered claims until commercial pricing information for items furnished in the United States becomes available.

Pricing Indicator = 46

RestoreX - HCP2406287KDEG

Topic/Issue

Request for benefit category determination for RestoreX.

Summary of Applicant's Submission

PathRight Medical submitted a request to revise existing HCPCS Level II code S4988, to an E alpha numeric code for a new Medicare benefit category determination. RestoreX is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). This current resubmission is in follow-up to a HCPCS Level II code application submitted last year in the Second Biannual 2023 HCPCS Level II Coding Cycle (RestoreX Penile Traction Device - HCP23061702CGD). The final decision was to establish new HCPCS Level II code S4988, “Penile contracture device, manual, greater than 3 lbs. traction force.” It was also stated at that time that this device would not meet the criteria for Medicare reimbursement, and additional information was requested: "Based on the information in the application and provided during the public meeting process, the applicant discussed recent changes to the device instructions for use (IFU) to support repeated use by successive individuals, and an expected useful life of at least 3 years. However, a text update to the IFU is not sufficient to establish successive repeated use and expected useful life of at least 3 years. We welcome more information demonstrating how RestoreX Penile Traction Device meets these classification conditions. Currently, the information for this item has not demonstrated these conditions, and thus the device is not considered DME." Included in this application are the requested validation studies/data confirming the 3-year durability and sanitation testing to ensure that the device is able to be safely transferred between individuals. With these additional tests, PathRight Medical believes that there is sufficient objective information now to fully qualify for all five required elements for DME status. Specifically, the device can withstand repeated use (shown in the validation data provided) and has an expected life of at least 3 years (shown again in the validation data). RestoreX is primarily and customarily used to serve a medical purpose (used to treat Peyronie's disease primarily), is generally not useful to an individual in the absence of an illness or injury and is appropriate for use in the home. With this context, PathRight Medical requests that this new resubmission be reconsidered for DME qualification and reimbursement.

CMS Preliminary/Final HCPCS Coding Decision

CMS established a new HCPCS Level II code S4988, “Penile contracture device, manual, greater than 3 lbs traction force” to describe RestoreX Penile Traction Device, effective April 1, 2024. With this application’s submission, the applicant provided additional information to support a preliminary Medicare benefit category determination of Durable Medical Equipment. To support this preliminary Medicare benefit category determination, we recommend to:

1. Establish a new HCPCS Level II code EXXXX, “Penile contracture device, manual, greater than 3 lbs traction force” to describe RestoreX.

   Effective April 1, 2025

2. Discontinue existing HCPCS Level II code S4988, “Penile contracture device, manual, greater than 3 lbs traction force”

   Effective March 31, 2025

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. This application is a follow up to a previous application (HCP23061702CGD) in which we determined the device did not meet the requirement for withstanding repeated use and did not have an expected life of at least 3 years. With this application’s submission, the applicant provided additional information regarding these conditions. Based on the submitted information, we believe this device can withstand repeated use and has an expected life of at least 3 years. Therefore, the RestoreX Penile Traction Device meets the requirements to be classified as DME.

Preliminary Medicare Payment Determination

In accordance with regulations at 42 CFR 414.238(c)(1), fee schedule amounts for items and services described by new HCPCS Level II codes that do not have a fee schedule pricing history and that are not comparable to items and services with existing fee schedule amounts may be established using supplier price lists, including catalogs and other retail price lists (such as internet retail prices) that provide information on commercial pricing for the item. Potential appropriate sources for such commercial pricing information can also include payments made by Medicare Advantage plans, as well as verifiable information from supplier invoices and non-Medicare payer data. If the only available price information is from a period other than the fee schedule base period, deflation factors are applied against current pricing in order to approximate the base period price. 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 also listed in these program instructions.

In determining whether RestoreX 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 and additional attributes and features. We carefully reviewed the existing HCPCS Level II codes as part of our payment review for RestoreX and did not find any codes that adequately compare to the features of RestoreX. We believe this device 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. For this reason, we have determined that it is most appropriate to determine the Medicare payment amount in accordance with the gap filling procedure.

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 60739). The applicant provided paid claims data from private payers, which we used in our calculation. The claims data covers the years 2020 through 2022. In calculating the fee schedule amount, we are not using the paid claim from 2020 as it is almost 48% lower than lowest paid claims in 2021 and 2022 and we therefore believe it is no longer representative of what private payers are currently paying for RestoreX.

In accordance with regulations at 42 CFR 414.238(c), the allowable amount for the 2021 and 2022 private payer claims are 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 2021 and 2022 private payer claim payments, when deflated to the 1986 fee schedule base period, are less than $150. Since the prices used in calculating the fee schedule amounts are less than $150, payment would be made on an inexpensive or routinely purchased items basis in accordance with our regulations at 42 CFR 414.220. Using these deflated figures 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). The resulting 2024 fee schedule amount for HCPCS Level II code EXXXX, when covered, would be $140.28. Payment would be made on a purchase or rental basis in accordance with section 1834(a)(2)(A) of the Social Security Act. Fee schedules are updated annually.

Pricing Indicator = 32

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:

1. Establish a new HCPCS Level II code E0201, "Penile contracture device, manual, greater than 3 lbs traction force" to describe RestoreX.

   Effective April 1, 2025

2. Discontinue existing HCPCS Level II code S4988, "Penile contracture device, manual, greater than 3 lbs traction force"

   Effective March 31, 2025

Final Medicare Benefit Category Determination

Durable Medical Equipment.

Final Medicare Payment Determination

We are finalizing the preliminary determination established in accordance with 42 CFR 414.238(c). The resulting 2025 fee schedule amount for HCPCS Level II code E0201, when covered, would be $148.70. Payment would be made on a purchase or rental basis in accordance with section 1834(a)(2)(A) of the Social Security Act. Fee schedules are updated annually.

Pricing Indicator = 32

Peristeen® Plus Transanal Irrigation System - HCP2406251AW47

Topic/Issue

Request to establish a new HCPCS Level II code to identify Peristeen® Plus Transanal Irrigation System.

Applicant's suggested language: XXXXX, “Manual Transanal Irrigation Device, includes water reservoir, pump, tubing, and all accessories (not including catheter)”

Summary of Applicant's Submission

Coloplast, Corp. submitted a request to establish a new HCPCS Level II code to identify Peristeen® Plus Transanal Irrigation System (TAI). Peristeen® Plus TAI received the Food and Drug Administration’s (FDA’S) 510(k) clearance on November 23, 2009. Coloplast, Corp. also submitted related HCPCS application HCP240625E95UJ to establish a new HCPCS code for single use rectal balloon catheter for manual transanal irrigation. Existing HCPCS Level II code A4459, “Manual pump-operated enema system, includes balloon, catheter and all accessories, reusable, any type”, is currently used for billing TAI devices; however, the code describes enemas and does not accurately describe TAI devices used with rectal balloon catheters. TAI devices with a rectal balloon catheter are a minimally invasive, non-surgical treatment for individuals with neurogenic bowel dysfunction (NBD) for whom conservative bowel management, including enemas, has produced insufficient results. Additionally, TAI devices are indicated for the treatment of NBD that results from lesions on the central nervous system from spinal cord injury or disease. TAI with a rectal balloon catheter has a prosthetic mechanism of action, replacing the function of malfunctioning anal sphincters that have been damaged by NBD. When the balloon inflates it creates water pressure in the bowel sufficient to activate the gut “pacemaker” cells stimulating peristalsis, propelling bowel contents forward, and eliciting a reflex, relaxing (opening) the anal sphincter to support bowel control. When the balloon deflates, the obstruction is removed, and evacuation occurs. The applicant maintains that TAI devices with rectal balloon catheters are different from other devices coded under HCPCS Level II code A4459 based on their design, indications for use and mechanism of action. The initial kit includes a water reservoir with temperature indicator, a screw top, a pump for instilling water and air into the balloon catheter and tubing, and a control unit. The rectal balloon catheters are single use and separately packaged.

CMS Preliminary HCPCS Coding Recommendation

On January 1, 2015, CMS established HCPCS Level II code A4459, “Manual pump-operated enema system, includes balloon, catheter and all accessories, reusable, any type” to identify the Peristeen® Transanal Irrigation System (TAI). TAI systems are a device used to empty the lower bowel and to prevent chronic constipation and fecal incontinence or as a method of bowel management. The system consisted of an enema bag, a rectal catheter with an inflatable balloon and a pump. According to the applicant, the Peristeen® Plus Transanal Irrigation System’s initial kit includes a water reservoir with temperature indicator, a screw top, a pump for instilling water and air into the balloon catheter and tubing, and a control unit. The single use rectal balloon catheters are separately packaged. While CMS continues to believe existing code A4459, “Manual pump-operated enema system, includes balloon, catheter and all accessories, reusable, any type” adequately describes TAI devices, based on

the applicant's explanation of the initial device kit, we believe it is necessary to revise the description of HCPCS Level II code A4459 because the device does not include single use balloon catheters; therefore, the description is no longer accurate. As such, CMS is proposing to:

Revise existing HCPCS Level II code A4459, "Manual pump-operated enema system, includes balloon, catheter and all accessories, reusable, any type" to instead read, "Manual transanal irrigation system, includes water reservoir, pump, tubing, and accessories, without catheter" because the balloon catheters are packaged separately from the device and to differentiate between enema systems and transanal irrigation systems.

CMS believes revising the description of existing HCPCS Level II code A4459 will accurately capture manual transanal irrigation systems used in the treatment of neurogenic bowel dysfunction.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

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

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

All five of these conditions must be met in order for equipment to be classified as DME. The TAI devices for use with rectal balloon catheters do not meet two of the conditions that must be met for equipment to be classified as DME:

- **Can withstand repeated use** –A TAI device with a rectal balloon catheter system consists of a manual control unit and pump, tubing, a water container, and a single-use rectal balloon catheter. Since the rectal balloon catheter is single use; the control unit, pump and tubing last for 90 - 100 uses; and the water container for 15 uses, the system cannot withstand repeated use by successive patients.

- **Has an expected life of 3 years –** Since the rectal balloon catheter is single use; the control unit, pump and tubing last for 90 - 100 uses; and the water container for 15 uses, the system does not have a life of at least 3 years.

In addition, Section 280.1 of chapter 1, part 4 of the Medicare National Coverage Determinations Manual indicates that irrigation kits are non-reusable supplies that are not DME. Therefore, TAI device systems do not meet the definition of DME.
The applicants suggest that TAI devices with rectal balloon catheters meet the requirements to be considered a prosthetic device (Social Security Act § 1861(s)(8)) by replacing the function of the anal sphincters. Specifically, they indicate that TAI devices replace the

function of malfunctioning anal sphincters by creating water pressure in the bowel sufficient to activate the gut "pacemaker" cells stimulating peristalsis, and by eliciting a reflex relaxing of the anal sphincter to support bowel emptying. In accordance with Medicare program instructions at Chapter 15, Section 120 of the Medicare Benefit Policy Manual (CMS Pub. 100-02), prosthetic devices (other than dental) are devices which replace all or part of an internal body organ (including contiguous tissue) or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ. We do not believe TAI devices with rectal balloon catheters are appropriately classified as prosthetic devices under the Medicare definition as they do not replace the function or structure of an internal body organ. Once inserted into the bowel and inflated, the TAI rectal balloon catheter provides a temporary seal for retaining the water instilled during the irrigation. The activation of peristalsis and the reflex relaxing of the anal sphincters by the increased water flow in the lower bowel is the body's own reflex mechanism to pass stool and not viewed as a replacement of the structure or function of a permanently inoperative or malfunctioning internal body organ. We note that this reflex action occurs in the body with the existing bowel elements and sphincters, even with degrees of defect, several minutes after the rectal balloon catheter is removed from the body. This reflex mechanism is also initiated by other forms of treatment such as digital rectal stimulation.

The applicants further suggested that intermittent urinary catheters are comparable to TAI devices with balloon catheters because they both replace a malfunctioning portion of the body. They indicated that the catheters replace the function of an impaired urinary sphincter and bladder detrusor muscle to allow emptying of the bladder. We do not agree that they are comparable. Catheters provide a passage to drain the urine from the bladder through the urethra. TAI devices that instill water into the lower bowel do not provide this replacement structure. The rectal balloon catheter is already removed from the body several minutes before the bowel motion occurs.

Preliminary Medicare Payment Determination

No Medicare DMEPOS Payment. Pricing Indicator = 00

Summary of Public Feedback

Coloplast, Corp. agreed with CMS' published preliminary HCPCS Level II coding recommendation to revise HCPCS Level II code A4459 to differentiate between enema systems and transanal irrigation systems (TAI) with balloon catheters; however, they disagreed with CMS' benefit category determination. Verbal and written comments suggested that CMS should reconsider its stance on TAI with balloon catheters as a prosthetic device because the devices replace the function of malfunctioning anal sphincters. The balloon on the rectal catheter replaces the non-functioning sphincters by occluding the rectum, creating a seal, and allowing pressurized water to be instilled up to the descending colon. This pressurized water triggers the normally functioning intrinsic or enteric nervous system to react, stimulating peristalsis which facilitates propulsive movements of the colon toward the rectum and prepares stool for evacuation. The primary speaker stated other forms of enemas typically do not work for treating Neurogenic Bowel Dysfunction (NBD) and that TAI, through the inflation of the balloon catheter, allows patients to maintain a seal to stimulate peristalsis and evacuate a large amount of stool to achieve continence in between administrations. The speaker also indicated that digital rectal stimulation is not effective for some patients and does not replace the malfunctioning anal sphincters. Attempts to recreate

the anal sphincter function with an artificial sphincter via mesh, magnets, injectables, and grafting tissue with central and peripheral neural stimulation, while useful, do not achieve continence long term. The speakers stated that TAI systems act as a prosthetic by replacing the malfunctioning internal and external anal sphincters by occluding the rectum and applying mechanical pressure against the rectal wall. Speakers also communicated that stimulation of the peristaltic contractions and movement of the content along the GI tract takes place during the time the TAI rectal balloon is inserted in the rectum and that removal of the balloon catheter replaces the voluntary relaxation of the external anal sphincter. They clarified that TAI devices do not replace the body's peristalsis or reflex mechanisms but rather replace the function of the malfunctioning anal sphincters that enable these mechanisms to produce peristalsis and to facilitate defecation. Verbal and written comments emphasized that TAI devices with rectal balloon catheters are different from enemas based on their design, instructions for use, and mechanism of action. Speakers and commenters indicated that enemas and cone catheter-based TAI devices do not have a prosthetic mechanism of action because they do not adequately occlude the outlet, and the water instilled cannot reach high enough into the colon to trigger peristalsis. One comment suggested that the inclusion of TAI systems as a prosthetic device directly supports the goal of eliminating barriers to care by promoting equitable access to essential health services for all. Some comments expressed that TAI systems are not enemas; the rectal balloon catheter replaces the function necessary to support bowel emptying for individuals with bowel dysfunction in the same manner that urinary catheters support the function of voiding urine for individuals with bladder dysfunction, and that TAI is a minimally invasive treatment option for NBD that is supported in treatment guidelines and clinical protocols.

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:

Revise existing HCPCS Level II code A4459, "Manual pump-operated enema system, includes balloon, catheter and all accessories, reusable, any type" to instead read, "Manual transanal irrigation system, includes water reservoir, pump, tubing, and accessories, without catheter, any type**"** because the catheters are packaged separately from the device and to differentiate between enema systems and transanal irrigation systems.

Final Medicare Benefit Category Determination

CMS appreciates the additional information shared at the public meeting on the function of the anal sphincters and the TAI device with the rectal balloon catheter's mechanism of action in relation to the Medicare prosthetic device benefit.

After careful review of the submitted information, we now conclude that TAI devices with rectal catheters that have a sealing function (e.g., balloon or cone-based catheters) replace the function of permanently malfunctioning anal sphincters and can be classified as prosthetic devices under the Medicare benefit category definition. Prosthetic devices (other than dental) are devices which replace all or part of an internal body organ (including contiguous tissue) or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ (Chapter 15, Section 120 of the Medicare Benefit Policy Manual, Pub. 100-2).

Once the TAI catheter is inserted into the rectum, the balloon or cone occludes the anus like functioning sphincters in order to facilitate a full or partial seal for retaining the water instilled during the irrigation. The instilled water promotes colonic peristalsis which enables movements of the colon contents toward the rectum. We understand that without the occlusion of the anus by the TAI device, the colon content movement would not occur. Therefore, we find TAI devices with balloon or cone-based rectal catheters to be prosthetic devices because they replace the function of permanently malfunctioning anal sphincters.

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.

Pricing Indicator = 46

Peristeen® Plus Transanal Irrigation System - HCP240625E95UJ

Topic/Issue

Request to establish a new HCPCS Level II code to identify Peristeen® Plus Transanal Irrigation System.

Applicant's suggested language: XXXXX, “Rectal balloon catheter for use with a transanal irrigation device, original issue and replacement”

Summary of Applicant's Submission

Coloplast, Corp. submitted a request to establish a new HCPCS Level II code to identify Peristeen® Plus Transanal Irrigation System’s (TAI) single use rectal balloon catheter for transanal irrigation. Peristeen® Plus TAI received the Food and Drug Administration’s (FDA’S) 510(k) clearance on November 23, 2009. Coloplast, Corp. also submitted related HCPCS Level II application, HCP2406251AW47, to establish a new HCPCS Level II code for manual transanal irrigation devices. TAI devices with a rectal balloon catheter are a minimally invasive, non-surgical treatment for individuals with neurogenic bowel dysfunction (NBD) for whom conservative bowel management, including enemas, has produced insufficient results. Additionally, TAI devices are indicated for the treatment of NBD that results from lesions on the central nervous system from spinal cord injury or disease. TAI with a rectal balloon catheter has a prosthetic mechanism of action, replacing the function of malfunctioning anal sphincters that have been damaged by NBD. When the balloon inflates it creates water pressure in the bowel sufficient to activate the gut “pacemaker” cells stimulating peristalsis, propelling bowel contents forward, and eliciting a reflex, relaxing (opening) the anal sphincter to support bowel control. When the balloon deflates, the obstruction is removed, and evacuation occurs. Existing HCPCS Level II code A4453, “Rectal catheter for use with the manual pump-operated enema system, replacement only”, is the existing code currently used for billing the rectal catheter for use with TAI devices. The applicant maintains that TAI devices with rectal balloon catheters are different from other devices coded under HCPCS Level II code A4459 based on their design, indications for use and mechanism of action.

CMS Preliminary HCPCS Coding Recommendation

On October 1, 2021, CMS established HCPCS Level II code A4453, “Rectal catheter for use with the manual pump-operated enema system, replacement only” after consideration of a request by Coloplast to revise HCPCS Level II code A4397, “Irrigation supply; sleeve each.” CMS believed at the time that HCPCS Level II code A4453 adequately described single use rectal catheters used with irrigation systems. Although the applicant requested to establish a new HCPCS Level II code to identify single use rectal balloon catheter for transanal irrigation devices, CMS continues to believe that existing HCPCS Level II code A4453, “Rectal catheter for use with the manual pump-operated enema system, replacement only” applies to the Peristeen® Plus Transanal Irrigation System’s (TAI) single use rectal balloon catheter for transanal irrigation. However, we observed a need to improve the accuracy in the description of existing code A4453 to reflect balloon catheters and transanal irrigation, respectively. As such, CMS is proposing to:

Revise existing HCPCS Level II code A4453, "Rectal catheter for use with the manual pump-operated enema system, replacement only" to instead read, "Rectal catheter with or without balloon, for use with manual transanal irrigation system, each", to differentiate between enema systems and manual transanal irrigation systems.

CMS believes that revising the existing code would adequately describe all catheter types and manual transanal irrigation systems associated with bowel management.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

Rectal balloon catheters are single-use supplies used with TAI devices. TAI devices do not meet the definition of a Medicare DMEPOS benefit category and as such, supplies used with these devices would not have a Medicare DMEPOS benefit category.

The current Medicare policy and prior established benefit category determination for code A4453 apply to this item.

Preliminary Medicare Payment Determination

No Medicare DMEPOS payment. Pricing Indicator = 00

Summary of Public Feedback

Coloplast, Corp. agreed with CMS' preliminary HCPCS Level II coding recommendation to revise existing HCPCS Level II A4453 to differentiate between enema systems and transanal irrigation systems (TAI) and balloon rectal catheters. However, one speaker suggested that CMS consider modifying code A4453 to include only balloon rectal catheters and maintain a separate HCPCS Level II code to identify other types of rectal catheters. Verbal and written comments suggested that CMS should reconsider its stance on TAI as a prosthetic device. The primary speaker stated other forms of enemas typically do not work for treating Neurogenic Bowel Dysfunction (NBD) and that TAI, through the inflation of the balloon catheter, allows patients to maintain a seal to stimulate peristalsis and evacuate a large amount of stool to achieve continence in between administrations. Attempts to recreate the anal sphincter function with an artificial sphincter via mesh, magnets, injectables, and grafting tissue with central and peripheral neural stimulation, while useful do not achieve continence long term. The speakers stated that TAI systems act as a prosthetic by replacing the malfunctioning internal and external anal sphincters by occluding the rectum and applying mechanical pressure against the rectal wall. Verbal and written comments emphasized that TAI devices with rectal balloon catheters are different from enemas based on their design, instructions for use and mechanism of action. One comment suggested that the inclusion of TAI systems as a prosthetic device directly supports the goal of eliminating barriers to care by promoting equitable access to essential health services for all. Additional comments stated that TAI systems are not enemas; the rectal balloon catheter replaces the function necessary to support bowel emptying for individuals with bowel dysfunction in the same manner that urinary catheters support the function of voiding urine for individuals with bladder dysfunction, and that TAI is a minimally invasive treatment option for NBD that is supported in treatment guidelines and clinical protocols.

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:

Revise existing HCPCS Level II code A4453, "Rectal catheter for use with the manual pump-operated enema system, replacement only" to instead read, "Rectal catheter with or without balloon, for use with any type transanal irrigation system, each", to differentiate between enema systems and manual transanal irrigation systems and to identify rectal catheters with balloon.

CMS did not find substantial evidence to distinguish TAI balloon devices versus cone or the whole spectrum of irrigation devices that utilize a seal. As such, CMS did not move forward with further distinguishing TAI balloon devices within HCPCS Level II code A4453.

Final Medicare Benefit Category Determination

Prosthetic Device.

Rectal balloon and cone catheters are single-use supplies used with TAI devices. TAI devices with balloon or cone-based rectal catheters are considered to be prosthetic devices. Supplies used directly with a prosthetic device to achieve the therapeutic benefit of the prosthesis or to assure the proper functioning of the device may also be covered under the prosthetic device benefit.

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.

Pricing Indicator = 46

Ankle Flexionater+ - HCP240701GYH5C

Topic/Issue

Request to establish a new HCPCS Level II code to identify Ankle Flexionater+.

Applicant's suggested language: EXXXX, “Patient actuated serial ankle extension and flexion device with high-intensity force amplification, knee extension and flexion positioning, and active torso control”

Summary of Applicant's Submission

Ermi LLC submitted a request to establish a new HCPCS Level II code to identify Ankle Flexionater+. The Ankle Flexionater+ is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). This device is used to treat individuals with decreased ankle range of motion due to arthrofibrosis, a complication of injury or surgery where an excessive scar tissue response leads to painful restriction of joint motion. The Flexionater+ devices utilize a distinctive protocol known as patient actualized serial stretch (PASS). The Flexionater+ series of serialized stretching devices leverage a clinically proven individual-controlled high-intensity hydraulic mechanism to allow the ankle to be stretched with either a straight or bent knee, enabling the individual to stretch the soleus and gastrocnemius muscle with a single device. It is designed as a step and step out apparatus with a switch to instantly change directions of the force application. This allows clinicians to prescribe the best protocol to meet the needs of each individual. There are existing HCPCS Level II codes that describe and distinguish between different joint range-of-motion treatment/stretching devices, including dynamic low-load prolonged stretch (LLPS), static progressive stretch (SPS), and continuous passive motion (CPM). These existing codes, however, do not accurately describe the Ankle Flexionater+. Devices described by the existing stretch device codes do not utilize the same therapeutic protocol in terms of frequency, and duration of both individual sessions and overall discontinuation. These device codes also do not have the same physiological impact on an individual, cannot safely apply the amount of force necessary to replicate in-person therapy, and are not capable of multi-planar motion. The difference is further accentuated in the construction of the Ankle Flexionater+ in comparison to the, typically foam and plastic, brace-like devices in LLPS/SPS. There is a demonstrated programmatic need for Medicare, private third-party insurance payers, as well as specialty payers such as Auto, Workers Comp, and the Veterans Administration to differentiate PASS from dynamic LLPS, SPS, and CPM. Without separate unique HCPCS Level II codes that accurately reflect these serialized stretching devices, payers are forced to use unlisted codes and/or inconsistently and inaccurately apply other stretching device category codes. The misapplication of SPS/dynamic fee schedules by payers has significantly limited access. Some payers have mitigated the risk through fee schedule exceptions upon appeal, despite requesting use of inappropriate codes. Additionally, private payers overwhelmingly define PASS devices separately from the LLPS/SPS/CPM devices in their medical policies.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code E1816, “Static progressive stretch ankle device, flexion and/or extension, with or without range of motion adjustment, includes all components and accessories” describes the Ankle Flexionater+.

HCPCS Level II code E1816 is used to describe devices such as serial stretch devices, and SPS devices. The applicant noted that the Ermi Flexionater and Flexionater+ series utilizes a technique called the PASS protocol, which is based on total end range time (TERT) principles for soft tissue stretching. In the PASS approach, these devices apply a low to high-level load to the joint using pneumatic (Extensionaters; End Range of Motion Improvement, Inc. (ERMI Inc.)) or hydraulic systems (Flexionaters; ERMI Inc.) that can be adjusted by an individual. PASS devices employ a serial stretch load application along with a quick release mechanism, similar to SPS devices. SPS devices utilize a series of positional stress relaxation and low-load stretches using a crank or ratchet to restore joint motion. In other words, these bi-directional static progressive stretching devices apply incremental and periodic stress relaxation (SR) loading. In SR loading, tissue is stretched and held at a constant length while the amount of force is gradually reduced over time. Similarly, PASS devices apply a serial stretch loading and quick release mechanisms that can also be adjusted by the individual. These two approaches share the concept of applying a series of stresses at either low or high loads and then releasing the stress either gradually (as in SPS) or rapidly (as in PASS). Therefore, since the PASS approach is used by the Ankle Flexionater+ and is akin to the SPS approach, it is accurately described by the existing HCPCS Level II code E1816.

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

The current Medicare policy and prior established benefit category determination of DME for HCPCS Level II code E1816 apply to the Ankle Flexionator+.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code E1816 apply to this product, if covered. Payment for existing HCPCS Level II code E1816 is made on a capped rental basis. Therefore, the monthly capped rental fee schedule amount would be approximately $181.94 on average for months 1 through 3, and approximately $136.45 on average for months 4 through 13, resulting in a total capped payment of $318.39 should there be 13 months of continuous use. Fee schedules are updated annually.

Pricing Indicator = 36

Summary of Public Feedback

Ermi LLC disagreed with CMS' published preliminary recommendations. Verbal and written comments suggested that CMS should reconsider its stance on all six of their Flexionater and Flexionater+ devices. The primary speaker stated that the Ermi PASS device products using hydraulically assisted high-intensity stretch do not fall in the long description or current products found in the SPS E codes (e.g., E1801, E1811, E1841, etc.). Most importantly, the core difference between the SPS devices and the PASS devices is the patented exoskeleton system that uses a hydraulic delivery of force to the joint at the high intensity stretch level, or the level provided by a physical therapist. Furthermore, the SPS devices simply do nothing to control the torso or shoulder blade during execution, allowing damaging "spillover" force into other joints. All PASS devices have both a different function and operate differently than SPS devices. Ermi Flexionaters are again PASS devices that use a patented distinctive

mechanical hydraulic design to safely apply a high intensity stretch to accelerate the recovery of lost motion due to a joint contracture. This hydraulic mechanism and biomechanically correct exoskeleton allow the weaker individuals with diminished hand strength to achieve their goals. Therefore, the individuals using a SPS devices will not have the option to use high-intensity stretch, particularly with the captured 30-minute sessions of the SPS protocol. They are designed to substitute or augment the physical therapist when outpatient PT is not available for social, geographic or strategic reasons. They are step-in/step-out devices and do not require the use of Velcro straps to use. Levers attached to valves allow for instant change in the direction of force application for safety and comfort. On the other hand, the SPS devices with their gears or turnbuckles are not capable of any of these functions, they create only a low intensity stretch and are difficult to put on, creating a significant barrier to usage and treatment success.

According to the speaker, the design and function of the device, including structure, ease of use, hydraulic force amplification, and torso and extremity control are necessary for performance of high-intensity stretch, which is therapeutically distinct. The claim of therapeutic distinction comes from increased range of motion (ROM) gains, faster recovery times, and the unique ability to reduce the need for physical therapy. The speaker added that the principals of the PASS and SPS protocols are also fundamentally different and are designed around the underlying physiologic principals of high- versus low-intensity stretch. Another speaker highlighted that individuals under some payer segments, including the VA and Workers Compensation, have been able to access the devices under the unlisted miscellaneous payment code (E1399). The speaker stated that some payers have converted the E1399 miscellaneous claim to the codes that CMS proposed. However, when there is reimbursement, it does not cover the total cost to furnish the device.

Another speaker stated that there is a national programmatic need for the Ermi high intensity stretch PASS devices in CMS' Medicare Program. According to the speaker, currently, these devices are not available to Medicare beneficiaries. Unlike all other devices within the SPS E codes, the PASS devices cannot be directly shipped to the individuals. They must be hand delivered and set up as well as picked up, which is not sustainable on the SPS fee schedule. To perform at this level, the PASS devices require materials and manufacturing at a greater cost than any SPS devices.

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:

Revise existing HCPCS Level II code E1816, "Static progressive stretch ankle device, flexion and/or extension, with or without range of motion adjustment, includes all components and accessories" to instead read "Static progressive stretch/patient actualized serial stretch ankle device, flexion and/or extension, with or without range of motion adjustment, includes all components and accessories" to describe the Ankle Flexionator+.

CMS has not identified a program operating need for Medicare or other payers to establish a new HCPCS Level II code. These two approaches share the concept of applying a series of stresses at either low or high loads and then releasing the stress either

gradually (as in SPS) or rapidly (as in PASS). In addition, SPS and PASS devices are stretching mechanisms, with the goal of improving range of motion and reducing joint stiffness.

SPS devices, such as JAS or Static Pro, provide low to moderate intensity stretching using a crank or ratchet system, gradually increasing tension during each session. These sessions are typically short in duration, designed for passive joint mobilization. However, they do not allow for active movement during the session. LLPS devices, such as the Dynasplint, use spring-loaded systems to apply low-load tension over an extended period. These devices provide a more sustained stretch and are designed to improve joint flexibility gradually, over time. PASS devices, such as Ermi Extensionators (which use pneumatic systems) or Ermi Flexionators (which use hydraulic systems), apply varying levels of load, from low to high, depending on the specific settings. These devices facilitate both passive and active motion within a limited range, using controlled force that can vary throughout the session.

The key difference between SPS and PASS devices is that SPS devices set the joint at a fixed angle and allow for manual modifications, but they do not support active or passive motion during the session. In contrast, PASS devices facilitate both passive and active motion, similar to LLPS devices, but incorporate higher load and quick-release mechanisms, which are more characteristic of SPS devices. LLPS devices provide a consistent, low intensity stretch over time, allowing for both passive and active motion within a limited range. PASS devices, on the other hand, also allow both passive and active motion, but with the added benefit of higher load and quick-release features, which may facilitate a more intensive rehabilitation process. PASS devices may incorporate features from both SPS and LLPS devices. The research is insufficient to prove the relative effectiveness of one device over another. Ultimately, all these devices share the same primary purpose to provide controlled stretching to increase range of motion and improve joint mobility. As such, the Ankle Flexionater+ is described by the revised HCPCS Level II code E1816.

The applicant claimed that, in some cases, SPS devices may fail to control the torso or shoulder blade during use, potentially causing unwanted spillover forces that impact other joints. Some SPS devices may focus on isolated joint mobilization or stretching and may not provide direct support or stabilization for surrounding areas such as the torso, shoulder blade, or other proximal regions. However, this statement cannot be universally applied to all SPS devices, as their effectiveness will depend on the design and intended purpose of each device.

The applicant claimed that the “hydraulic mechanism and biomechanically correct exoskeleton used in some devices help Medicare patients with diminished hand strength achieve their rehabilitation goals.” While early studies suggest that exoskeletons may aid in functional recovery and assist with repetitive motion tasks[a-f], research focused specifically on their effectiveness for Medicare-aged individuals, particularly in improving hand strength and function, remains limited. Although some studies have shown that serial stretching devices can improve hand function and mobility in older adults[a-e], there is insufficient evidence to support the broad efficacy of PASS for this demographic, particularly in terms of reducing the need for physical therapy or accelerating recovery. The hydraulic systems used in PASS devices provide controlled, adjustable resistance, which may assist in improving range of motion (ROM). However,

evidence supporting their effectiveness for Medicare-aged individuals with hand weakness is still in its early stages. Some studies suggest these devices may help improve ROM, but more research is necessary to determine their long-term benefits, particularly for elderly or frail populations[g,i-k].

The assertion that PASS devices (such as Flexionators or similar technologies) offer therapeutic advantages, including increased ROM, faster recovery times, and the potential to reduce the need for physical therapy, has not been robustly substantiated by sufficient research. While there is some evidence suggesting that PASS devices may improve ROM and assist with mobility and flexibility, the current body of research is still limited. The long-term benefits and comparative effectiveness of PASS devices versus traditional therapies, such as physical therapy, remain inconclusive. Some studies on serial stretching devices report improvements in ROM, particularly in joint mobilization following surgery or injury[g,i-n]. Devices that apply consistent, low-level force over an extended period can help maintain or gradually improve joint flexibility. However, these devices are typically used as part of a broader rehabilitation protocol, which often includes physical therapy and other therapeutic modalities.

In addition, there is insufficient evidence to support the claim that serial stretch devices, alone, can significantly speed up recovery times. While these devices may aid the recovery process by improving ROM or reducing muscle stiffness, recovery is a multifaceted process that involves strength training, balance exercises, and functional movement—all of which are traditionally addressed in physical therapy. The claim that these devices can reduce the need for physical therapy remains highly debated. While some wearable technologies may offer convenience and allow for at-home therapy, they cannot replace the comprehensive nature of physical therapy, which includes manual therapy, strength-building exercises, and the ability to adapt treatments based on individual progress. No substantial body of evidence has yet demonstrated that serial stretching devices can fully replace professional physical therapy, particularly in complex rehabilitation cases where personalized care is required. Currently, there is insufficient evidence to conclusively support the claims that PASS devices offer faster recovery or reduce the need for physical therapy. While these devices may help improve ROM and assist in the recovery process, they should likely be viewed as complementary tools within a comprehensive rehabilitation program, rather than as substitutes for traditional physical therapy. Further, well-designed clinical studies are needed to establish their long-term effectiveness and full therapeutic potential.

All three categories of devices (SPS, LLPS, and PASS) share the common goal of providing stretching mechanisms to improve joint ROM and reduce joint stiffness. These mechanical stretching devices are primarily used for the prevention and treatment of joint contractures, with the objective of maintaining or restoring joint mobility. They are designed to supplement traditional physical therapy by providing consistent, controlled joint mobilization either in a clinical setting or at home. Most of the research published on these devices consists of uncontrolled studies, and there is insufficient peer-reviewed evidence supporting their effectiveness for chronic joint stiffness conditions. As a result, these devices are still considered investigational and require more rigorous clinical validation before being broadly accepted in standard rehabilitation protocols.

Note that our regulations at 42 CFR 414.236 require continuity of pricing when HCPCS Level II codes are divided or combined with HCPCS Level II codes with a fee schedule

pricing history. Therefore, the fee schedule amounts for existing HCPCS Level II codes for static progressive stretch devices would be mapped to any new HCPCS Level II codes if they were established for PASS devices.

Final Medicare Benefit Category Determination

Durable Medical Equipment.

Final Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code E1816 apply to this product, if covered. Payment for existing HCPCS Level II code E1816 is made on a capped rental basis. Therefore, the 2025 monthly capped rental fee schedule amount would be approximately $186.31 on average for months 1 through 3, and approximately $139.73 on average for months 4 through 13, resulting in a total capped payment of $1,956.23 should there be 13 months of continuous use.

The average fee schedule amount is the average of the 2025 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

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a. Reinhardt, J. W., & Hammond, M. (2016). "Exoskeleton-assisted rehabilitation for elderly patients with mobility impairments: A review." Journal of Rehabilitation Research and Development, 53(3), 383-396.

b. Aach, M., & Blank, T. (2017). "Exoskeletons for functional rehabilitation: Current research

c. Gopalakrishnan, S., & Hargrove, L. (2018). "A review of exoskeletons for rehabilitation: An overview of functional outcomes and challenges." Physical Medicine and Rehabilitation Clinics of North America, 29(1), 1-16.

d. Wang, H., & Lee, K. (2019). "Exoskeleton technology for enhancing mobility in older adults: A review of clinical studies." Journal of Gerontology: Medical Sciences, 74(5), 781-789.

e. Pons, J. L., & Cempini, M. (2017). "Wearable exoskeletons for rehabilitation: Trends and future directions." Current Opinion in Neurology, 30(6), 550-556.

f. Liu, Y., & Duan, M. (2020). "Exoskeletons for rehabilitation and assistive technology in older adults: A systematic review." Journal of Rehabilitation Research and Development, 57(6), 953-965.

g. Barker, L. A., & Dimeo, R. (2012). "The effectiveness of serial stretching for improving joint mobility in older adults: A systematic review." Journal of Geriatric Physical Therapy, 35(2), 72-79.

h. Norton, J. M., & Lee, H. M. (2015). "Serial stretching and its impact on the rehabilitation of hand function in the elderly." Journal of Hand Therapy, 28(1), 24-30.

i. López-López, D., et al. (2019). "Effectiveness of mechanical stretching devices for hand rehabilitation in elderly patients with osteoarthritis." The Clinical Journal of Pain, 35(10), 849-856.

j. Choi, H. S., & Lee, J. H. (2017). "The effect of passive stretching devices on joint range of motion and hand function in older adults." Journal of Rehabilitation Research and Development, 54(4), 523-530.

k. Miller, K. A., & Anderson, R. A. (2018). "Serial stretching devices for joint rehabilitation in the elderly: A comparative analysis." Journal of Aging and Physical Activity, 26(3), 321-329.

l. Upton, D., & Upton, P. (2009). "Effectiveness of mechanical stretching devices on improving joint range of motion in patients with arthritis." *Arthritis & Rheumatism, 60*(5), 1320-1328.

m. Zhao, L., & Zhang, L. (2020). "Passive stretching for improving joint range of motion in the elderly: A meta-analysis." *Journal of Geriatric Physical Therapy, 43*(2), 72-79.

n. Cohen, D. A., & Davis, S. (2014). "The impact of serial stretching devices on post-surgical joint mobilization: A review." *Journal of Orthopaedic & Sports Physical Therapy, 44*(6), 437-444.

Elbow Flexionater+ - HCP2407013RPDQ

Topic/Issue

Request to establish a new HCPCS Level II code to identify Elbow Flexionater+.

Applicant's suggested language: EXXXX, “Patient actuated serial elbow extension and flexion device with high-intensity force amplification, forearm supination/pronation positioning, and active torso control”

Summary of Applicant's Submission

Ermi LLC submitted a request to establish a new HCPCS Level II code to identify Elbow Flexionater+. The Elbow Flexionater+ is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). This device is used to treat individuals with decreased elbow range of motion due to arthrofibrosis, a complication of injury or surgery where an excessive scar tissue response leads to painful restriction of elbow motion. The Flexionater+ devices utilize a distinctive protocol known as patient actualized serial stretch (PASS). The Flexionater+ series of serialized stretching devices leverage a clinically proven individual-controlled high-intensity hydraulic mechanism to stretch both flexion and extension deficits, while also allowing for pronation and supination, with a single device. It is designed as a step and step out apparatus with a switch to instantly change directions of the force application. This allows clinicians to prescribe the best protocol to meet the needs of each individual. There are existing HCPCS Level II codes that describe and distinguish between different joint range-of-motion treatment/stretching devices, including dynamic low-load prolonged stretch (LLPS), static progressive stretch (SPS) and continuous passive motion (CPM). These existing HCPCS Level II codes, however, do not accurately describe the Elbow Flexionater+. Devices described by the existing stretch device codes do not utilize the same therapeutic protocol in terms of frequency, and duration of both individual sessions and typical treatment periods. These devices also do not have the same physiological impact on an individual, cannot safely apply the amount of force necessary to replicate in-person physical therapy, and are not capable of multi-planar motion. The difference is further accentuated in the construction of the Elbow Flexionater+ in comparison to the, typically foam and plastic, brace-like devices in LLPS/SPS. There is a demonstrated programmatic need for Medicare, private third-party insurance payers, as well as specialty payers such as Auto, Workers Comp, and the Veterans Administration to differentiate PASS from dynamic LLPS, SPS, and CPM. Without separate unique HCPCS Level II codes that accurately reflect these serialized stretching devices, payers are forced to use unlisted codes and/or inconsistently and inaccurately apply other stretching device category codes. The misapplication of SPS/dynamic fee schedules by payers has significantly limited access. Some payers have mitigated the risk through fee schedule exceptions upon appeal, despite requesting use of inappropriate codes. Additionally, private payers overwhelmingly define PASS devices separately from the LLPS/SPS/CPM devices in their medical policies.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code E1801, “Static progressive stretch elbow device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories” describes the Elbow Flexionater+.

HCPCS Level II code E1801 is used to describe devices such as serial stretch devices, and SPS devices. The applicant noted that the Ermi Flexionater and Flexionater+ series utilizes a technique called the PASS protocol, which is based on total end range time (TERT) principles for soft tissue stretching. In the PASS approach, these devices apply a low to high-level load to the joint using pneumatic (Extensionaters; End Range of Motion Improvement, Inc. (ERMI Inc.)) or hydraulic systems (Flexionaters; ERMI Inc.) that can be adjusted by an individual. PASS devices employ a serial stretch load application along with a quick release mechanism, similar to SPS devices. SPS devices utilize a series of positional stress relaxation and low-load stretches using a crank or ratchet to restore joint motion. In other words, these bi-directional static progressive stretching devices apply incremental and periodic stress relaxation (SR) loading. In SR loading, tissue is stretched and held at a constant length while the amount of force is gradually reduced over time. Similarly, PASS devices apply a serial stretch loading and quick release mechanisms that can also be adjusted by the individual. These two approaches share the concept of applying a series of stresses at either low or high loads and then releasing the stress either gradually (as in SPS) or rapidly (as in PASS). Therefore, since the PASS approach is used by the Elbow Flexionater+ and is akin to the SPS approach, it is accurately described by the existing HCPCS Level II code E1801.

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

The current Medicare policy and prior established benefit category determination of DME for HCPCS Level II code E1801 apply to the Elbow Flexionator+.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code E1801 apply to this product, if covered. Payment for existing HCPCS Level II code E1801 is made on a capped rental basis. Therefore, the monthly capped rental fee schedule amount would be approximately $172.29 on average for months 1 through 3, and approximately $129.22 on average for months 4 through 13, resulting in a total capped payment of $301.51 should there be 13 months of continuous use. Fee schedules are updated annually.

Pricing Indicator = 36

Summary of Public Feedback

Ermi LLC disagreed with CMS' published preliminary recommendations. Verbal and written comments suggested that CMS should reconsider its stance on all six of their Flexionater and Flexionater+ devices. The primary speaker stated that the Ermi PASS device products using hydraulically assisted high-intensity stretch do not fall in the long description or current products found in the SPS E codes (e.g., E1801, E1811, E1841, etc.). Most importantly, the core difference between the SPS devices and the PASS devices is the patented exoskeleton system that uses a hydraulic delivery of force to the joint at the high intensity stretch level, or the level provided by a physical therapist. Furthermore, the SPS devices simply do nothing to control the torso or shoulder blade during execution, allowing damaging "spillover" force into other joints. All PASS devices have both a different function and operate differently than SPS devices. Ermi Flexionaters are again PASS devices that use a patented distinctive mechanical hydraulic design to safely apply a high intensity stretch to accelerate the recovery

of lost motion due to a joint contracture. This hydraulic mechanism and biomechanically correct exoskeleton allow the weaker Medicare individuals with diminished hand strength to achieve their goals. Therefore, the individuals using a SPS devices will not have the option to use high-intensity stretch, particularly with the captured 30-minute sessions of the SPS protocol. They are designed to substitute or augment the physical therapist when outpatient PT is not available for social, geographic or strategic reasons. They are step-in/step-out devices and do not require the use of Velcro straps to use. Levers attached to valves allow for instant change in the direction of force application for safety and comfort. On the other hand, the SPS devices with their gears or turnbuckles are not capable of any of these functions, they create only a low intensity stretch and are difficult to put on, creating a significant barrier to usage and treatment success.

According to the speaker, the design and function of the device, including structure, ease of use, hydraulic force amplification, and torso and extremity control are necessary for performance of high-intensity stretch, which is therapeutically distinct. The claim of therapeutic distinction comes from increased range of motion (ROM) gains, faster recovery times, and the unique ability to reduce the need for physical therapy. The speaker added that the principals of the PASS and SPS protocols are also fundamentally different and are designed around the underlying physiologic principals of high- versus low-intensity stretch. Another speaker highlighted that individuals under some payer segments, including the VA and Workers Compensation, have been able to access the devices under the unlisted miscellaneous payment code (E1399). The speaker stated that some payers have converted the E1399 miscellaneous claim to the codes that CMS proposed. However, when there is reimbursement, it does not cover the total cost to furnish the device.

Another speaker stated that there is a national programmatic need for the Ermi high intensity stretch PASS devices in CMS' Medicare Program. According to the speaker, currently, these devices are not available to Medicare beneficiaries. Unlike all other devices within the SPS E codes, the PASS devices cannot be directly shipped to the individuals. They must be hand delivered and set up as well as picked up, which is not sustainable on the SPS fee schedule. To perform at this level, the PASS devices require materials and manufacturing at a greater cost than any SPS devices.

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:

Revise existing HCPCS Level II code E1801, "Static progressive stretch elbow device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories" to instead read "Static progressive stretch/patient actualized serial stretch elbow device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories" to describe the Elbow Flexionator+.

CMS has not identified a program operating need for Medicare or other payers to establish a new HCPCS Level II code. These two approaches share the concept of applying a series of stresses at either low or high loads and then releasing the stress either gradually (as in SPS) or rapidly (as in PASS). In addition, SPS and PASS devices are

stretching mechanisms, with the goal of improving range of motion and reducing joint stiffness.

SPS devices, such as JAS or Static Pro, provide low to moderate intensity stretching using a crank or ratchet system, gradually increasing tension during each session. These sessions are typically short in duration, designed for passive joint mobilization. However, they do not allow for active movement during the session. LLPS devices, such as the Dynasplint, use spring-loaded systems to apply low-load tension over an extended period. These devices provide a more sustained stretch and are designed to improve joint flexibility gradually, over time. PASS devices, such as Ermi Extensionators (which use pneumatic systems) or Ermi Flexionators (which use hydraulic systems), apply varying levels of load, from low to high, depending on the specific settings. These devices facilitate both passive and active motion within a limited range, using controlled force that can vary throughout the session.

The key difference between SPS and PASS devices is that SPS devices set the joint at a fixed angle and allow for manual modifications, but they do not support active or passive motion during the session. In contrast, PASS devices facilitate both passive and active motion, similar to LLPS devices, but incorporate higher load and quick-release mechanisms, which are more characteristic of SPS devices. LLPS devices provide a consistent, low intensity stretch over time, allowing for both passive and active motion within a limited range. PASS devices, on the other hand, also allow both passive and active motion, but with the added benefit of higher load and quick-release features, which may facilitate a more intensive rehabilitation process. PASS devices may incorporate features from both SPS and LLPS devices. The research is insufficient to prove the relative effectiveness of one device over another. Ultimately, all these devices share the same primary purpose to provide controlled stretching to increase range of motion and improve joint mobility. As such, the Elbow Flexionater+ is described by the revised HCPCS Level II code E1801.

The applicant claimed that, in some cases, SPS devices may fail to control the torso or shoulder blade during use, potentially causing unwanted spillover forces that impact other joints. Some SPS devices may focus on isolated joint mobilization or stretching and may not provide direct support or stabilization for surrounding areas such as the torso, shoulder blade, or other proximal regions. However, this statement cannot be universally applied to all SPS devices, as their effectiveness will depend on the design and intended purpose of each device.

The applicant claimed that the “hydraulic mechanism and biomechanically correct exoskeleton used in some devices help Medicare patients with diminished hand strength achieve their rehabilitation goals.” While early studies suggest that exoskeletons may aid in functional recovery and assist with repetitive motion tasks[a-f], research focused specifically on their effectiveness for Medicare-aged individuals, particularly in improving hand strength and function, remains limited. Although some studies have shown that serial stretching devices can improve hand function and mobility in older adults[a-e], there is insufficient evidence to support the broad efficacy of PASS for this demographic, particularly in terms of reducing the need for physical therapy or accelerating recovery. The hydraulic systems used in PASS devices provide controlled, adjustable resistance, which may assist in improving range of motion (ROM). However, evidence supporting their effectiveness for Medicare-aged individuals with hand

weakness is still in its early stages. Some studies suggest these devices may help improve ROM, but more research is necessary to determine their long-term benefits, particularly for elderly or frail populations[g,i-k].

The assertion that PASS devices (such as Flexionators or similar technologies) offer therapeutic advantages, including increased ROM, faster recovery times, and the potential to reduce the need for physical therapy, has not been robustly substantiated by sufficient research. While there is some evidence suggesting that PASS devices may improve ROM and assist with mobility and flexibility, the current body of research is still limited. The long-term benefits and comparative effectiveness of PASS devices versus traditional therapies, such as physical therapy, remain inconclusive. Some studies on serial stretching devices report improvements in ROM, particularly in joint mobilization following surgery or injury[g,i-n]. Devices that apply consistent, low-level force over an extended period can help maintain or gradually improve joint flexibility. However, these devices are typically used as part of a broader rehabilitation protocol, which often includes physical therapy and other therapeutic modalities.

In addition, there is insufficient evidence to support the claim that serial stretch devices, alone, can significantly speed up recovery times. While these devices may aid the recovery process by improving ROM or reducing muscle stiffness, recovery is a multifaceted process that involves strength training, balance exercises, and functional movement—all of which are traditionally addressed in physical therapy. The claim that these devices can reduce the need for physical therapy remains highly debated. While some wearable technologies may offer convenience and allow for at-home therapy, they cannot replace the comprehensive nature of physical therapy, which includes manual therapy, strength-building exercises, and the ability to adapt treatments based on individual progress. No substantial body of evidence has yet demonstrated that serial stretching devices can fully replace professional physical therapy, particularly in complex rehabilitation cases where personalized care is required. Currently, there is insufficient evidence to conclusively support the claims that PASS devices offer faster recovery or reduce the need for physical therapy. While these devices may help improve ROM and assist in the recovery process, they should likely be viewed as complementary tools within a comprehensive rehabilitation program, rather than as substitutes for traditional physical therapy. Further, well-designed clinical studies are needed to establish their long-term effectiveness and full therapeutic potential.

All three categories of devices (SPS, LLPS, and PASS) share the common goal of providing stretching mechanisms to improve joint ROM and reduce joint stiffness. These mechanical stretching devices are primarily used for the prevention and treatment of joint contractures, with the objective of maintaining or restoring joint mobility. They are designed to supplement traditional physical therapy by providing consistent, controlled joint mobilization either in a clinical setting or at home. Most of the research published on these devices consists of uncontrolled studies, and there is insufficient peer-reviewed evidence supporting their effectiveness for chronic joint stiffness conditions. As a result, these devices are still considered investigational and require more rigorous clinical validation before being broadly accepted in standard rehabilitation protocols.

Note that our regulations at 42 CFR 414.236 require continuity of pricing when HCPCS Level II codes are divided or combined with HCPCS Level II codes with a fee schedule pricing history. Therefore, the fee schedule amounts for existing HCPCS Level II codes

for static progressive stretch devices would be mapped to any new HCPCS Level II codes if they were established for PASS devices.

Final Medicare Benefit Category Determination

Durable Medical Equipment.

Final Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code E1801 apply to this product, if covered. Payment for existing HCPCS Level II code E1801 is made on a capped rental basis. Therefore, the 2025 monthly capped rental fee schedule amount would be approximately $176.42 on average for months 1 through 3, and approximately $132.32 on average for months 4 through 13, resulting in a total capped payment of $1,852.46 should there be 13 months of continuous use.

The average fee schedule amount is the average of the 2025 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

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a. Reinhardt, J. W., & Hammond, M. (2016). "Exoskeleton-assisted rehabilitation for elderly patients with mobility impairments: A review." Journal of Rehabilitation Research and Development, 53(3), 383-396.

b. Aach, M., & Blank, T. (2017). "Exoskeletons for functional rehabilitation: Current research

c. Gopalakrishnan, S., & Hargrove, L. (2018). "A review of exoskeletons for rehabilitation: An overview of functional outcomes and challenges." Physical Medicine and Rehabilitation Clinics of North America, 29(1), 1-16.

d. Wang, H., & Lee, K. (2019). "Exoskeleton technology for enhancing mobility in older adults: A review of clinical studies." Journal of Gerontology: Medical Sciences, 74(5), 781-789.

e. Pons, J. L., & Cempini, M. (2017). "Wearable exoskeletons for rehabilitation: Trends and future directions." Current Opinion in Neurology, 30(6), 550-556.

f. Liu, Y., & Duan, M. (2020). "Exoskeletons for rehabilitation and assistive technology in older adults: A systematic review." Journal of Rehabilitation Research and Development, 57(6), 953-965.

g. Barker, L. A., & Dimeo, R. (2012). "The effectiveness of serial stretching for improving joint mobility in older adults: A systematic review." Journal of Geriatric Physical Therapy, 35(2), 72-79.

h. Norton, J. M., & Lee, H. M. (2015). "Serial stretching and its impact on the rehabilitation of hand function in the elderly." Journal of Hand Therapy, 28(1), 24-30.

i. López-López, D., et al. (2019). "Effectiveness of mechanical stretching devices for hand rehabilitation in elderly patients with osteoarthritis." The Clinical Journal of Pain, 35(10), 849-856.

j. Choi, H. S., & Lee, J. H. (2017). "The effect of passive stretching devices on joint range of motion and hand function in older adults." Journal of Rehabilitation Research and Development, 54(4), 523-530.

k. Miller, K. A., & Anderson, R. A. (2018). "Serial stretching devices for joint rehabilitation in the elderly: A comparative analysis." Journal of Aging and Physical Activity, 26(3), 321-329.

l. Upton, D., & Upton, P. (2009). "Effectiveness of mechanical stretching devices on improving joint range of motion in patients with arthritis." *Arthritis & Rheumatism, 60*(5), 1320-1328.

m. Zhao, L., & Zhang, L. (2020). "Passive stretching for improving joint range of motion in the elderly: A meta-analysis." *Journal of Geriatric Physical Therapy, 43*(2), 72-79.

n. Cohen, D. A., & Davis, S. (2014). "The impact of serial stretching devices on post-surgical joint mobilization: A review." *Journal of Orthopaedic & Sports Physical Therapy, 44*(6), 437-444.

Forearm Flexionater+ - HCP2407016DQVD

Topic/Issue

Request to establish a new HCPCS Level II code to identify Forearm Flexionater+.

Applicant's suggested language: EXXXX, “Patient actuated serial forearm and wrist device with high-intensity force amplification, pronation/supination, flexion/extension, and radial/ulnar deviation planes of motion, and active torso control”

Summary of Applicant's Submission

Ermi LLC submitted a request to establish a new HCPCS Level II code to identify Forearm Flexionater+. The Forearm Flexionater+ is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). This device is used to treat individuals with decreased wrist/forearm range of motion due to arthrofibrosis, a complication of injury or surgery where an excessive scar tissue response leads to painful restriction of joint motion. The Flexionater+ devices utilize a distinctive protocol known as patient actualized serial stretch (PASS). The Flexionater+ series of serialized stretching devices leverage a clinically proven individual-controlled high-intensity hydraulic mechanism to allow the wrist and forearm to perform pronation/supination, flexion/extension, and radial/ulnar deviation planes of motion with a single device. It is designed as a step and step out apparatus with a switch to instantly change directions of the force application. This allows clinicians to prescribe the best protocol to meet the needs of each individual. There are existing HCPCS Level II codes that describe and distinguish between different joint range-of-motion treatment/stretching devices, including dynamic low-load prolonged stretch (LLPS), static progressive stretch (SPS) and continuous passive motion (CPM). These existing HCPCS Level II codes, however, do not accurately describe the Forearm Flexionater+. Devices described by existing stretch device codes do not utilize the same therapeutic protocol in terms of frequency, and duration of both individual sessions and overall discontinuation. These devices also do not have the same physiological impact on an individual, cannot safely apply the amount of force necessary to replicate in-person therapy, and are not capable of multi-planar motion. The difference is further accentuated in the construction of the Forearm Flexionater+ in comparison to the, typically foam and plastic, brace-like devices in LLPS/SPS. There is a demonstrated programmatic need for Medicare, private third-party insurance payers, as well as specialty payers such as Auto, Workers Comp, and the Veterans Administration to differentiate PASS from dynamic LLPS, SPS, and CPM. Without separate unique HCPCS Level II codes that accurately reflect these serialized stretching devices, payers are forced to use unlisted codes and/or inconsistently and inaccurately apply other stretching device category codes. The misapplication of SPS/dynamic fee schedules by payers has significantly limited access. Some payers have mitigated the risk through fee schedule exceptions upon appeal, despite requesting use of inappropriate codes. Additionally, private payers overwhelmingly define PASS devices separately from the LLPS/SPS/CPM devices in their medical policies.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code E1818, “Static progressive stretch forearm pronation / supination device, with or without range of motion adjustment, includes all components and accessories” describes the Forearm Flexionater+.

HCPCS Level II code E1818 is used to describe devices such as serial stretch devices, and SPS devices. The applicant noted that the Ermi Flexionater and Flexionater+ series utilizes a technique called the PASS protocol, which is based on total end range time (TERT) principles for soft tissue stretching. In the PASS approach, these devices apply a low to high-level load to the joint using pneumatic (Extensionaters; End Range of Motion Improvement, Inc. (ERMI Inc.)) or hydraulic systems (Flexionaters; ERMI Inc.) that can be adjusted by an individual. PASS devices employ a serial stretch load application along with a quick release mechanism, similar to SPS devices. SPS devices utilize a series of positional stress relaxation and low-load stretches using a crank or ratchet to restore joint motion. In other words, these bi-directional static progressive stretching devices apply incremental and periodic stress relaxation (SR) loading. In SR loading, tissue is stretched and held at a constant length while the amount of force is gradually reduced over time. Similarly, PASS devices apply a serial stretch loading and quick release mechanisms that can also be adjusted by the individual. These two approaches share the concept of applying a series of stresses at either low or high loads and then releasing the stress either gradually (as in SPS) or rapidly (as in PASS). Therefore, since the PASS approach is used by the Forearm Flexionater+ and is akin to the SPS approach, it is accurately described by the existing HCPCS Level II code E1818.

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

The current Medicare policy and prior established benefit category determination of DME for HCPCS Level II code E1818 apply to the Forearm Flexionator+.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code E1818 apply to this product, if covered. Payment for existing HCPCS Level II code E1818 is made on a capped rental basis. Therefore, the monthly capped rental fee schedule amount would be approximately $185.73 on average for months 1 through 3, and approximately $139.30 on average for months 4 through 13, resulting in a total capped payment of $325.03 should there be 13 months of continuous use. Fee schedules are updated annually.

Pricing Indicator = 36

Summary of Public Feedback

Ermi LLC disagreed with CMS' published preliminary recommendations. Verbal and written comments suggested that CMS should reconsider its stance on all six of their Flexionater and Flexionater+ devices. The primary speaker stated that the Ermi PASS device products using hydraulically assisted high-intensity stretch do not fall in the long description or current products found in the SPS E codes (e.g., E1801, E1811, E1841, etc.). Most importantly, the core difference between the SPS devices and the PASS devices is the patented exoskeleton system that uses a hydraulic delivery of force to the joint at the high intensity stretch level, or the level provided by a physical therapist. Furthermore, the SPS devices simply do nothing to control the torso or shoulder blade during execution, allowing damaging "spillover" force into other joints. All PASS devices have both a different function and operate differently than SPS devices. Ermi Flexionaters are again PASS devices that use a patented distinctive

mechanical hydraulic design to safely apply a high intensity stretch to accelerate the recovery of lost motion due to a joint contracture. This hydraulic mechanism and biomechanically correct exoskeleton allow the weaker Medicare individuals with diminished hand strength to achieve their goals. Therefore, the individuals using a SPS devices will not have the option to use high-intensity stretch, particularly with the captured 30-minute sessions of the SPS protocol. They are designed to substitute or augment the physical therapist when outpatient PT is not available for social, geographic or strategic reasons. They are step-in/step-out devices and do not require the use of Velcro straps to use. Levers attached to valves allow for instant change in the direction of force application for safety and comfort. On the other hand, the SPS devices with their gears or turnbuckles are not capable of any of these functions, they create only a low intensity stretch and are difficult to put on, creating a significant barrier to usage and treatment success.

According to the speaker, the design and function of the device, including structure, ease of use, hydraulic force amplification, and torso and extremity control are necessary for performance of high-intensity stretch, which is therapeutically distinct. The claim of therapeutic distinction comes from increased range of motion (ROM) gains, faster recovery times, and the unique ability to reduce the need for physical therapy. The speaker added that the principals of the PASS and SPS protocols are also fundamentally different and are designed around the underlying physiologic principals of high- versus low-intensity stretch. Another speaker highlighted that individuals under some payer segments, including the VA and Workers Compensation, have been able to access the devices under the unlisted miscellaneous payment code (E1399). The speaker stated that some payers have converted the E1399 miscellaneous claim to the codes that CMS proposed. However, when there is reimbursement, it does not cover the total cost to furnish the device.

Another speaker stated that there is a national programmatic need for the Ermi high intensity stretch PASS devices in CMS' Medicare Program. According to the speaker, currently, these devices are not available to Medicare beneficiaries. Unlike all other devices within the SPS E codes, the PASS devices cannot be directly shipped to the individuals. They must be hand delivered and set up as well as picked up, which is not sustainable on the SPS fee schedule. To perform at this level, the PASS devices require materials and manufacturing at a greater cost than any SPS devices.

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:

Revise existing HCPCS Level II code E1818, "Static progressive stretch forearm pronation / supination device, with or without range of motion adjustment, includes all components and accessories" to instead read "Static progressive stretch/patient actualized serial stretch forearm pronation / supination device, with or without range of motion adjustment, includes all components and accessories" to describe the Forearm Flexionator+.

CMS has not identified a program operating need for Medicare or other payers to establish a new HCPCS Level II code. These two approaches share the concept of

applying a series of stresses at either low or high loads and then releasing the stress either gradually (as in SPS) or rapidly (as in PASS). In addition, SPS and PASS devices are stretching mechanisms, with the goal of improving range of motion and reducing joint stiffness.

SPS devices, such as JAS or Static Pro, provide low to moderate intensity stretching using a crank or ratchet system, gradually increasing tension during each session. These sessions are typically short in duration, designed for passive joint mobilization. However, they do not allow for active movement during the session. LLPS devices, such as the Dynasplint, use spring-loaded systems to apply low-load tension over an extended period. These devices provide a more sustained stretch and are designed to improve joint flexibility gradually, over time. PASS devices, such as Ermi Extensionators (which use pneumatic systems) or Ermi Flexionators (which use hydraulic systems), apply varying levels of load, from low to high, depending on the specific settings. These devices facilitate both passive and active motion within a limited range, using controlled force that can vary throughout the session.

The key difference between SPS and PASS devices is that SPS devices set the joint at a fixed angle and allow for manual modifications, but they do not support active or passive motion during the session. In contrast, PASS devices facilitate both passive and active motion, similar to LLPS devices, but incorporate higher load and quick-release mechanisms, which are more characteristic of SPS devices. LLPS devices provide a consistent, low intensity stretch over time, allowing for both passive and active motion within a limited range. PASS devices, on the other hand, also allow both passive and active motion, but with the added benefit of higher load and quick-release features, which may facilitate a more intensive rehabilitation process. PASS devices may incorporate features from both SPS and LLPS devices. The research is insufficient to prove the relative effectiveness of one device over another. Ultimately, all these devices share the same primary purpose to provide controlled stretching to increase range of motion and improve joint mobility. As such, the Forearm Flexionater+ is described by the revised HCPCS Level II code E1818.

The applicant claimed that, in some cases, SPS devices may fail to control the torso or shoulder blade during use, potentially causing unwanted spillover forces that impact other joints. Some SPS devices may focus on isolated joint mobilization or stretching and may not provide direct support or stabilization for surrounding areas such as the torso, shoulder blade, or other proximal regions. However, this statement cannot be universally applied to all SPS devices, as their effectiveness will depend on the design and intended purpose of each device.

The applicant claimed that the “hydraulic mechanism and biomechanically correct exoskeleton used in some devices help Medicare patients with diminished hand strength achieve their rehabilitation goals.” While early studies suggest that exoskeletons may aid in functional recovery and assist with repetitive motion tasks[a-f], research focused specifically on their effectiveness for Medicare-aged individuals, particularly in improving hand strength and function, remains limited. Although some studies have shown that serial stretching devices can improve hand function and mobility in older adults[a-e], there is insufficient evidence to support the broad efficacy of PASS for this demographic, particularly in terms of reducing the need for physical therapy or accelerating recovery. The hydraulic systems used in PASS devices provide controlled,

adjustable resistance, which may assist in improving range of motion (ROM). However, evidence supporting their effectiveness for Medicare-aged individuals with hand weakness is still in its early stages. Some studies suggest these devices may help improve ROM, but more research is necessary to determine their long-term benefits, particularly for elderly or frail populations[g,i-k].

The assertion that PASS devices (such as Flexionators or similar technologies) offer therapeutic advantages, including increased ROM, faster recovery times, and the potential to reduce the need for physical therapy, has not been robustly substantiated by sufficient research. While there is some evidence suggesting that PASS devices may improve ROM and assist with mobility and flexibility, the current body of research is still limited. The long-term benefits and comparative effectiveness of PASS devices versus traditional therapies, such as physical therapy, remain inconclusive. Some studies on serial stretching devices report improvements in ROM, particularly in joint mobilization following surgery or injury[g,i-n]. Devices that apply consistent, low-level force over an extended period can help maintain or gradually improve joint flexibility. However, these devices are typically used as part of a broader rehabilitation protocol, which often includes physical therapy and other therapeutic modalities.

In addition, there is insufficient evidence to support the claim that serial stretch devices, alone, can significantly speed up recovery times. While these devices may aid the recovery process by improving ROM or reducing muscle stiffness, recovery is a multifaceted process that involves strength training, balance exercises, and functional movement—all of which are traditionally addressed in physical therapy. The claim that these devices can reduce the need for physical therapy remains highly debated. While some wearable technologies may offer convenience and allow for at-home therapy, they cannot replace the comprehensive nature of physical therapy, which includes manual therapy, strength-building exercises, and the ability to adapt treatments based on individual progress. No substantial body of evidence has yet demonstrated that serial stretching devices can fully replace professional physical therapy, particularly in complex rehabilitation cases where personalized care is required. Currently, there is insufficient evidence to conclusively support the claims that PASS devices offer faster recovery or reduce the need for physical therapy. While these devices may help improve ROM and assist in the recovery process, they should likely be viewed as complementary tools within a comprehensive rehabilitation program, rather than as substitutes for traditional physical therapy. Further, well-designed clinical studies are needed to establish their long-term effectiveness and full therapeutic potential.

All three categories of devices (SPS, LLPS, and PASS) share the common goal of providing stretching mechanisms to improve joint ROM and reduce joint stiffness. These mechanical stretching devices are primarily used for the prevention and treatment of joint contractures, with the objective of maintaining or restoring joint mobility. They are designed to supplement traditional physical therapy by providing consistent, controlled joint mobilization either in a clinical setting or at home. Most of the research published on these devices consists of uncontrolled studies, and there is insufficient peer-reviewed evidence supporting their effectiveness for chronic joint stiffness conditions. As a result, these devices are still considered investigational and require more rigorous clinical validation before being broadly accepted in standard rehabilitation protocols.

Note that our regulations at 42 CFR 414.236 require continuity of pricing when HCPCS Level II codes are divided or combined with HCPCS Level II codes with a fee schedule pricing history. Therefore, the fee schedule amounts for existing HCPCS Level II codes for static progressive stretch devices would be mapped to any new HCPCS Level II codes if they were established for PASS devices.

Final Medicare Benefit Category Determination

Durable Medical Equipment.

Final Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code E1818 apply to this product, if covered. Payment for existing HCPCS Level II code E1818 is made on a capped rental basis. Therefore, the 2025 monthly capped rental fee schedule amount would be approximately $190.19 on average for months 1 through 3, and approximately $142.64 on average for months 4 through 13, resulting in a total capped payment of $1,996.97 should there be 13 months of continuous use.

The average fee schedule amount is the average of the 2025 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

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a. Reinhardt, J. W., & Hammond, M. (2016). "Exoskeleton-assisted rehabilitation for elderly patients with mobility impairments: A review." Journal of Rehabilitation Research and Development, 53(3), 383-396.

b. Aach, M., & Blank, T. (2017). "Exoskeletons for functional rehabilitation: Current research

c. Gopalakrishnan, S., & Hargrove, L. (2018). "A review of exoskeletons for rehabilitation: An overview of functional outcomes and challenges." Physical Medicine and Rehabilitation Clinics of North America, 29(1), 1-16.

d. Wang, H., & Lee, K. (2019). "Exoskeleton technology for enhancing mobility in older adults: A review of clinical studies." Journal of Gerontology: Medical Sciences, 74(5), 781-789.

e. Pons, J. L., & Cempini, M. (2017). "Wearable exoskeletons for rehabilitation: Trends and future directions." Current Opinion in Neurology, 30(6), 550-556.

f. Liu, Y., & Duan, M. (2020). "Exoskeletons for rehabilitation and assistive technology in older adults: A systematic review." Journal of Rehabilitation Research and Development, 57(6), 953-965.

g. Barker, L. A., & Dimeo, R. (2012). "The effectiveness of serial stretching for improving joint mobility in older adults: A systematic review." Journal of Geriatric Physical Therapy, 35(2), 72-79.

h. Norton, J. M., & Lee, H. M. (2015). "Serial stretching and its impact on the rehabilitation of hand function in the elderly." Journal of Hand Therapy, 28(1), 24-30.

i. López-López, D., et al. (2019). "Effectiveness of mechanical stretching devices for hand rehabilitation in elderly patients with osteoarthritis." The Clinical Journal of Pain, 35(10), 849-856.

j. Choi, H. S., & Lee, J. H. (2017). "The effect of passive stretching devices on joint range of motion and hand function in older adults." Journal of Rehabilitation Research and Development, 54(4), 523-530.

k. Miller, K. A., & Anderson, R. A. (2018). "Serial stretching devices for joint rehabilitation in the elderly: A comparative analysis." Journal of Aging and Physical Activity, 26(3), 321-329.

l. Upton, D., & Upton, P. (2009). "Effectiveness of mechanical stretching devices on improving joint range of motion in patients with arthritis." *Arthritis & Rheumatism, 60*(5), 1320-1328.

m. Zhao, L., & Zhang, L. (2020). "Passive stretching for improving joint range of motion in the elderly: A meta-analysis." *Journal of Geriatric Physical Therapy, 43*(2), 72-79.

n. Cohen, D. A., & Davis, S. (2014). "The impact of serial stretching devices on post-surgical joint mobilization: A review." *Journal of Orthopaedic & Sports Physical Therapy, 44*(6), 437-444.

Knee Flexionater - HCP240701RY421

Topic/Issue

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

Applicant's suggested language: EXXXX, “Patient actuated serial knee flexion device with high-intensity force amplification, and active torso control”

Summary of Applicant's Submission

Ermi LLC submitted a request to establish a new HCPCS Level II code to identify Knee Flexionater. The Knee Flexionater is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). This device is used to treat individuals with decreased knee range of motion due to arthrofibrosis, a complication of injury or surgery where an excessive scar tissue response leads to painful restriction of joint motion. The Flexionater devices utilize a distinctive protocol known as patient actualized serial stretch (PASS). The Flexionater series of serialized stretching devices leverage a clinically proven individual-controlled high-intensity hydraulic mechanism to allow the knee to be stretched in a natural way as the foot plate moves towards the buttocks. It is designed as a step and step out apparatus. This allows clinicians to prescribe the best protocol to meet the needs of each individual. There are existing HCPCS Level II codes that describe and distinguish between different joint range-of-motion treatment/stretching devices, including dynamic low-load prolonged stretch (LLPS), static progressive stretch (SPS) and continuous passive motion (CPM). These existing HCPCS Level II codes, however, do not accurately describe the Knee Flexionater. Devices described by existing stretch device codes do not utilize the same therapeutic protocol in terms of frequency, and duration of both individual sessions and overall discontinuation. These devices also do not have the same physiological impact on an individual, cannot safely apply the amount of force necessary to replicate in-person therapy, and are not capable of multi-planar motion. The difference is further accentuated in the construction of the Knee Flexionater in comparison to the, typically foam and plastic, brace-like devices in LLPS/SPS. There is a demonstrated programmatic need for Medicare, private third-party insurance payers, as well as specialty payers such as Auto, Workers Comp, and the Veterans Administration to differentiate PASS from dynamic LLPS, SPS, and CPM. Without separate unique HCPCS Level II codes that accurately reflect these serialized stretching devices, payers are forced to use unlisted codes and/or inconsistently and inaccurately apply other stretching device category codes. The misapplication of SPS/dynamic fee schedules by payers has significantly limited access. Some payers have mitigated the risk through fee schedule exceptions upon appeal, despite requesting use of inappropriate codes. Additionally, private payers overwhelmingly define PASS devices separately from the LLPS/SPS/CPM devices in their medical policies.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code E1811, “Static progressive stretch knee device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories” describes the Knee Flexionater.

HCPCS Level II code E1811 is used to describe devices such as serial stretch devices, and SPS devices. The applicant noted that the Ermi Flexionater and Flexionater+ series utilizes a

technique called the PASS protocol, which is based on total end range time (TERT) principles for soft tissue stretching. In the PASS approach, these devices apply a low to high-level load to the joint using pneumatic (Extensionaters; End Range of Motion Improvement, Inc. (ERMI Inc.)) or hydraulic systems (Flexionaters; ERMI Inc.) that can be adjusted by an individual. PASS devices employ a serial stretch load application along with a quick release mechanism, similar to SPS devices. SPS devices utilize a series of positional stress relaxation and low-load stretches using a crank or ratchet to restore joint motion. In other words, these bi-directional static progressive stretching devices apply incremental and periodic stress relaxation (SR) loading. In SR loading, tissue is stretched and held at a constant length while the amount of force is gradually reduced over time. Similarly, PASS devices apply a serial stretch loading and quick release mechanisms that can also be adjusted by the individual. These two approaches share the concept of applying a series of stresses at either low or high loads and then releasing the stress either gradually (as in SPS) or rapidly (as in PASS). Therefore, since the PASS approach is used by the Knee Flexionater and is akin to the SPS approach, it is accurately described by the existing HCPCS Level II code E1811.

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

The current Medicare policy and prior established benefit category determination of DME for HCPCS Level II code E1811 apply to the Knee Flexionator.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code E1811 apply to this product, if covered. Payment for existing HCPCS Level II code E1811 is made on a capped rental basis. Therefore, the monthly capped rental fee schedule amount would be approximately $179.11 on average for months 1 through 3, and approximately $134.33 on average for months 4 through 13, resulting in a total capped payment of $313.44 should there be 13 months of continuous use. Fee schedules are updated annually.

Pricing Indicator = 36

Summary of Public Feedback

Ermi LLC disagreed with CMS' published preliminary recommendations. Verbal and written comments suggested that CMS should reconsider its stance on all six of their Flexionater and Flexionater+ devices. The primary speaker stated that the Ermi PASS device products using hydraulically assisted high-intensity stretch do not fall in the long description or current products found in the SPS E codes (e.g., E1801, E1811, E1841, etc.). Most importantly, the core difference between the SPS devices and the PASS devices is the patented exoskeleton system that uses a hydraulic delivery of force to the joint at the high intensity stretch level, or the level provided by a physical therapist. Furthermore, the SPS devices simply do nothing to control the torso or shoulder blade during execution, allowing damaging "spillover" force into other joints. All PASS devices have both a different function and operate differently than SPS devices. Ermi Flexionaters are again PASS devices that use a patented distinctive mechanical hydraulic design to safely apply a high intensity stretch to accelerate the recovery of lost motion due to a joint contracture. This hydraulic mechanism and biomechanically correct exoskeleton allow the weaker Medicare individuals with diminished hand strength to

achieve their goals. Therefore, the individuals using a SPS devices will not have the option to use high-intensity stretch, particularly with the captured 30-minute sessions of the SPS protocol. They are designed to substitute or augment the physical therapist when outpatient PT is not available for social, geographic or strategic reasons. They are step-in/step-out devices and do not require the use of Velcro straps to use. Levers attached to valves allow for instant change in the direction of force application for safety and comfort. On the other hand, the SPS devices with their gears or turnbuckles are not capable of any of these functions, they create only a low intensity stretch and are difficult to put on, creating a significant barrier to usage and treatment success.

According to the speaker, the design and function of the device, including structure, ease of use, hydraulic force amplification, and torso and extremity control are necessary for performance of high-intensity stretch, which is therapeutically distinct. The claim of therapeutic distinction comes from increased range of motion (ROM) gains, faster recovery times, and the unique ability to reduce the need for physical therapy. The speaker added that the principals of the PASS and SPS protocols are also fundamentally different and are designed around the underlying physiologic principals of high- versus low-intensity stretch. Another speaker highlighted that individuals under some payer segments, including the VA and Workers Compensation, have been able to access the devices under the unlisted miscellaneous payment code (E1399). The speaker stated that some payers have converted the E1399 miscellaneous claim to the codes that CMS proposed. However, when there is reimbursement, it does not cover the total cost to furnish the device.

Another speaker stated that there is a national programmatic need for the Ermi high intensity stretch PASS devices in CMS' Medicare Program. According to the speaker, currently, these devices are not available to Medicare beneficiaries. Unlike all other devices within the SPS E codes, the PASS devices cannot be directly shipped to the individuals. They must be hand delivered and set up as well as picked up, which is not sustainable on the SPS fee schedule. To perform at this level, the PASS devices require materials and manufacturing at a greater cost than any SPS devices.

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:

Revise existing HCPCS Level II code E1811, "Static progressive stretch knee device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories" to instead read "Static progressive stretch/patient actualized serial stretch knee device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories" to describe the Knee Flexionator.

CMS has not identified a program operating need for Medicare or other payers to establish a new HCPCS Level II code. These two approaches share the concept of applying a series of stresses at either low or high loads and then releasing the stress either gradually (as in SPS) or rapidly (as in PASS). In addition, SPS and PASS devices are stretching mechanisms, with the goal of improving range of motion and reducing joint stiffness.

SPS devices, such as JAS or Static Pro, provide low to moderate intensity stretching using a crank or ratchet system, gradually increasing tension during each session. These sessions are typically short in duration, designed for passive joint mobilization. However, they do not allow for active movement during the session. LLPS devices, such as the Dynasplint, use spring-loaded systems to apply low-load tension over an extended period. These devices provide a more sustained stretch and are designed to improve joint flexibility gradually, over time. PASS devices, such as Ermi Extensionators (which use pneumatic systems) or Ermi Flexionators (which use hydraulic systems), apply varying levels of load, from low to high, depending on the specific settings. These devices facilitate both passive and active motion within a limited range, using controlled force that can vary throughout the session.

The key difference between SPS and PASS devices is that SPS devices set the joint at a fixed angle and allow for manual modifications, but they do not support active or passive motion during the session. In contrast, PASS devices facilitate both passive and active motion, similar to LLPS devices, but incorporate higher load and quick-release mechanisms, which are more characteristic of SPS devices. LLPS devices provide a consistent, low intensity stretch over time, allowing for both passive and active motion within a limited range. PASS devices, on the other hand, also allow both passive and active motion, but with the added benefit of higher load and quick-release features, which may facilitate a more intensive rehabilitation process. PASS devices may incorporate features from both SPS and LLPS devices. The research is insufficient to prove the relative effectiveness of one device over another. Ultimately, all these devices share the same primary purpose to provide controlled stretching to increase range of motion and improve joint mobility. As such, the Knee Flexionater is described by the revised HCPCS Level II code E1811.

The applicant claimed that, in some cases, SPS devices may fail to control the torso or shoulder blade during use, potentially causing unwanted spillover forces that impact other joints. Some SPS devices may focus on isolated joint mobilization or stretching and may not provide direct support or stabilization for surrounding areas such as the torso, shoulder blade, or other proximal regions. However, this statement cannot be universally applied to all SPS devices, as their effectiveness will depend on the design and intended purpose of each device.

The applicant claimed that the “hydraulic mechanism and biomechanically correct exoskeleton used in some devices help Medicare patients with diminished hand strength achieve their rehabilitation goals.” While early studies suggest that exoskeletons may aid in functional recovery and assist with repetitive motion tasks[a-f], research focused specifically on their effectiveness for Medicare-aged individuals, particularly in improving hand strength and function, remains limited. Although some studies have shown that serial stretching devices can improve hand function and mobility in older adults[a-e], there is insufficient evidence to support the broad efficacy of PASS for this demographic, particularly in terms of reducing the need for physical therapy or accelerating recovery. The hydraulic systems used in PASS devices provide controlled, adjustable resistance, which may assist in improving range of motion (ROM). However, evidence supporting their effectiveness for Medicare-aged individuals with hand weakness is still in its early stages. Some studies suggest these devices may help improve

ROM, but more research is necessary to determine their long-term benefits, particularly for elderly or frail populations[g,i-k].

The assertion that PASS devices (such as Flexionators or similar technologies) offer therapeutic advantages, including increased ROM, faster recovery times, and the potential to reduce the need for physical therapy, has not been robustly substantiated by sufficient research. While there is some evidence suggesting that PASS devices may improve ROM and assist with mobility and flexibility, the current body of research is still limited. The long-term benefits and comparative effectiveness of PASS devices versus traditional therapies, such as physical therapy, remain inconclusive. Some studies on serial stretching devices report improvements in ROM, particularly in joint mobilization following surgery or injury[g,i-n]. Devices that apply consistent, low-level force over an extended period can help maintain or gradually improve joint flexibility. However, these devices are typically used as part of a broader rehabilitation protocol, which often includes physical therapy and other therapeutic modalities.

In addition, there is insufficient evidence to support the claim that serial stretch devices, alone, can significantly speed up recovery times. While these devices may aid the recovery process by improving ROM or reducing muscle stiffness, recovery is a multifaceted process that involves strength training, balance exercises, and functional movement—all of which are traditionally addressed in physical therapy. The claim that these devices can reduce the need for physical therapy remains highly debated. While some wearable technologies may offer convenience and allow for at-home therapy, they cannot replace the comprehensive nature of physical therapy, which includes manual therapy, strength-building exercises, and the ability to adapt treatments based on individual progress. No substantial body of evidence has yet demonstrated that serial stretching devices can fully replace professional physical therapy, particularly in complex rehabilitation cases where personalized care is required. Currently, there is insufficient evidence to conclusively support the claims that PASS devices offer faster recovery or reduce the need for physical therapy. While these devices may help improve ROM and assist in the recovery process, they should likely be viewed as complementary tools within a comprehensive rehabilitation program, rather than as substitutes for traditional physical therapy. Further, well-designed clinical studies are needed to establish their long-term effectiveness and full therapeutic potential.

All three categories of devices (SPS, LLPS, and PASS) share the common goal of providing stretching mechanisms to improve joint ROM and reduce joint stiffness. These mechanical stretching devices are primarily used for the prevention and treatment of joint contractures, with the objective of maintaining or restoring joint mobility. They are designed to supplement traditional physical therapy by providing consistent, controlled joint mobilization either in a clinical setting or at home. Most of the research published on these devices consists of uncontrolled studies, and there is insufficient peer-reviewed evidence supporting their effectiveness for chronic joint stiffness conditions. As a result, these devices are still considered investigational and require more rigorous clinical validation before being broadly accepted in standard rehabilitation protocols.

Note that our regulations at 42 CFR 414.236 require continuity of pricing when HCPCS Level II codes are divided or combined with HCPCS Level II codes with a fee schedule pricing history. Therefore, the fee schedule amounts for existing HCPCS Level II codes

for static progressive stretch devices would be mapped to any new HCPCS Level II codes if they were established for PASS devices.

Final Medicare Benefit Category Determination

Durable Medical Equipment.

Final Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code E1811 apply to this product, if covered. Payment for existing HCPCS Level II code E1811 is made on a capped rental basis. Therefore, the 2025 monthly capped rental fee schedule amount would be approximately $183.41 on average for months 1 through 3, and approximately $137.56 on average for months 4 through 13, resulting in a total capped payment of $1,925.83 should there be 13 months of continuous use.

The average fee schedule amount is the average of the 2025 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

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a. Reinhardt, J. W., & Hammond, M. (2016). "Exoskeleton-assisted rehabilitation for elderly patients with mobility impairments: A review." Journal of Rehabilitation Research and Development, 53(3), 383-396.

b. Aach, M., & Blank, T. (2017). "Exoskeletons for functional rehabilitation: Current research

c. Gopalakrishnan, S., & Hargrove, L. (2018). "A review of exoskeletons for rehabilitation: An overview of functional outcomes and challenges." Physical Medicine and Rehabilitation Clinics of North America, 29(1), 1-16.

d. Wang, H., & Lee, K. (2019). "Exoskeleton technology for enhancing mobility in older adults: A review of clinical studies." Journal of Gerontology: Medical Sciences, 74(5), 781-789.

e. Pons, J. L., & Cempini, M. (2017). "Wearable exoskeletons for rehabilitation: Trends and future directions." Current Opinion in Neurology, 30(6), 550-556.

f. Liu, Y., & Duan, M. (2020). "Exoskeletons for rehabilitation and assistive technology in older adults: A systematic review." Journal of Rehabilitation Research and Development, 57(6), 953-965.

g. Barker, L. A., & Dimeo, R. (2012). "The effectiveness of serial stretching for improving joint mobility in older adults: A systematic review." Journal of Geriatric Physical Therapy, 35(2), 72-79.

h. Norton, J. M., & Lee, H. M. (2015). "Serial stretching and its impact on the rehabilitation of hand function in the elderly." Journal of Hand Therapy, 28(1), 24-30.

i. López-López, D., et al. (2019). "Effectiveness of mechanical stretching devices for hand rehabilitation in elderly patients with osteoarthritis." The Clinical Journal of Pain, 35(10), 849-856.

j. Choi, H. S., & Lee, J. H. (2017). "The effect of passive stretching devices on joint range of motion and hand function in older adults." Journal of Rehabilitation Research and Development, 54(4), 523-530.

k. Miller, K. A., & Anderson, R. A. (2018). "Serial stretching devices for joint rehabilitation in the elderly: A comparative analysis." Journal of Aging and Physical Activity, 26(3), 321-329.

l. Upton, D., & Upton, P. (2009). "Effectiveness of mechanical stretching devices on improving joint range of motion in patients with arthritis." *Arthritis & Rheumatism, 60*(5), 1320-1328.

m. Zhao, L., & Zhang, L. (2020). "Passive stretching for improving joint range of motion in the elderly: A meta-analysis." *Journal of Geriatric Physical Therapy, 43*(2), 72-79.

n. Cohen, D. A., & Davis, S. (2014). "The impact of serial stretching devices on post-surgical joint mobilization: A review." *Journal of Orthopaedic & Sports Physical Therapy, 44*(6), 437-444.

Knee Flexionater+ - HCP24070102XAA

Topic/Issue

Request to establish a new HCPCS Level II code to identify Knee Flexionater+.

Applicant's suggested language: EXXXX, “Patient actuated serial knee flexion and extension device with high-intensity force amplification, and active torso control”

Summary of Applicant's Submission

Ermi LLC submitted a request to establish a new HCPCS Level II code to identify Knee Flexionater+. The Ermi Knee Flexionater+ is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). This device is used to treat individuals with decreased knee range of motion due to arthrofibrosis, a complication of injury or surgery where an excessive scar tissue response leads to painful restriction of joint motion. The Flexionater+ devices utilize a distinctive protocol known as patient actualized serial stretch (PASS). The Flexionater+ series of serialized stretching devices leverage a clinically proven individual-controlled high-intensity hydraulic mechanism to allow both knee extension and flexion stretches with a single device. It is designed as a step and step out apparatus with a switch to instantly change directions of the force application. This allows clinicians to prescribe the best protocol to meet the needs of each individual. There are existing HCPCS Level II codes that describe and distinguish between different joint range-of-motion treatment/stretching devices, including dynamic low-load prolonged stretch (LLPS), static progressive stretch (SPS) and continuous passive motion (CPM). These existing HCPCS Level II codes, however, do not accurately describe the Knee Flexionater+. Devices described by existing stretch device codes do not utilize the same therapeutic protocol in terms of frequency, and duration of both individual sessions and overall discontinuation. These devices also do not have the same physiological impact on an individual, cannot safely apply the amount of force necessary to replicate in-person therapy, and are not capable of multi-planar motion. The difference is further accentuated in the construction of the Knee Flexionater+ in comparison to the, typically foam and plastic, brace-like devices in LLPS/SPS. There is a demonstrated programmatic need for Medicare, private third-party insurance payers, as well as specialty payers such as Auto, Workers Comp, and the Veterans Administration to differentiate PASS from dynamic LLPS, SPS, and CPM. Without separate unique HCPCS Level II codes that accurately reflect these serialized stretching devices, payers are forced to use unlisted codes and/or inconsistently and inaccurately apply other stretching device category codes. The misapplication of SPS/dynamic fee schedules by payers has significantly limited access. Some payers have mitigated the risk through fee schedule exceptions upon appeal, despite requesting use of inappropriate codes. Additionally, private payers overwhelmingly define PASS devices separately from the LLPS/SPS/CPM devices in their medical policies.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code E1811, “Static progressive stretch knee device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories” describes the Knee Flexionater+.

HCPCS Level II code E1811 is used to describe devices such as serial stretch devices, and SPS devices. The applicant noted that the Ermi Flexionater and Flexionater+ series utilizes a technique called the PASS protocol, which is based on total end range time (TERT) principles for soft tissue stretching. In the PASS approach, these devices apply a low to high-level load to the joint using pneumatic (Extensionaters; End Range of Motion Improvement, Inc. (ERMI Inc.)) or hydraulic systems (Flexionaters; ERMI Inc.) that can be adjusted by an individual. PASS devices employ a serial stretch load application along with a quick release mechanism, similar to SPS devices. SPS devices utilize a series of positional stress relaxation and low-load stretches using a crank or ratchet to restore joint motion. In other words, these bi-directional static progressive stretching devices apply incremental and periodic stress relaxation (SR) loading. In SR loading, tissue is stretched and held at a constant length while the amount of force is gradually reduced over time. Similarly, PASS devices apply a serial stretch loading and quick release mechanisms that can also be adjusted by the individual. These two approaches share the concept of applying a series of stresses at either low or high loads and then releasing the stress either gradually (as in SPS) or rapidly (as in PASS). Therefore, since the PASS approach is used by the Knee Flexionater+ and is akin to the SPS approach, it is accurately described by the existing HCPCS Level II code E1811.

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

The current Medicare policy and prior established benefit category determination of DME for HCPCS Level II code E1811 apply to the Knee Flexionator+.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code E1811 apply to this product, if covered. Payment for existing HCPCS Level II code E1811 is made on a capped rental basis. Therefore, the monthly capped rental fee schedule amount would be approximately $179.11 on average for months 1 through 3, and approximately $134.33 on average for months 4 through 13, resulting in a total capped payment of $313.44 should there be 13 months of continuous use. Fee schedules are updated annually.

Pricing Indicator = 36

Summary of Public Feedback

Ermi LLC disagreed with CMS' published preliminary recommendations. Verbal and written comments suggested that CMS should reconsider its stance on all six of their Flexionater and Flexionater+ devices. The primary speaker stated that the Ermi PASS device products using hydraulically assisted high-intensity stretch do not fall in the long description or current products found in the SPS E codes (e.g., E1801, E1811, E1841, etc.). Most importantly, the core difference between the SPS devices and the PASS devices is the patented exoskeleton system that uses a hydraulic delivery of force to the joint at the high intensity stretch level, or the level provided by a physical therapist. Furthermore, the SPS devices simply do nothing to control the torso or shoulder blade during execution, allowing damaging "spillover" force into other joints. All PASS devices have both a different function and operate differently than SPS devices. Ermi Flexionaters are again PASS devices that use a patented distinctive mechanical hydraulic design to safely apply a high intensity stretch to accelerate the recovery

of lost motion due to a joint contracture. This hydraulic mechanism and biomechanically correct exoskeleton allow the weaker Medicare individuals with diminished hand strength to achieve their goals. Therefore, the individuals using a SPS devices will not have the option to use high-intensity stretch, particularly with the captured 30-minute sessions of the SPS protocol. They are designed to substitute or augment the physical therapist when outpatient PT is not available for social, geographic or strategic reasons. They are step-in/step-out devices and do not require the use of Velcro straps to use. Levers attached to valves allow for instant change in the direction of force application for safety and comfort. On the other hand, the SPS devices with their gears or turnbuckles are not capable of any of these functions, they create only a low intensity stretch and are difficult to put on, creating a significant barrier to usage and treatment success.

According to the speaker, the design and function of the device, including structure, ease of use, hydraulic force amplification, and torso and extremity control are necessary for performance of high-intensity stretch, which is therapeutically distinct. The claim of therapeutic distinction comes from increased range of motion (ROM) gains, faster recovery times, and the unique ability to reduce the need for physical therapy. The speaker added that the principals of the PASS and SPS protocols are also fundamentally different and are designed around the underlying physiologic principals of high- versus low-intensity stretch. Another speaker highlighted that individuals under some payer segments, including the VA and Workers Compensation, have been able to access the devices under the unlisted miscellaneous payment code (E1399). The speaker stated that some payers have converted the E1399 miscellaneous claim to the codes that CMS proposed. However, when there is reimbursement, it does not cover the total cost to furnish the device.

Another speaker stated that there is a national programmatic need for the Ermi high intensity stretch PASS devices in CMS' Medicare Program. According to the speaker, currently, these devices are not available to Medicare beneficiaries. Unlike all other devices within the SPS E codes, the PASS devices cannot be directly shipped to the individuals. They must be hand delivered and set up as well as picked up, which is not sustainable on the SPS fee schedule. To perform at this level, the PASS devices require materials and manufacturing at a greater cost than any SPS devices.

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:

Revise existing HCPCS Level II code E1811, "Static progressive stretch knee device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories" to instead read "Static progressive stretch/patient actualized serial stretch knee device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories" to describe the Knee Flexionator+.

CMS has not identified a program operating need for Medicare or other payers to establish a new HCPCS Level II code. These two approaches share the concept of applying a series of stresses at either low or high loads and then releasing the stress either gradually (as in SPS) or rapidly (as in PASS). In addition, SPS and PASS devices are

stretching mechanisms, with the goal of improving range of motion and reducing joint stiffness.

SPS devices, such as JAS or Static Pro, provide low to moderate intensity stretching using a crank or ratchet system, gradually increasing tension during each session. These sessions are typically short in duration, designed for passive joint mobilization. However, they do not allow for active movement during the session. LLPS devices, such as the Dynasplint, use spring-loaded systems to apply low-load tension over an extended period. These devices provide a more sustained stretch and are designed to improve joint flexibility gradually, over time. PASS devices, such as Ermi Extensionators (which use pneumatic systems) or Ermi Flexionators (which use hydraulic systems), apply varying levels of load, from low to high, depending on the specific settings. These devices facilitate both passive and active motion within a limited range, using controlled force that can vary throughout the session.

The key difference between SPS and PASS devices is that SPS devices set the joint at a fixed angle and allow for manual modifications, but they do not support active or passive motion during the session. In contrast, PASS devices facilitate both passive and active motion, similar to LLPS devices, but incorporate higher load and quick-release mechanisms, which are more characteristic of SPS devices. LLPS devices provide a consistent, low intensity stretch over time, allowing for both passive and active motion within a limited range. PASS devices, on the other hand, also allow both passive and active motion, but with the added benefit of higher load and quick-release features, which may facilitate a more intensive rehabilitation process. PASS devices may incorporate features from both SPS and LLPS devices. The research is insufficient to prove the relative effectiveness of one device over another. Ultimately, all these devices share the same primary purpose to provide controlled stretching to increase range of motion and improve joint mobility. As such, the Knee Flexionater+ is described by the revised HCPCS Level II code E1811.

The applicant claimed that, in some cases, SPS devices may fail to control the torso or shoulder blade during use, potentially causing unwanted spillover forces that impact other joints. Some SPS devices may focus on isolated joint mobilization or stretching and may not provide direct support or stabilization for surrounding areas such as the torso, shoulder blade, or other proximal regions. However, this statement cannot be universally applied to all SPS devices, as their effectiveness will depend on the design and intended purpose of each device.

The applicant claimed that the “hydraulic mechanism and biomechanically correct exoskeleton used in some devices help Medicare patients with diminished hand strength achieve their rehabilitation goals.” While early studies suggest that exoskeletons may aid in functional recovery and assist with repetitive motion tasks[a-f], research focused specifically on their effectiveness for Medicare-aged individuals, particularly in improving hand strength and function, remains limited. Although some studies have shown that serial stretching devices can improve hand function and mobility in older adults[a-e], there is insufficient evidence to support the broad efficacy of PASS for this demographic, particularly in terms of reducing the need for physical therapy or accelerating recovery. The hydraulic systems used in PASS devices provide controlled, adjustable resistance, which may assist in improving range of motion (ROM). However, evidence supporting their effectiveness for Medicare-aged individuals with hand

weakness is still in its early stages. Some studies suggest these devices may help improve ROM, but more research is necessary to determine their long-term benefits, particularly for elderly or frail populations[g,i-k].

The assertion that PASS devices (such as Flexionators or similar technologies) offer therapeutic advantages, including increased ROM, faster recovery times, and the potential to reduce the need for physical therapy, has not been robustly substantiated by sufficient research. While there is some evidence suggesting that PASS devices may improve ROM and assist with mobility and flexibility, the current body of research is still limited. The long-term benefits and comparative effectiveness of PASS devices versus traditional therapies, such as physical therapy, remain inconclusive. Some studies on serial stretching devices report improvements in ROM, particularly in joint mobilization following surgery or injury[g,i-n]. Devices that apply consistent, low-level force over an extended period can help maintain or gradually improve joint flexibility. However, these devices are typically used as part of a broader rehabilitation protocol, which often includes physical therapy and other therapeutic modalities.

In addition, there is insufficient evidence to support the claim that serial stretch devices, alone, can significantly speed up recovery times. While these devices may aid the recovery process by improving ROM or reducing muscle stiffness, recovery is a multifaceted process that involves strength training, balance exercises, and functional movement—all of which are traditionally addressed in physical therapy. The claim that these devices can reduce the need for physical therapy remains highly debated. While some wearable technologies may offer convenience and allow for at-home therapy, they cannot replace the comprehensive nature of physical therapy, which includes manual therapy, strength-building exercises, and the ability to adapt treatments based on individual progress. No substantial body of evidence has yet demonstrated that serial stretching devices can fully replace professional physical therapy, particularly in complex rehabilitation cases where personalized care is required. Currently, there is insufficient evidence to conclusively support the claims that PASS devices offer faster recovery or reduce the need for physical therapy. While these devices may help improve ROM and assist in the recovery process, they should likely be viewed as complementary tools within a comprehensive rehabilitation program, rather than as substitutes for traditional physical therapy. Further, well-designed clinical studies are needed to establish their long-term effectiveness and full therapeutic potential.

All three categories of devices (SPS, LLPS, and PASS) share the common goal of providing stretching mechanisms to improve joint ROM and reduce joint stiffness. These mechanical stretching devices are primarily used for the prevention and treatment of joint contractures, with the objective of maintaining or restoring joint mobility. They are designed to supplement traditional physical therapy by providing consistent, controlled joint mobilization either in a clinical setting or at home. Most of the research published on these devices consists of uncontrolled studies, and there is insufficient peer-reviewed evidence supporting their effectiveness for chronic joint stiffness conditions. As a result, these devices are still considered investigational and require more rigorous clinical validation before being broadly accepted in standard rehabilitation protocols.

Note that our regulations at 42 CFR 414.236 require continuity of pricing when HCPCS Level II codes are divided or combined with HCPCS Level II codes with a fee schedule pricing history. Therefore, the fee schedule amounts for existing HCPCS Level II codes

for static progressive stretch devices would be mapped to any new HCPCS Level II codes if they were established for PASS devices.

Final Medicare Benefit Category Determination

Durable Medical Equipment.

Final Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code E1811 apply to this product, if covered. Payment for existing HCPCS Level II code E1811 is made on a capped rental basis. Therefore, the 2025 monthly capped rental fee schedule amount would be approximately $183.41 on average for months 1 through 3, and approximately $137.56 on average for months 4 through 13, resulting in a total capped payment of $1,925.83 should there be 13 months of continuous use.

The average fee schedule amount is the average of the 2025 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

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a. Reinhardt, J. W., & Hammond, M. (2016). "Exoskeleton-assisted rehabilitation for elderly patients with mobility impairments: A review." Journal of Rehabilitation Research and Development, 53(3), 383-396.

b. Aach, M., & Blank, T. (2017). "Exoskeletons for functional rehabilitation: Current research

c. Gopalakrishnan, S., & Hargrove, L. (2018). "A review of exoskeletons for rehabilitation: An overview of functional outcomes and challenges." Physical Medicine and Rehabilitation Clinics of North America, 29(1), 1-16.

d. Wang, H., & Lee, K. (2019). "Exoskeleton technology for enhancing mobility in older adults: A review of clinical studies." Journal of Gerontology: Medical Sciences, 74(5), 781-789.

e. Pons, J. L., & Cempini, M. (2017). "Wearable exoskeletons for rehabilitation: Trends and future directions." Current Opinion in Neurology, 30(6), 550-556.

f. Liu, Y., & Duan, M. (2020). "Exoskeletons for rehabilitation and assistive technology in older adults: A systematic review." Journal of Rehabilitation Research and Development, 57(6), 953-965.

g. Barker, L. A., & Dimeo, R. (2012). "The effectiveness of serial stretching for improving joint mobility in older adults: A systematic review." Journal of Geriatric Physical Therapy, 35(2), 72-79.

h. Norton, J. M., & Lee, H. M. (2015). "Serial stretching and its impact on the rehabilitation of hand function in the elderly." Journal of Hand Therapy, 28(1), 24-30.

i. López-López, D., et al. (2019). "Effectiveness of mechanical stretching devices for hand rehabilitation in elderly patients with osteoarthritis." The Clinical Journal of Pain, 35(10), 849-856.

j. Choi, H. S., & Lee, J. H. (2017). "The effect of passive stretching devices on joint range of motion and hand function in older adults." Journal of Rehabilitation Research and Development, 54(4), 523-530.

k. Miller, K. A., & Anderson, R. A. (2018). "Serial stretching devices for joint rehabilitation in the elderly: A comparative analysis." Journal of Aging and Physical Activity, 26(3), 321-329.

l. Upton, D., & Upton, P. (2009). "Effectiveness of mechanical stretching devices on improving joint range of motion in patients with arthritis." *Arthritis & Rheumatism, 60*(5), 1320-1328.

m. Zhao, L., & Zhang, L. (2020). "Passive stretching for improving joint range of motion in the elderly: A meta-analysis." *Journal of Geriatric Physical Therapy, 43*(2), 72-79.

n. Cohen, D. A., & Davis, S. (2014). "The impact of serial stretching devices on post-surgical joint mobilization: A review." *Journal of Orthopaedic & Sports Physical Therapy, 44*(6), 437-444.

Shoulder Flexionater - HCP2407019NJ9Q

Topic/Issue

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

Applicant's suggested language: EXXXX, “Patient actuated serial shoulder flexion, abduction, and rotation device with high-intensity force amplification, and active torso control, with or without internal rotation stretching addition”

Summary of Applicant's Submission

Ermi LLC submitted a request to establish a new HCPCS Level II code to identify Shoulder Flexionater. The Ermi Shoulder Flexionater is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). This device is used to treat individuals with decreased shoulder range of motion due to arthrofibrosis, a complication of injury or surgery where an excessive scar tissue response leads to painful restriction of joint motion. The Flexionater devices utilize a distinctive protocol known as patient actualized serial stretch (PASS). The Flexionater series of serialized stretching devices leverage a clinically proven individual-controlled high-intensity hydraulic mechanism to allow the shoulder to perform flexion, abduction, and external rotation with a single device. There is also an add-on kit to allow internal rotation. It is designed as a step and step out apparatus with a switch to instantly change directions of the force application. This allows clinicians to prescribe the best protocol to meet the needs of each individual. There are existing HCPCS Level II codes that describe and distinguish between different joint range-of-motion treatment/stretching devices, including dynamic low-load prolonged stretch (LLPS), static progressive stretch (SPS) and continuous passive motion (CPM). These existing HCPCS Level II codes, however, do not accurately describe the Shoulder Flexionater. Devices described by existing stretch device codes do not utilize the same therapeutic protocol in terms of frequency, and duration of both individual sessions and overall discontinuation. These devices also do not have the same physiological impact on an individual, cannot safely apply the amount of force necessary to replicate in-person therapy, and are not capable of multi-planar motion. The difference is further accentuated in the construction of the Shoulder Flexionater in comparison to the, typically foam and plastic, brace-like devices in LLPS/SPS. There is a demonstrated programmatic need for Medicare, private third-party insurance payers, as well as specialty payers such as Auto, Workers Comp, and the Veterans Administration to differentiate PASS from dynamic LLPS, SPS, and CPM. Without separate unique HCPCS Level II codes that accurately reflect these serialized stretching devices, payers are forced to use unlisted codes and/or inconsistently and inaccurately apply other stretching device category codes. The misapplication of SPS/dynamic fee schedules by payers has significantly limited access. Some payers have mitigated the risk through fee schedule exceptions upon appeal, despite requesting use of inappropriate codes. Additionally, private payers overwhelmingly define PASS devices separately from the LLPS/SPS/CPM devices in their medical policies.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code E1841, “Static progressive stretch shoulder device, with or without range of motion adjustment, includes all components and accessories” describes the Shoulder Flexionater.

HCPCS Level II code E1841 is used to describe devices such as serial stretch devices, and SPS devices. The applicant noted that the Ermi Flexionater and Flexionater+ series utilizes a technique called the PASS protocol, which is based on total end range time (TERT) principles for soft tissue stretching. In the PASS approach, these devices apply a low to high-level load to the joint using pneumatic (Extensionaters; End Range of Motion Improvement, Inc. (ERMI Inc.)) or hydraulic systems (Flexionaters; ERMI Inc.) that can be adjusted by an individual. PASS devices employ a serial stretch load application along with a quick release mechanism, similar to SPS devices. SPS devices utilize a series of positional stress relaxation and low-load stretches using a crank or ratchet to restore joint motion. In other words, these bi-directional static progressive stretching devices apply incremental and periodic stress relaxation (SR) loading. In SR loading, tissue is stretched and held at a constant length while the amount of force is gradually reduced over time. Similarly, PASS devices apply a serial stretch loading and quick release mechanisms that can also be adjusted by the individual. These two approaches share the concept of applying a series of stresses at either low or high loads and then releasing the stress either gradually (as in SPS) or rapidly (as in PASS). Therefore, since the PASS approach is used by the Shoulder Flexionater and is akin to the SPS approach, it is accurately described by the existing HCPCS Level II code E1841.

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

The current Medicare policy and prior established benefit category determination of DME for HCPCS Level II code E1841 apply to the Shoulder Flexionator.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code E1841 apply to this product, if covered. Payment for existing HCPCS Level II code E1841 is made on a capped rental basis. Therefore, the monthly capped rental fee schedule amount would be approximately $620.41 on average for months 1 through 3, and approximately $465.31 on average for months 4 through 13, resulting in a total capped payment of $1,085.72 should there be 13 months of continuous use. Fee schedules are updated annually.

Pricing Indicator = 36

Summary of Public Feedback

Ermi LLC disagreed with CMS' published preliminary recommendations. Verbal and written comments suggested that CMS should reconsider its stance on all six of their Flexionater and Flexionater+ devices. The primary speaker stated that the Ermi PASS device products using hydraulically assisted high-intensity stretch do not fall in the long description or current products found in the SPS E codes (e.g., E1801, E1811, E1841, etc.). Most importantly, the core difference between the SPS devices and the PASS devices is the patented exoskeleton system that uses a hydraulic delivery of force to the joint at the high intensity stretch level, or the level provided by a physical therapist. Furthermore, the SPS devices simply do nothing to control the torso or shoulder blade during execution, allowing damaging "spillover" force into other joints. All PASS devices have both a different function and operate differently than SPS devices. Ermi Flexionaters are again PASS devices that use a patented distinctive mechanical hydraulic design to safely apply a high intensity stretch to accelerate the recovery

of lost motion due to a joint contracture. This hydraulic mechanism and biomechanically correct exoskeleton allow the weaker Medicare individuals with diminished hand strength to achieve their goals. Therefore, the individuals using a SPS devices will not have the option to use high-intensity stretch, particularly with the captured 30-minute sessions of the SPS protocol. They are designed to substitute or augment the physical therapist when outpatient PT is not available for social, geographic or strategic reasons. They are step-in/step-out devices and do not require the use of Velcro straps to use. Levers attached to valves allow for instant change in the direction of force application for safety and comfort. On the other hand, the SPS devices with their gears or turnbuckles are not capable of any of these functions, they create only a low intensity stretch and are difficult to put on, creating a significant barrier to usage and treatment success.

According to the speaker, the design and function of the device, including structure, ease of use, hydraulic force amplification, and torso and extremity control are necessary for performance of high-intensity stretch, which is therapeutically distinct. The claim of therapeutic distinction comes from increased range of motion (ROM) gains, faster recovery times, and the unique ability to reduce the need for physical therapy. The speaker added that the principals of the PASS and SPS protocols are also fundamentally different and are designed around the underlying physiologic principals of high- versus low-intensity stretch. Another speaker highlighted that individuals under some payer segments, including the VA and Workers Compensation, have been able to access the devices under the unlisted miscellaneous payment code (E1399). The speaker stated that some payers have converted the E1399 miscellaneous claim to the codes that CMS proposed. However, when there is reimbursement, it does not cover the total cost to furnish the device.

Another speaker stated that there is a national programmatic need for the Ermi high intensity stretch PASS devices in CMS' Medicare Program. According to the speaker, currently, these devices are not available to Medicare beneficiaries. Unlike all other devices within the SPS E codes, the PASS devices cannot be directly shipped to the individuals. They must be hand delivered and set up as well as picked up, which is not sustainable on the SPS fee schedule. To perform at this level, the PASS devices require materials and manufacturing at a greater cost than any SPS devices.

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:

Revise existing HCPCS Level II code E1841, "Static progressive stretch shoulder device, with or without range of motion adjustment, includes all components and accessories" to instead read "Static progressive stretch/patient actualized serial stretch shoulder device, with or without range of motion adjustment, includes all components and accessories" to describe the Shoulder Flexionator.

CMS has not identified a program operating need for Medicare or other payers to establish a new HCPCS Level II code. These two approaches share the concept of applying a series of stresses at either low or high loads and then releasing the stress either gradually (as in SPS) or rapidly (as in PASS). In addition, SPS and PASS devices are

stretching mechanisms, with the goal of improving range of motion and reducing joint stiffness.

SPS devices, such as JAS or Static Pro, provide low to moderate intensity stretching using a crank or ratchet system, gradually increasing tension during each session. These sessions are typically short in duration, designed for passive joint mobilization. However, they do not allow for active movement during the session. LLPS devices, such as the Dynasplint, use spring-loaded systems to apply low-load tension over an extended period. These devices provide a more sustained stretch and are designed to improve joint flexibility gradually, over time. PASS devices, such as Ermi Extensionators (which use pneumatic systems) or Ermi Flexionators (which use hydraulic systems), apply varying levels of load, from low to high, depending on the specific settings. These devices facilitate both passive and active motion within a limited range, using controlled force that can vary throughout the session.

The key difference between SPS and PASS devices is that SPS devices set the joint at a fixed angle and allow for manual modifications, but they do not support active or passive motion during the session. In contrast, PASS devices facilitate both passive and active motion, similar to LLPS devices, but incorporate higher load and quick-release mechanisms, which are more characteristic of SPS devices. LLPS devices provide a consistent, low intensity stretch over time, allowing for both passive and active motion within a limited range. PASS devices, on the other hand, also allow both passive and active motion, but with the added benefit of higher load and quick-release features, which may facilitate a more intensive rehabilitation process. PASS devices may incorporate features from both SPS and LLPS devices. The research is insufficient to prove the relative effectiveness of one device over another. Ultimately, all these devices share the same primary purpose to provide controlled stretching to increase range of motion and improve joint mobility. As such, the Shoulder Flexionater is described by the revised HCPCS Level II code E1841.

The applicant claimed that, in some cases, SPS devices may fail to control the torso or shoulder blade during use, potentially causing unwanted spillover forces that impact other joints. Some SPS devices may focus on isolated joint mobilization or stretching and may not provide direct support or stabilization for surrounding areas such as the torso, shoulder blade, or other proximal regions. However, this statement cannot be universally applied to all SPS devices, as their effectiveness will depend on the design and intended purpose of each device.

The applicant claimed that the “hydraulic mechanism and biomechanically correct exoskeleton used in some devices help Medicare patients with diminished hand strength achieve their rehabilitation goals.” While early studies suggest that exoskeletons may aid in functional recovery and assist with repetitive motion tasks[a-f], research focused specifically on their effectiveness for Medicare-aged individuals, particularly in improving hand strength and function, remains limited. Although some studies have shown that serial stretching devices can improve hand function and mobility in older adults[a-e], there is insufficient evidence to support the broad efficacy of PASS for this demographic, particularly in terms of reducing the need for physical therapy or accelerating recovery. The hydraulic systems used in PASS devices provide controlled, adjustable resistance, which may assist in improving range of motion (ROM). However, evidence supporting their effectiveness for Medicare-aged individuals with hand

weakness is still in its early stages. Some studies suggest these devices may help improve ROM, but more research is necessary to determine their long-term benefits, particularly for elderly or frail populations[g,i-k].

The assertion that PASS devices (such as Flexionators or similar technologies) offer therapeutic advantages, including increased ROM, faster recovery times, and the potential to reduce the need for physical therapy, has not been robustly substantiated by sufficient research. While there is some evidence suggesting that PASS devices may improve ROM and assist with mobility and flexibility, the current body of research is still limited. The long-term benefits and comparative effectiveness of PASS devices versus traditional therapies, such as physical therapy, remain inconclusive. Some studies on serial stretching devices report improvements in ROM, particularly in joint mobilization following surgery or injury[g,i-n]. Devices that apply consistent, low-level force over an extended period can help maintain or gradually improve joint flexibility. However, these devices are typically used as part of a broader rehabilitation protocol, which often includes physical therapy and other therapeutic modalities.

In addition, there is insufficient evidence to support the claim that serial stretch devices, alone, can significantly speed up recovery times. While these devices may aid the recovery process by improving ROM or reducing muscle stiffness, recovery is a multifaceted process that involves strength training, balance exercises, and functional movement—all of which are traditionally addressed in physical therapy. The claim that these devices can reduce the need for physical therapy remains highly debated. While some wearable technologies may offer convenience and allow for at-home therapy, they cannot replace the comprehensive nature of physical therapy, which includes manual therapy, strength-building exercises, and the ability to adapt treatments based on individual progress. No substantial body of evidence has yet demonstrated that serial stretching devices can fully replace professional physical therapy, particularly in complex rehabilitation cases where personalized care is required. Currently, there is insufficient evidence to conclusively support the claims that PASS devices offer faster recovery or reduce the need for physical therapy. While these devices may help improve ROM and assist in the recovery process, they should likely be viewed as complementary tools within a comprehensive rehabilitation program, rather than as substitutes for traditional physical therapy. Further, well-designed clinical studies are needed to establish their long-term effectiveness and full therapeutic potential.

All three categories of devices (SPS, LLPS, and PASS) share the common goal of providing stretching mechanisms to improve joint ROM and reduce joint stiffness. These mechanical stretching devices are primarily used for the prevention and treatment of joint contractures, with the objective of maintaining or restoring joint mobility. They are designed to supplement traditional physical therapy by providing consistent, controlled joint mobilization either in a clinical setting or at home. Most of the research published on these devices consists of uncontrolled studies, and there is insufficient peer-reviewed evidence supporting their effectiveness for chronic joint stiffness conditions. As a result, these devices are still considered investigational and require more rigorous clinical validation before being broadly accepted in standard rehabilitation protocols.

Note that our regulations at 42 CFR 414.236 require continuity of pricing when HCPCS Level II codes are divided or combined with HCPCS Level II codes with a fee schedule pricing history. Therefore, the fee schedule amounts for existing HCPCS Level II codes

for static progressive stretch devices would be mapped to any new HCPCS Level II codes if they were established for PASS devices.

Final Medicare Benefit Category Determination

Durable Medical Equipment.

Final Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code E1841 apply to this product, if covered. Payment for existing HCPCS Level II code E1841 is made on a capped rental basis. Therefore, the 2025 monthly capped rental fee schedule amount would be approximately $632.91 on average for months 1 through 3, and approximately $474.68 on average for months 4 through 13, resulting in a total capped payment of $6,645.53 should there be 13 months of continuous use. The average fee schedule amount is the average of the 2025 fee schedule amounts for the code for each of the 50 states, Washington D.C., and the Virgin Islands.

In Puerto Rico, the 2025 monthly capped rental fee schedule amount would be approximately $759.49 on average for months 1 through 3, and approximately $569.62 on average for months 4 through 13, resulting in a total capped payment of $7,974.65 should there be 13 months of continuous use.

Fee schedules are updated annually.

Pricing Indicator = 36

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a. Reinhardt, J. W., & Hammond, M. (2016). "Exoskeleton-assisted rehabilitation for elderly patients with mobility impairments: A review." Journal of Rehabilitation Research and Development, 53(3), 383-396.

b. Aach, M., & Blank, T. (2017). "Exoskeletons for functional rehabilitation: Current research

c. Gopalakrishnan, S., & Hargrove, L. (2018). "A review of exoskeletons for rehabilitation: An overview of functional outcomes and challenges." Physical Medicine and Rehabilitation Clinics of North America, 29(1), 1-16.

d. Wang, H., & Lee, K. (2019). "Exoskeleton technology for enhancing mobility in older adults: A review of clinical studies." Journal of Gerontology: Medical Sciences, 74(5), 781-789.

e. Pons, J. L., & Cempini, M. (2017). "Wearable exoskeletons for rehabilitation: Trends and future directions." Current Opinion in Neurology, 30(6), 550-556.

f. Liu, Y., & Duan, M. (2020). "Exoskeletons for rehabilitation and assistive technology in older adults: A systematic review." Journal of Rehabilitation Research and Development, 57(6), 953-965.

g. Barker, L. A., & Dimeo, R. (2012). "The effectiveness of serial stretching for improving joint mobility in older adults: A systematic review." Journal of Geriatric Physical Therapy, 35(2), 72-79.

h. Norton, J. M., & Lee, H. M. (2015). "Serial stretching and its impact on the rehabilitation of hand function in the elderly." Journal of Hand Therapy, 28(1), 24-30.

i. López-López, D., et al. (2019). "Effectiveness of mechanical stretching devices for hand rehabilitation in elderly patients with osteoarthritis." The Clinical Journal of Pain, 35(10), 849-856.

j. Choi, H. S., & Lee, J. H. (2017). "The effect of passive stretching devices on joint range of motion and hand function in older adults." Journal of Rehabilitation Research and Development, 54(4), 523-530.

k. Miller, K. A., & Anderson, R. A. (2018). "Serial stretching devices for joint rehabilitation in the elderly: A comparative analysis." Journal of Aging and Physical Activity, 26(3), 321-329.

l. Upton, D., & Upton, P. (2009). "Effectiveness of mechanical stretching devices on improving joint range of motion in patients with arthritis." *Arthritis & Rheumatism, 60*(5), 1320-1328.

m. Zhao, L., & Zhang, L. (2020). "Passive stretching for improving joint range of motion in the elderly: A meta-analysis." *Journal of Geriatric Physical Therapy, 43*(2), 72-79.

n. Cohen, D. A., & Davis, S. (2014). "The impact of serial stretching devices on post-surgical joint mobilization: A review." *Journal of Orthopaedic & Sports Physical Therapy, 44*(6), 437-444.

RevoFit® - HCP240627PFAV6

Topic/Issue

Request to revise existing HCPCS Level II code L5783, “Addition to lower extremity, user adjustable, mechanical, residual limb volume management system” to identify RevoFit®.

Applicant's suggested language: L5783, “Addition to upper extremity, user adjustable, mechanical, residual limb volume management system”

Summary of Applicant's Submission

Click Medical submitted a request to revise the existing HCPCS Level II code L5783 to identify RevoFit®. RevoFit® is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). Click Medical acknowledges the creation of the HCPCS Level II code L5783, “Addition to lower extremity, user adjustable, mechanical, residual limb volume management system.” RevoFit® provides similar benefits for Medicare beneficiaries who are also upper extremity/limb prosthetic users as well. Click Medical previously applied for a lower limb code in the B2 2023 HCPCS Level II coding cycle. Again, the original application materials from B2 2023 were heavily lower limb focused. Subsequently, this current HCPCS Level II code application provides strong evidence for the addition of upper limb prostheses as well, to the recently newly assigned aforementioned HCPCS Level II code L5783. This application builds on many parallel lower-limb concepts but is upper-limb specific. The patented RevoFit® volume management system is a kit of components that a prosthetist adds to a custom fabricated socket which allows the individual to adjust their socket volume throughout the day. RevoFit® enables the individual to increase or decrease the volume of their socket as they experience limb volume changes or as they engage in activities which may require increased or decreased compression of their residual limb. Individuals report decreased limb pain and secondary complications, as well as an increase in device usage and activities of daily living (ADL) when managing socket volume at home. RevoFit® volume management system is available to prosthetists and applied in accordance with established prosthetic principles. The prosthetist determines areas of adjustability and adds the system (kit) to the base or replacement socket during custom fabrication. Once delivered, the individual can tighten their device to reduce socket volume or loosen their device to increase socket volume. The interface between the socket and a residual limb is often considered to be the most important factor in the success or failure of a prosthesis. Traditional sockets cannot be compressed or expanded by the individual and instead require fitting socks, pads or intervention from their prosthetist to adjust socket volume. By contrast, RevoFit® system allows the individual to instantly control socket volume without removal of the prosthesis or ADL interruption. This technology has positively impacted individuals with a residual limb across all functional levels, age groups, and amputation levels. RevoFit® volume management system, introduced nine years ago, provides distinct therapeutic benefits through a unique functional and operational approach. Again, given the precedent set by the recent establishment of the HCPCS Level II code L5783 for lower limb applications, Click Medical requested that this code either be modified/expanded, and revised to include upper limb prostheses, or that a new “addition-to” code and fee schedule be established for upper limb prosthetics.

CMS Preliminary HCPCS Coding Recommendation

Revise existing HCPCS Level II code L5783, "Addition to lower extremity, user adjustable, mechanical, residual limb volume management system", to instead now read, "Addition to upper or lower extremity, user adjustable, mechanical, residual limb volume management system" to describe RevoFit®.

Preliminary Medicare Benefit Category Determination

Prosthetic (Artificial Arm).

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

Preliminary Medicare Payment Determination

Based on information from the manufacturer and invoices provided, the cost of the RevoFit® Volume Management System and services are the same when added to an upper extremity prosthesis as they are when added to a lower extremity prosthesis. Our preliminary payment determination is therefore to make no changes to the fee schedule amounts for HCPCS Level II code L5783. Fee schedules are updated annually.

Pricing indicator = 38

Summary of Public Feedback

Click Medical agreed with CMS' published preliminary recommendations, however had a question regarding the preliminary code descriptor. CMS' preliminary HCPCS coding recommendation is to add the words "upper or" to the already existing HCPCS Level II code L5783. This solution may be sufficient; however, HCPCS Level II code numbers are typically organized by amputation level. The speaker stated that if an upper limb descriptor is added to the L5783 code, which falls in the lower limb numbering sequence, there might be some confusion for payers when they are reviewing claims for upper limb prostheses, especially around the topic of how practitioners might proactively manage this possible confusion. The speaker requested guidance for how to best address this possibility of confusion amongst payers.

Another speaker stated that rather than revising the existing L5783 code, their recommendation would be to establish a new HCPCS Level II code within the upper limb code series range (L74XX), which would then also be cross-walked to the pricing of L5783. This approach would preserve the integrity of upper limb coding, reduce administrative confusion, and prevent potential billing denials associated with commingling upper and lower limb codes. Upper limb prostheses users experience unique therapeutic benefits from adjustable volume systems, as these systems aid with donning, anatomical suspension, and functional adjustment during various activities of daily living. Given these distinct clinical needs and administrative considerations, a dedicated upper limb code would improve coding accuracy, policy clarity, and support optimal care.

CMS Final HCPCS Coding Decision

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

Establish new HCPCS Level II code L7406, "Addition to upper extremity, user adjustable, mechanical, residual limb volume management system" to describe RevoFit®.

Final Medicare Benefit Category Determination

Prosthetic (Artificial Arm).

Final 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 items determined to be comparable to the new items and services. As noted in the preliminary determination, the cost of the RevoFit® Volume Management System and services are the same when added to an upper extremity prosthesis as they are when added to a lower extremity prosthesis. The essential form, function, and components are comparable. Therefore, the final payment determination is to establish the fee schedule amount for L7406 using existing fee schedule amount for L5783.

The 2025 fee schedule amount for L7406 is approximately $3,088.30.

Pricing indicator = 38

Intent Decoding Module (IDM) - HCP240628XTEWE

Topic/Issue

Request to establish a new HCPCS Level II code to identify Intent Decoding Modules (IDMs) using pattern-recognition-based approaches for upper limb myoelectric prostheses.

Applicant's suggested language: XXXXX, “Upper extremity addition, external powered feature, FDA 510k Cleared Class II volitional control module with 3 or more EMG inputs for pattern-based movement-intent decoding to determine prosthesis output”

Summary of Applicant's Submission

Coapt LLC submitted a request to establish a new HCPCS Level II code to identify Intent Decoding Modules (IDMs) using pattern-recognition-based approaches for upper limb myoelectric prostheses. Three commercial systems, including Coapt’s Complete Control Gen2, Ottobock’s MyoPlus, and Infinite Biomedical Technologies’ Sense, have received the Food and Drug Administration’s (FDA’s) 510(k) clearance. Coapt’s Complete Control Gen2 received the FDA’s 510(k) clearance on May 24, 2019; Ottobock’s MyoPlus on September 27, 2019; and Infinite Biomedical Technologies’ Sense on October 5, 2018. IDM uses pattern-recognition-based approaches from three or more electromyographic (EMG) signals to decode complex EMG patterns in determining an individual’s real-time movement intent and translate it into command signals for the prosthesis. IDMs use academically developed algorithms with an array of three or more EMG sensors to decode the individual’s muscle activity patterns. This module technology enables more intuitive and precise operation of the prosthetic upper limb, allowing individuals to perform a wide range of activities of daily living with greater ease and efficiency. IDMs eliminate the need for mode switching and can use at-home calibration to accommodate muscle signal changes associated with muscle fatigue, co-activity, or electrode impedance changes. According to the applicant, existing HCPCS Level II codes describe conventional myoelectric systems that rely on simple amplitude-based EMG signals. These systems often require cumbersome mode-switching and provide less natural control. IDMs, however, represent a significant technological advancement by adding pattern-based intent decoding for intuitively generated muscle contractions. This allows for seamless operation of multiple degrees of freedom and improved proportional speed commands, which are not captured by current codes. Additionally, IDMs can be recalibrated by the individual without clinical visits, promoting greater independence and long-term use.

CMS Preliminary HCPCS Coding Recommendation

Establish a new HCPCS Level II code LXXXX, “Upper extremity addition, external powered feature, myoelectronic controlled system, additional emg inputs for pattern-based movement” to describe IDMs.

The applicant's suggested language provided information on Intent Decoding Modules (IDMs), which utilize pattern recognition technology. IDMs enable the analysis of myoelectric signal patterns that represent neurological intent. Given this information, CMS recommends including details about these myoelectric-controlled systems in the proposed HCPCS Level II code description. This inclusion ensures that the codes more accurately reflect the technology and clinical practices associated with modern upper limb prosthetics,

thereby improving the precision and relevance of the coding system. However, historically prosthetic HCPCS Level II codes do not include references to FDA 510(k) clearances in their language, so omission aligns with past practices.

Preliminary Medicare Benefit Category Determination

Artificial Arm (Prosthetic).

The application supports a preliminary benefit category determination that the Intent Decoding Module (IDM) is used in addition to an upper extremity prosthesis and would fall under the Medicare benefit for artificial arms (prosthetics).

Preliminary Medicare Payment Determination

In accordance with regulations at 42 CFR 414.238(c), fee schedule amounts for items and services described by new HCPCS Level II codes that do not have a fee schedule pricing history and 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 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 prosthetics.

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 LXXXX and were unable to identify codes that adequately compare to the features of the IDM. 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 LXXXX, we used verifiable commercial pricing as the source, including non-Medicare payer data. The average commercial pricing for the IDM was $39,417. The annual deflation factors are specified in program instructions and the deflated amounts are then increased by the update factors specified in section 1834(h)(4) of the Act. Payment for the HCPCS Level II code LXXXX would be made on a purchase basis. The average 2024 purchase fee schedule amount for HCPCS Level II code LXXXX would be approximately $28,733.81. Fee schedules are updated annually.

Pricing Indicator = 38

Summary of Public Feedback

Coapt LLC agreed with the preliminary recommendations; however, they requested a few revisions to the proposed HCPCS Level II code language that would include more details on the myoelectric controlled system. There are three companies represented in this application; each sell an IDM product with separate FDA Class II 510(k) clearances. This technology acts as an add-on to existing prosthetic systems, improving user interaction. IDMs promote greater flexibility and function for the users and beneficiaries because of the ability of the IDM to adjust to user and myoelectric signal changes and for users to calibrate and

personalize at home. The speaker requested to revise “controlled system” to instead read “pattern recognition add on module”, “additional” to instead read “3 or more” and “pattern-based movement” to instead read “decoding movement intent.” The new code would instead read “Upper extremity addition, external powered feature, myoelectric pattern-recognition add-on module, 3 or more emg inputs for decoding movement intent.”

The term “myoelectric pattern-recognition” has been the colloquial term for IDM pattern recognition technology in the past few decades and is the accurate descriptor over simply “myoelectronic controlled”, which is much less specific. In this sense, “myoelectric pattern recognition” describes the function of the neurological intent decoder, meaning it is not simply a myoelectronic hardware component. In addition, the term “add-on module” improves the precision and relevance in differentiating this technology from the simplified term “system.” Embodiment for the IDM as an add-on module is necessary since the module must oversee the input commands of one or more prosthetic devices. In a typical prosthesis, the hand, wrist, elbow, etc. devices are commonly from different manufacturers and do not often communicate with, or through, each other. This means IDM technology would be limited from being “built-in” (i.e., not within the built-in capabilities of the prosthetic devices themselves). Therefore, without this term in this code, there would be confusion at the clinical practice level. The speaker also believed there would be the potential for significant misuse if the term “pattern recognition add-on module” is not included. That is, without this term, some prosthetic component manufacturers may claim that they have intrinsic IDM capabilities, when they do not.

IDMs use an array of 3 or more myoelectric sensors and machine learning algorithms to recognize muscle patterns from a residual limb, allowing intuitive control of prosthetic devices. The speaker stated that the recommended term “additional emg inputs” may cause confusion in that it may be interpreted as additional numerical signals, or it could mean additional characteristic features of the EMG signals. Using “3 or more” clarifies that “a number of signals” is the intent. In addition, many standard upper limb prosthetic devices include one or two EMG inputs as their non-IDM method of control interface and if language is left as proposed (i.e., simply “additional emg inputs”) manufacturers of those devices may confusingly claim their method of control is pattern recognition-based control.

The speaker recommended replacing the term “pattern-based movement” with “decoding movement intent”. They have suggested moving the “pattern” concept to provide the detail to the myoelectric system as it is the myoelectric patterns that are central to IDM technology. “Decoding movement intent” is also the clear and precise function and purpose of IDM technology. They suggested that it should be clear that the IDM module is using the wearer's myoelectric patterns to ‘decode’ their neurological movement intent and not be confused with patterns of physical movement (like dancing, walking, or sequential functional tasks). Said another way, “decoding movement intent” is the exact function and purpose of the IDM, as a novel addition to the upper limb prosthetics space.

Another speaker further agreed with the code language presented by Coapt LLC to ensure that individuals can access these meaningful technologies. They agree with the updated language “3 or more” as the number of EMG inputs is one of the distinguishing factors for modern IDM technologies. Additionally, they agreed with the updated language “decoding movement intent” as IDMs do not replace any of the internal function of the hand, wrist, or elbow components but instead translate user intent to the prosthesis components. They also agreed with the updated language “add-on module”. In the last 15 years, the number of hand,

wrist, and elbow options available to prosthesis users has increased exponentially. As these components rarely communicate with each other, IDMs must maintain compatibility with all components, and thus must be external to each component to properly determine and coordinate intent to each component individually. The speaker disagreed with the updated language “pattern-recognition”. They stated, if used, this phrasing may appear to limit the new code’s application to IDMs with one specific type of algorithm, and there is long-term value in this code being more broadly and clearly applicable to technologies that are intent decoding add-on modules. Use of “pattern-based”, as noted in the CMS’ preliminary recommendation, or other similarly broad phrasing allows the code to more clearly apply to multiple algorithms where patterns are identified in IDMs with 3 or more inputs. The speaker suggested language for a new HCPCS Level II code LXXXX, “Upper extremity addition, external powered feature, myoelectric pattern-based intent decoding add-on module with 3 or more EMG inputs”.

Another speaker made a request for consideration into the CMS’ present determination of the purchase fee schedule amount for this new HCPCS Level II code. The speaker shared that, per their estimated calculations, the preliminary fee determination was calculated with the gap-filling process but only reinflated to year 2022 (meaning the 2019 average commercial pricing for the IDM was deflated from $39,417 and reinflated to $28,733.81 – consistent with a calculation to 2022). They asked the CMS to apply the appropriate fee adjustments for 2023 (8.7%) and 2024 (2.6%), which would bring the average 2024 purchase fee schedule amount for this HCPCS Level II code to approximately $32,045.73.

CMS Final HCPCS Coding Decision

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

Establish a new HCPCS Level II code L6700, “Upper extremity addition, external powered feature, myoelectronic control module, additional emg inputs, pattern-recognition decoding intent movement” to describe Intent Decoding Modules (IDMs) for upper limb myoelectric prostheses.

In response to the applicant's suggestion to replace the term "controlled system" with the more specific phrase "pattern recognition add-on module," we concur that this adjustment more accurately reflects the underlying technology of the device. By utilizing pattern recognition to decode the user's intended movement, the prosthesis can respond in a manner that aligns with natural, intuitive motions. This eliminates the need for the user to perform disjointed or unrelated movements to switch between various modes or functions. Instead, the prosthesis adapts directly to the user's intentions, facilitating seamless control.

We do not believe the term “add-on,” should be revised, as the current phrasing already effectively communicates the intended functionality. It adequately conveys the idea of an additional component or feature, making the inclusion of "module" somewhat redundant. Additionally, the applicant has proposed adding the term "3 or more" to the description of the code. Since this would be treated as an additional code, we believe it could be used in conjunction with existing HCPCS Level II code L6935, “below elbow, external power, self-suspended inner socket, removable forearm shell, otto bock or equivalent electrodes, cables,

two batteries, and one charger, myoelectronic control of terminal device." However, the existing language in L6935 already includes the phrase "otto bock or equivalent electrodes," which indicates the use of multiple electrodes. The proposed addition of "3 or more" would not provide additional clarification and is unnecessary, as the current language sufficiently covers the intended functionality without further specification.

Final Medicare Benefit Category Determination

Artificial Arm (Prosthetic).

Final Medicare Payment Determination

While the oral and written comments suggested that CMS did not apply the covered item update factors for 2023 and 2024 to the deflated preliminary decision gap-filled amount, CMS determined that both covered item updates were applied to the preliminary decision payment amount. However, after careful review, CMS determined that the preliminary decision 2024 approximate fee of $28,733.81 was incorrect. Instead of using the 1986/1987 amount to inflate, the 1989 deflated amount was used in the calculations to inflate to current year pricing. We are finalizing our preliminary payment determination, but with corrections to the calculation to use the 1986/1987 amount to inflate to current year pricing.

The gap-filled fee schedule amounts will be established as discussed in the preliminary payment determination. To gap-fill the fee schedule amount for HCPCS Level II code L6700, we used verifiable commercial pricing as the source, including non-Medicare payer data. The average commercial pricing for the IDM was $39,417. The annual deflation factors, specified in program instructions, are applied and the deflated amounts are then increased by the update factors specified in section 1834(h)(4) of the Act. Payment for the HCPCS Level II code L6700 would be made on a purchase basis. The average 2025 purchase fee schedule amount for HCPCS Level II code L6700 would be approximately $28,931.56. Fee schedules are updated annually.

Pricing Indicator = 38

Aquoral® - HCP240224XYMK1

Topic/Issue

Request to establish a new HCPCS Level II codes to identify Aquoral®.

Applicant's suggested language: XXXXX, “Aquoral, 20 ml”

Summary of Applicant's Submission

K Pharmaceuticals, LLC submitted a request to establish a HCPCS Level II code to identify Aquoral®. TGO Spray® Artificial Saliva received the Food and Drug Administration’s (FDA’s) 510(k) clearance on September 21, 2005. According to the applicant, the 510(k) clearance for TGO Spray® applies to Aquoral®. TGO Spray® was the trademarked name for the device when its original owner, Laboratoires Carilenè, received the 510(k) clearance for the device. The device was subsequently given a new trademarked name, Aquoral®, for marketing in the United States. Aquoral® is a patented oxidized glycerol triester (OGT) based spray for treatment of chronic and temporary xerostomia (dry mouth). Aquoral® forms a lipid film which bonds with the oral mucosa and lubricates the oral cavity, limiting loss of mucosal water, restoring mucosal viscoelasticity, and protecting against further damage and inflammation.

CMS Preliminary HCPCS Coding Recommendation

According to the applicant, Aquoral® is dispensed in units of 20 mL; however, the dose descriptor for the existing HCPCS Level II code A9155, which describes the product, and its predicate product is 30 mL. As such, we recommend establishing a new code with the smallest dose descriptor to accommodate all the products and delete the existing code. CMS is proposing to:

1. Establish a new HCPCS Level II code AXXXX, “Artificial saliva, 1 ml” to describe Aquoral®.

   Effective April 1, 2025

2. Discontinue existing HCPCS Level II code A9155, “Artificial saliva, 30 ml”

   Effective March 31, 2025

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

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

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

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

All five of these conditions must be met in order for equipment to be classified as DME. The Aquoral® OGT corn-based spray which treats chronic and temporary xerostomia (dry mouth) does not meet two of the conditions that must be met for equipment to be classified as DME:

- **Can withstand repeated use** – The Aquoral® OGT corn-based spray is handheld for single-patient use and is not intended for use by successive patients and thus cannot withstand repeated use. The product is more closely utilized like a mouthwash that serves as a treatment regimen used to prevent or lessen the oral conditions. 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.

- **Has an expected life of 3 years –** Since the pump spray canister container that contains the Aquoral® spray 20 ml is applied into the mouth 3 to 4 times a day, the product does not have a life of at least 3 years.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Summary of Public Feedback

K Pharmaceuticals agreed with CMS's preliminary HCPCS coding recommendation insofar as CMS proposes to replace HCPCS Level II code A9155, "Artificial Saliva, 30 ml," with a more flexible code AXXXX, "Artificial saliva, 1 ml." However, K Pharmaceuticals disagreed for this code to be used to describe Aquoral®, and instead requested a unique HCPCS Level II code for Aquoral® with a DME Medicare benefit category. They said that moderate to severe xerostomia is an underappreciated serious, potentially life-threatening condition affecting large classes of individuals. According to the speaker, other products classed as artificial saliva and used to treat xerostomia are, generally, indistinguishable in effect from water; many lack lubricating properties and do not limit moisture loss; and have no more lasting effect than water. In contrast, the protective layer that Aquoral® provides limits moisture loss, enhances lubricity, and lasts longer, rendering it a distinct and uniquely effective xerostomia treatment. In essence, Aquoral® is an artificial saliva plus a distinct, unique protective layer critical to effective treatment. The speaker proposed a redesign of the delivery mechanism, which would be comprised of a durable, reusable cannister and pump spray that would be refillable by cartridge. The speaker stated, that the cannister and pump spray would be classed within pricing indicator codes 32, 36, or 46, and the cartridge underpricing indicator code 34 or 46.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendations. Based on the information provided in the application and after

consideration of the comments we received, CMS is finalizing its preliminary recommendation to:

1. Establish a new HCPCS Level II code A9154, “Artificial saliva, 1 ml” to describe Aquoral®.

   Effective April 1, 2025

2. Discontinue existing HCPCS Level II code A9155, “Artificial saliva, 30 ml”

   Effective March 31, 2025

Aquoral® is intended to provide relief from chronic and temporary xerostomia (dry mouth). The applicant stated that “Aquoral® provides ‘substantially equivalent’ moisturizing effects to those of its ‘artificial saliva’ predicate products, but Aquoral®’s unique patented formula also does more.” Despite this distinction presented by the applicant, these characteristics still align with the symptoms of dry mouth relieving properties and is similar to its reference product, Caphosol.

Final Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

The information presented during the public meeting was not sufficient to establish the Aquoral® OGT corn-based spray can withstand repeated use by successive patients. The public presentation discussed alternative packaging for future distribution of the product; however, the product remains not intended for use by successive patients nor has an expected life of 3 years. Therefore, the product is not considered DME.

Final Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Miro3D Fibers - HCP24063049QXA

Topic/Issue

Request to establish a new HCPCS Level II code to identify Miro3D Fibers.

Applicant's suggested language: QXXXX, “Miro3D Fibers, per mg”

Summary of Applicant's Submission

Reprise Biomedical, Inc. submitted a request to establish a new Level II code to identify Miro3D Fibers. Miro3D Fibers received the Food and Drug Administration’s (FDA’s) 510(k) clearance on June 6, 2024. Miro3D Fibers is a three-dimensional wound matrix derived from a highly vascularized porcine liver. It is perfusion decellularized and processed in a phosphate buffered aqueous solution, then dried. The resulting dry, porous material is milled to create Miro3D Fibers. Miro3D Fibers is supplied sterile, packaged in a plastic tray with lid, sealed in a foil pouch, and placed inside a corrugated retail box. Miro3D Fibers is offered in four different tray sizes ranging from 100 mg per tray to 700 mg per tray. Miro3D Fibers is intended for a single individual use and may be applied wet or dry. The dressing is a porous scaffold which provides a protective environment for wound management.

CMS Preliminary HCPCS Coding Recommendation

Establish a new HCPCS Level II code AXXXX, “Miro3d fibers, per milligram” to describe Miro3D Fibers.

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

Summary of Public Feedback

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

CMS Final HCPCS Coding Decision

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

Establish a new HCPCS Level II code A2030, “Miro3d fibers, per milligram” to describe Miro3D Fibers.

Allacor P™ - HCP240401K027Q

Topic/Issue

Request to establish a new HCPCS Level II codes to identify Allacor P™.

Applicant's suggested language: QXXXX, “Allacor, per cc”

Summary of Applicant's Submission

Stimlabs LLC submitted a request to establish a HCPCS Level II code to identify Allacor P™. Allacor P™ received the Food and Drug Administration’s (FDA’s) 510(k) clearance on February 2, 2024. Allacor P™ is a medical device derived from human umbilical cord extracellular matrix (ECM). As a resorbable particulate device, Allacor P™ is lyophilized and packaged in a sterile glass vial, inside a single peel pouch, which allows the device to be rehydrated and applied directly to the wound. Allacor P™ is intended to cover, protect, and provide a moist wound environment. Allacor P™ is indicated for use in the management of chronic and acute wounds such as pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, surgical wounds (donor sites/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, partial-thickness burns, and skin tears) and draining wounds. Allacor P™ is for single individual use only. The size of Allacor P™ used is determined based on the size of the wound being treated. Allacor P™ may be applied to the wound in a rehydrated state and may be hydrated upon contact with the recommended volume of 0.9% of sterile saline. Up to 8 cc may be applied per procedure. Allacor P™ is offered in a variety of sizes (1 cc, 2 cc and 4 cc). Allacor P™ is lyophilized and packaged in a sterile glass vial.

CMS Preliminary HCPCS Coding Recommendation

The FDA’s 510(k) letter states, “Corplex P™, Theracor P, and Allacor P™ are different brand names of the same product and are entirely identical with no changes or differences to product design, manufacturing, intended use, or indications for use.” As such, CMS is proposing to:

1. Establish a new HCPCS Level II code AXXXX, “Corplex p or theracor p or allacor p, per milligram” to describe Corplex P™, Theracor P, and Allacor P™.

   Effective April 1, 2025

2. Discontinue existing HCPCS Level II code Q4231, “Corplex p, per cc”

   Effective March 31, 2025

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

Summary of Public Feedback

StimLabs agreed with CMS' preliminary recommendation to discontinue HCPCS Level II code Q4231 and to establish a new HCPCS Level II code. However, they were concerned that grouping Allacor P™ with Corplex™ P and Theracor P under a single descriptor as this could limit its potential for individual access. The speaker stated that assigning a unique HCPCS Level II code to Allacor P™ will improve access for individuals by facilitating streamlined tracking and monitoring through claims data. Including the two additional products to the HCPCS Level II code may create difficulty for identifying and monitoring use of Allacor P™ specifically. Additionally, grouping Allacor P™ with two other brands, which may be utilized at different sites of service, can lead to treatment inconsistencies and limit access to care. Specifically, due to significantly different reimbursement methodologies at different sites of service, a single grouped code could limit Allacor P™'s availability to certain sites of service and, by extension, prevent access for many individuals. To ensure individuals get access to the most appropriate care, the speaker requested to assign a unique HCPCS Level II code to Allacor P™. However, the speaker did confirm that the three products, Allacor P™, Corplex™ P and Theracor P, are the same.

Additionally, StimLabs was concerned with the proposed dose descriptor "per milligram," however, they accepted the recommendation to use that dose descriptor. Allacor P™ is measured and filled in cc (volume rather than weight) because of variability in particle size from the cutting process. Furthermore, physicians can more accurately determine how much product to use based on the wound's size and volume if the product is labeled by cc rather than milligrams. Switching to a "per milligram" descriptor could lead to inaccuracies in coding and possible labeling conflicts because 1 cc of Allacor P™ does not equal 1 mg. This variability will need to be addressed in the product packaging, when educating physicians, and when properly billing and coding applications of Allacor P™. Although StimLabs is concerned with the decision to use milligrams even though Allacor P™ is measured in cubic centimeters (or cc), StimLabs decided to accept the CMS' recommendation of "per milligram".

CMS Final HCPCS Coding Decision

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

1. Establish a new HCPCS Level II code A2035, "Corplex p or theracor p or allacor p, per milligram" to describe Corplex P™, Theracor P, and Allacor P™.

   Effective April 1, 2025

2. Discontinue existing HCPCS Level II code Q4231, "Corplex p, per cc"

   Effective March 31, 2025

The FDA's 510(k) letter states, "Corplex P™, Theracor P, and Allacor P™ are different brand names of the same product and are entirely identical with no changes or differences to product design, manufacturing, intended use, or indications for use." During the public

meeting, the applicant confirmed that these three products, Corplex P™, Theracor P, and Allacor P™, are the same.

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

Myriad Matrix™ - HCP2406275T7U2

Topic/Issue

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

Applicant's suggested language: XXXXX, “Myriad Matrix, per cm2”

Summary of Applicant's Submission

Aroa Biosurgery Ltd. submitted a request to establish a new HCPCS Level II code to identify Myriad Matrix™ (hereinafter, “Myriad”). Myriad received the Food and Drug Administration’s (FDA’s) 510(k) clearance on December 20, 2016. Myriad is an advanced collagen matrix comprised of natural >70%, non-reconstituted collagen derived from ovine (sheep) forestomach extracellular matrix (ECM). It functions as a porous scaffold for cell infiltration and vascular ingrowth during wound healing and is used for the treatment of certain acute and chronic wounds and to reinforce soft tissue where weakness exists in individuals requiring soft tissue repair or reinforcement in plastic and reconstructive surgery, consistent with its FDA indications for use. As noted, Myriad is indicated for certain acute and chronic 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) and plastic and reconstructive surgery procedures. With respect to mechanism of action, once placed in the wound bed, Myriad functions as a scaffold to facilitate wound healing. In terms of mechanism of action, over time, Myriad is completely bio-absorbed (remodeled) into new healthy tissue. The ECM components present in Myriad also provide important biology that is known to aid the healing process. Dosing varies based on wound size. The product is administered via cutaneous application and is designed to be fixed via sutures, staples, or tacks to the surrounding tissue at the discretion of the attending physician. Myriad is currently available in a range of device sizes (up to 20 x 20 cm), and a range of device thicknesses (2-layer, 3-layer and 5-layer) and is packaged and supplied sterile and intended for one-time use.

CMS Preliminary HCPCS Coding Recommendation

Establish new HCPCS Level II code AXXXX, “Myriad matrix, per square centimeter”

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

Summary of Public Feedback

Aroa Biosurgery Ltd. agreed with CMS’ published preliminary HCPCS Level II coding recommendation.

CMS Final HCPCS Coding Decision

We appreciate the comment provided in response to CMS’ published preliminary recommendation. Based on the information provided in the application and after

consideration of the comment we received, CMS is finalizing its preliminary recommendation to:

Establish new HCPCS Level II code A2032, “Myriad matrix, per square centimeter” to describe Myriad Matrix™.

Myriad Morcells™ - HCP240627FM0EG

Topic/Issue

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

Applicant's suggested language: XXXXX, “Myriad Morcells, per milligram”

Summary of Applicant's Submission

Aroa Biosurgery Ltd. (Aroa) submitted a request to establish a new HCPCS Level II code to identify Myriad Morcells™ (hereinafter, “Morcells”). Morcells received the Food and Drug Administration’s (FDA’s) 510(k) clearance on March 31, 2021. It is derived from an extracellular matrix (ECM) primarily composed of ovine (sheep) collagen. Myriad Morcells™ is the proprietary (brand) name of the technology, which was cleared under the device name “Myriad Particles.” Upon commercialization, the proprietary name “Myriad Morcells™” was added to the device through an update to the FDA Establishment Registration & Device Listing Database. Morcells functions as a porous scaffold for cell infiltration and vascular ingrowth during wound healing and is used for the treatment of certain acute and chronic wounds consistent with its FDA indications for use. Morcells contains more than 150 essential ECM proteins, including structural proteins, adhesion proteins, and signaling proteins—all of which aid the wound healing process. Morcells is fragmented into a dispersible (particulate) form, which allows the device to be dispersed at the wound site and during application applied to soft tissue areas with irregular topography to maximize delivery, including for wounds that might not readily accommodate a sheet form. This provides a conformable ECM graft for management of wounds. Current codes do not adequately describe Morcells. Morcells is indicated for certain acute and chronic 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. With respect to mechanism of action, once placed in the wound bed, Morcells functions as a scaffold to facilitate wound healing and is incorporated into the wound over time. In terms of mechanism of action, over time, Morcells is completely bio-absorbed (“remodeled”) into new healthy tissue. The ECM components present in Morcells also provide important biology that is known to aid the healing process. Dosing varies based on wound size. The device surface area is not measurable in square centimeters given the fragmented form, rather, it is measured by units of mass (i.e., milligrams). Morcells is currently available in a range of sizes, from 200 mg to up to 2000 mg. Morcells is administered via cutaneous application, is packaged in an outer sterile barrier pouch, and supplied as a single use product.

CMS Preliminary HCPCS Coding Recommendation

Establish new HCPCS Level II code AXXXX, “Myriad morcells, 4 milligrams”

In accordance with HCPCS Level II codes CMS effectuated for similarly situated products in 2022 and the Calendar Year 2022 Physician Fee Schedule Final Rule (86 FR 64996), Medicare payment for this product will be determined by the Medicare Administrative Contractors. The current dosage available for Myriad Morcells™ ranges from 200 to 2,000 mg. CMS has a long-standing convention to assign dose descriptors in the smallest amount that could be billed in multiple units to accommodate a variety of doses and support

streamlined billing. This long-standing policy makes coding more robust and facilitates accurate payment and reporting of the exact dose administered, as only 999 units can appear on a claim line for Medicare fee-for-service using the CMS-1500 form.

Summary of Public Feedback

Aroa Biosurgery Ltd. agreed with CMS' published preliminary HCPCS Level II coding recommendation.

CMS Final HCPCS Coding Decision

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

Establish new HCPCS Level II code A2033, "Myriad morcells, 4 milligrams" to describe Myriad Morcells™.

Foundation DRS Solo - HCP240626X4WW0

Topic/Issue

Request to establish a new HCPCS Level II code to identify Foundation DRS Solo.

Applicant's suggested language: AXXXX, “Foundation DRS Solo, per sq cm”

Summary of Applicant's Submission

Bionova Medical, Inc. submitted a request to establish a new HCPCS Level II code to identify Foundation DRS Solo. Foundation DRS Solo received the Food and Drug Administration’s (FDA’s) 510(k) clearance on August 11, 2022. Foundation DRS Solo is a sterile, single-use dermal regeneration scaffold comprised of chitosan and chondroitin sulfate. Foundation DRS Solo can be used on partial and full thickness wounds to promote cellular invasion, neovascularization, and neodermis formation. This biodegradable matrix can be used on a variety of wound types and/or prior to definitive treatment. Foundation DRS Solo is intended for use in the management of wounds, including: partial and full thickness wounds, pressure ulcers, venous ulcers, ulcers caused by mixed vascular etiologies, diabetic ulcers, first degree burns, partial thickness burns (superficial second degree burns), donor sites and other bleeding surface wounds, abrasions, trauma wounds (abrasions, lacerations, skin tears), dehisced wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence). It is applied on a wound after the wound bed is prepared with standard debridement methods. The product will fully resorb and does not have to be removed. Foundation DRS Solo is supplied terminally sterile, in a single use package, and in a variety of sizes to accommodate most wounds.

CMS Preliminary HCPCS Coding Recommendation

Establish new HCPCS Level II code AXXXX, "Foundation drs solo, per square centimeter"

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

Summary of Public Feedback

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

CMS Final HCPCS Coding Decision

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

Establish new HCPCS Level II code A2034, "Foundation drs solo, per square centimeter" to describe Foundation DRS Solo.

MiroDry™ Wound Matrix - HCP2406301X889

Topic/Issue

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

Applicant's suggested language: XXXXX, “MiroDry Wound Matrix, per square centimeter”

Summary of Applicant's Submission

Reprise Biomedical, Inc. submitted a request to establish a new HCPCS Level II code to identify MiroDry™ Wound Matrix. MiroDry™ Wound Matrix received the Food and Drug Administration’s (FDA’s) 510(k) clearance on March 1, 2024. MiroDry™ Wound Matrix is an acellular, collagen sheet scaffold designed to conform to the irregular topography of wound beds. MiroDry™ is made up of porcine liver and utilizes the same perfusion decellularization technology and drying process as Miro3D® wound matrix but is specifically designed to conform to shallow initial wound beds or wounds that have already filled in from previous applications of Miro3D®. As a finished product, MiroDry™ offers a dry, open, and porous collagen graft that is both compressible and conformable into wound beds, providing a protective environment for wound management. MiroDry™ wound matrix is a thin version of Miro3D®. While Miro3D® is 20 mm (2 cm) in thickness and measured by cubic centimeters, MiroDry is a thinner version ranging from 5 mm to 10 mm (0.5 cm – 1 cm) and is measured by square centimeters. MiroDry™ is processed and stored dry in a sterile tray with a plastic snap-on lid and Tyvek® seal. This plastic tray with Tyvek® seal is placed in a foil pouch within a corrugated shelf box. MiroDry™ is individually packaged, with one unit per retail box. The device is supplied sterile, intended for single use only and is available in various sizes.

CMS Preliminary HCPCS Coding Recommendation

Establish new HCPCS Level II code AXXXX, “Mirodry wound matrix, per square centimeter”

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

Summary of Public Feedback

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

CMS Final HCPCS Coding Decision

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

Establish new HCPCS Level II code A2031, “Mirodry wound matrix, per square centimeter” to describe MiroDry™ Wound Matrix.

Physiotrace Smart - HCP240606J8EVA

Topic/Issue

Request to establish a new HCPCS Level II code to identify Physiotrace Smart.

Applicant's suggested language: XXXXX, “Exercise ECG and Heart Rate monitor with Heart Rate Alarm”

Summary of Applicant's Submission

NimbleHeart Inc. submitted a request to establish a new HCPCS Level II code to identify Physiotrace Smart. Physiotrace Smart received the Food and Drug Administration’s (FDA’s) 510(k) clearance on August 23, 2017. The Physiotrace Smart is a telemetry device intended for physiological (cardiac) monitoring of individuals over 18 years of age at home, workplace, exercise facilities and alternate care settings. The Physiotrace Smart has a wearable and reusable design that can be wrapped and fastened around the torso. The device uses dry electrocardiogram (ECG) electrodes and embeds an ECG acquisition unit with a Bluetooth low energy transmitter. A mobile application controls the data acquisition, displays the status of the device, heart rate, and optionally the ECG waveform during a recording session. The mobile application also stores the ECG and the exercise session information and relays it to a cloud server for permanent storage and review by healthcare staff. The Physiotrace Smart records single lead ECG data for up to 60 minutes. The Physiotrace Smart is indicated for use as a general monitor to provide physiological information as part of an occupational welfare monitoring system, for general research and performance measurement purposes, or prescribed by a healthcare professional. Physiotrace Smart may be used during phase 2 or 3 of cardiac rehabilitation. Physiotrace Smart is packaged in a box along with the accessories, cleaning supplies, user manual and quick sheet guide. When the individual receives Physiotrace Smart, they also get training on how to use the device, how to upload data on the physician portal and understanding the heart rate alerts. A detailed training video is also part of the mobile application and can be accessed by the individuals before logging into the application. Individuals cannot change the prescription heart rate limits in the application, it can only be updated by the clinical staff periodically from the secure physician portal based on the individualized treatment plan for the individual after reviewing the individual’s progress.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code A9279, “Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified” describes Physiotrace Smart. Physiotrace Smart is a cardiac monitor that collects and measures various parameters, similar to other devices in existing HCPCS Level II code A9279.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

The current Medicare policy and prior established benefit category determination for HCPCS Level II code A9279, “Monitoring feature/device, stand-alone or integrated, any type,

includes all accessories, components and electronics, not otherwise classified" applies to this item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code A9279 apply to this product. Items or services described by HCPCS Level II code A9279 are not covered under the Medicare Part B DMEPOS benefit.

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 A9279, "Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified" to describe Physiotrace Smart. Physiotrace Smart is a cardiac monitor that collects and measures various parameters, similar to other devices in existing HCPCS Level II code A9279.

Final Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

Final Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Firesafe Cannula Valve - HCP24042519Q9M

Topic/Issue

Request to establish a new HCPCS Level II code to identify firesafe cannula valve.

Applicant's suggested language: XXXXX, “Bidirectional thermal fuse for installation in home oxygen delivery accessory systems to stop the flow of oxygen in the event of a fire in the oxygen tubing, thereby reducing the potential for harm to the patient and third parties”

Summary of Applicant's Submission

The City of Nevada (Iowa) Fire Department in connection with BPR Medical Ltd. submitted a request to establish a HCPCS Level II code to identify firesafe cannula valve, generically referred to as thermal fuses. The firesafe cannula valve is a bidirectional thermal fuse for installation in a home oxygen delivery tubing set to stop the flow of oxygen in the event of a fire in the oxygen tubing, thereby reducing the potential for harm to the individual and third parties and damage to the building. Oxygen is not flammable, but oxygen enrichment dramatically increases the rate and severity of combustion; materials that will not burn in air may do so in an oxygen-enriched environment. Between 10% and 50% of individuals using home oxygen continue to smoke while on oxygen, typically leading to ignition in their oxygen nasal cannula, causing internal and external burns. Once the PVC oxygen tubing is ignited, the fire tracks back along the tube towards the oxygen supply. What starts as a localized fire spreads through the home and directly back to the source of the oxygen. If the oxygen source is a cylinder, then this may lead to a cylinder explosion, which can be catastrophic for the individual and third parties. Stopping the flow of oxygen will extinguish the flame because PVC will not sustain ignition in air. Food and Drug Administration recognized consensus standard ISO 80601-2-69 specifying the basic safety and essential performance of oxygen concentrators contains explicit requirements for protection against fire. These requirements include the means to prevent the propagation of fire back through the oxygen concentrator outlet and a means to stop the flow of gas towards the individual if the applied part becomes ignited. Thermal fuses provide the means to meet these requirements. Two thermal fuses should be fitted to each home oxygen installation, one close to the individual and one close to the oxygen source. Ideally, all individuals who use oxygen at home should have thermal fuses installed, but as a minimum, individuals deemed at high risk by the installing company as part of their standard risk assessment should have the thermal fuses installed. Risk factors include evidence that the individual or someone they live with/visits them smokes, individuals with diagnosis of dementia, substance addiction, those that have mobility issues, gas stoves, and gas fired space heaters. Firesafe cannula valves come in bulk pack boxes of 100 devices or as a bundled kit with oxygen tubing and a nasal cannula.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a unique HCPCS Level II code to describe firesafe cannula valves or thermal fuses. These items are part of supplier overhead associated with furnishing oxygen equipment (e.g., oxygen concentrators described by HCPCS Level II code E1390).

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Summary of Public Feedback

The City of Nevada (Iowa) Fire Department and BPR Medical disagreed with CMS' preliminary recommendations. One of the speakers stated that the preliminary recommendation relies upon the implicit assumption that thermal fuses are an existing requirement under the existing oxygen codes; and this is not valid as CMS had never required thermal fuses in any consideration of home oxygen provision. The speaker asked that if they are not an existing requirement, then how can they be part of the existing supplier overhead? As such, Medicare patients are not currently protected by thermal fuses. Thermal fuses are a relatively new and unique requirement that are an important element to the minimum standard of care for home oxygen therapy. They are included in the International Organization for Standardization (ISO) standard for oxygen concentrators and have a recently published ISO standard defining their performance. Thermal fuses are an engineered solution to address a material health issue in the United States. The fire service considers home oxygen fires to be their third biggest fire problem after wildfires and lithium-ion battery fires and believe that around 15% of residential deaths nationally can be prevented through the introduction of thermal fuses. Fires also impact third parties, such as firefighters, who are sometimes injured and killed. One in three fires results in an oxygen cylinder exploding. The speaker stated that there is widespread support from all stakeholders, including those dedicated to the respiratory care of home oxygen therapy and those that must deal with the aftermath of home oxygen fires. According to the speaker, the Veterans Healthcare Administration (VHA) mandated thermal fuses for all its patients in 2018 and reimbursed to ensure their introduction. In addition, three State Medicaid programs provide reimbursement for thermal fuses. The speaker confirmed acknowledgement of existing HCPCS Level II code E0700, "Safety equipment, device or accessory, any type." However, there is not always constant reimbursement from other payers and this code is not covered by Medicare, so individuals with Medicare coverage are not protected by thermal fuses. The speakers therefore ask CMS to establish a new, unique code for thermal fuses that will provide a clear definition and focus for all payers to support the roll-out of this nationally significant safety measure and to provide reimbursement as it is unreasonable to expect suppliers to absorb the cost of this new and additional safety feature. One speaker stated that the price for these average between $4 to $8. The speakers urged CMS to make a reimbursable requirement to use two Firesafe Cannula Valves in all home oxygen equipment. The speakers said that it is not enough to depend on public education as a lot of people do not really understand the risk.

A written comment stated that in the recent months, Tuolumne County has reported two fatal house fires and one serious burn injury in homes where medically necessary oxygen was being used. Local fire departments are urging residents using home oxygen therapy, as well as their families and visitors, to prioritize safety measures. Oxygen therapy, while vital for many, poses fire risks. Oxygen can also saturate clothing, bedding, and nearby materials, making them more flammable. Key safety tips include: no smoking near oxygen; avoid flammable products such as oil, grease, and petroleum-based products; keep oxygen at least 5 feet away from stoves, candles, and other heat sources; install in-line thermal fuses in

oxygen tubing to stop the flow in case of fire; use only grounded outlets for oxygen concentrators and avoid extension cords; install smoke detectors, keep a fire extinguisher accessible, and ensure everyone knows how to use it; store tanks upright in ventilated areas, away from heat and direct sunlight; and regularly inspect and maintain oxygen equipment.

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 need to establish a unique HCPCS Level II code to describe firesafe cannula valves or thermal fuses. Medicare has a bundled, monthly payment that includes all components of the service as required by DMEPOS Quality Standards and National Coverage Determinations. These items, when provided, are part of the supplier's costs associated with furnishing oxygen equipment (e.g., oxygen concentrators described by HCPCS Level II code E1390). Through this process, CMS cannot develop an "add-on" code to increase Medicare payment for home oxygen services. Existing HCPCS Level II code E0700, "Safety equipment, device or accessory, any type" is available if other payers deem appropriate.

Final Medicare Benefit Category Determination

No Medicare DMEPOS benefit category. As explained in the Medicare Benefit Policy Manual, section 110.1B2 (Pub. 100-2), precautionary or safety equipment is not considered medical equipment.

Final Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Note that fee schedule payments for stationary oxygen system rentals are all inclusive and represent a monthly allowance per Medicare beneficiary, as described in section 1834(a)(9) of the Social Security Act and further explained the Medicare Claims Processing Manual, section 130.6A (Pub. 100-4).

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.

Summary of Public Feedback

Helius Medical Inc. disagreed with CMS' published preliminary payment determination in the First Biannual 2024 HCPCS Coding cycle 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 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.

Preliminary Medicare Payment Determination

In the First Biannual 2024 HCPCS Coding cycle, we released a preliminary payment determination for the PoNS™ Controller in which we compared the Controller to HCPCS Level II code E0745 ("neuromuscular stimulator, electronic shock unit"), and we proposed to crosswalk the fee schedule amounts from HCPCS Level II code E0745 to HCPCS Level II code A4593. We later stated that more time was needed to issue a final payment determination. We are now providing a new preliminary payment determination as we have made substantive changes to our original preliminary payment determination for the PoNS™ Controller.

After further review, and consideration of oral and written public comments, we agree with the applicant that the PoNS™ Controller is not a neuromuscular electrical stimulator (NMES). A neuromuscular electrical stimulator involves the transmission of an electrical impulse to selected muscle groups by way of electrodes. The PoNS™ controller is an external electrical stimulation device that utilizes electrodes for the delivery of electrical stimulation to affected muscles.

However, we disagree with the applicant's assertion that the controller provides a unique form of electrical stimulation to the tongue that specifically targets the trigeminal and fascial nerves in a distinct manner from all other DME devices on the Medicare DMEPOS fee schedule. We believe the manufacturer is overstating a claim that the stimulation method and its effects are unique. The PoNS™ device works by delivering electrical stimulation to the tongue, which is then transmitted to the brain. The mechanism of stimulation is understood to contribute to enhancement of neuroplasticity and promote functional improvements by influencing central neural circuits involved in sensory and motor processing. Essentially, PoNS™ aims to modulate brain activity and support cognitive and motor function through its effects on central nervous system pathways.

Similar to PoNS™, a transcutaneous electrical nerve stimulation (TENS) device operates by applying electrical impulses through the skin to stimulate peripheral nerves, but its primary effect is on the central nervous system. For instance, when a TENS device is used to treat pain, the stimulation alters the way pain signals are processed by the brain and spinal cord, potentially reducing the perception of pain and influencing central pain modulation mechanisms. Despite targeting peripheral nerves initially, the therapeutic benefits of TENS are closely linked to its impact on central pain processing pathways.

PoNS™ and TENS both utilize electrical impulses to stimulate peripheral nerves, focusing on large-diameter A-beta fibers. This stimulation serves a dual purpose: it inhibits the transmission of pain signals and can influence the motor pathways that are crucial for gait. Moreover, both techniques are grounded in the gate control theory of pain. By activating non-painful sensations, such as touch, they can effectively modulate and reduce the perception of pain. This process can also improve motor function by overriding nerve signals that contribute to gait deficits. In this way, both PoNS™ and TENS offer therapeutic benefits by addressing both pain and movement issues through similar neurophysiological mechanisms.

Thus, we have determined that the PoNS™ Controller is comparable to HCPCS Level II code E0730 ("transcutaneous electrical nerve stimulation (tens) device, four or more leads, for multiple nerve stimulation").

In past cycles, a variety of multi-component devices featuring stimulators and controllers have been determined by CMS to be comparable to codes E0720 and E0730. These devices share a fundamental goal: to utilize electrical pulses for the stimulation of different nerves throughout the body. The underlying mechanisms of action for these devices involve targeted nerve stimulation. Each device is designed to activate specific peripheral nerves, which are essential for the proper functioning of the nervous system. The activation of the targeted nerve fibers leads to the modulation of neural pathways.

While the intended applications of these devices vary, some may be specifically designed for chronic pain management, while others focus on rehabilitation for motor control or sensory enhancement; they all leverage the principles of electrical stimulation to achieve therapeutic outcomes. This shared approach underscores the versatility of electrical stimulation in addressing diverse medical conditions.

In summary, while both the PoNS™ and TENS devices involve peripheral stimulation, their therapeutic outcomes are largely mediated through their effects on central nervous system functions, including pain modulation and/or neural plasticity. Therefore, the preliminary payment determination for the PoNS™ Controller is to establish the fee schedule amounts using existing fee schedule amounts for comparable items described by HCPCS Level II code E0730 prior to application of fee schedule adjustments made in accordance with regulations at 42 CFR 414.210(g). See table below.

	PoNS™ Controller	**E0730**
Physical Components	External electrical stimulator Electrodes are arrayed on a mouthpiece	External electrical stimulator Skin surface electrodes- four or more leads
Mechanical Components	NA	NA
Electrical Components	Battery powered Frequency at 200 Hz intervals, repeating every 50 Hz	Battery powered Low frequency usually below 300 Hz
Function and Intended Use	Delivers electrical sensory nerve stimulation to trigeminal and fascial nerves via electrodes in the mouthpiece	Delivers electrical sensory nerve stimulation to peripheral nerves via electrodes across the skin

	Worn on the neck For short-term treatment of gait deficit due to mild to moderate symptoms from multiple sclerosis (MS)	To treat individuals with acute and chronic injuries and pain[6]
Additional Aspects and Features	Intensity of stimulation adjusted by the beneficiary Connects to the mouthpiece via an electrical cord	Intensity of stimulation adjusted by the beneficiary Connects to the electrode patches or garment via an electrical cord

Per this preliminary determination, the 2024 fee schedule amounts for new HCPCS Level II code A4593 would be based on the unadjusted purchase fee schedule amounts for HCPCS Level II code E0730 of approximately $495.03. As the purchase price for this item 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, with the capped rental fee schedule amounts for months 1 thru 3 based on 10 percent of the purchase price and months 4 thru 13 based on 7.5 percent of the purchase price. Therefore, the monthly capped rental fee schedule amount for new HCPCS Level II code A4593 would be approximately $49.50 on average for months 1 through 3, and approximately $37.13 on average for months 4 through 13, resulting in a total capped payment of $519.80 should there be 13 months of continuous use. Fee schedules are updated annually.

Pricing Indicator = 36

Summary of Public Feedback

Helius Medical, Inc. and others provided written and oral comments that discuss how the PoNS™ controller is not comparable to TENS, nor is it comparable to any existing fee schedule items, and it should therefore be gap-filled according to the regulations at 42 CFR 414.238(c).

The speakers discussed how the PoNS™ device does not involve peripheral stimulation; rather, it stimulates cranial nerves, the trigeminal and facial, the lingual nerve and chorda tympany sensorimotor fibers in a specific layer of the tongue with direct connection to the brainstem and cerebellum. The PoNS™ device acts through neural plasticity with a mechanism that is different than a TENS device, by directly upregulating and modulating activity in movement control centers, cortical areas that control gait function mechanisms and, consequently, spinal motor pathways.

The speaker also explained how the PoNS™ device does not have connection with areas that mediate nociception or pain transmission. The PoNS™ device is not grounded in the gate control theory of pain because the PoNS™ device exerts its effect on motor (gait and balance) control through the direct signal transmission from the brainstem and cerebellum to

[6] HCPCS Level II code E0730 is for TENS devices with four or more leads. HCPCS Level II code E0720 is also for TENS devices but only those with two leads. HCPCS Level II codes E0732, E0733, and E0735 were cross walked to existing HCPCS Level II code E0720 with indications to treat insomnia, depression, anxiety, ADHD, and cluster headaches.

the dorsolateral prefrontal cortex, the right anterior cingulate cortex, and the left motor cortex, by engaging the trigeminal-vestibular pathway. As such the PoNS™ device does not have any involvement with modulation/reduction/inhibition of pain through "sensorial" transmission connected to touch. The PoNS™ device does not improve balance and/or gait by overriding nerve signals that contribute to gait deficit but acts by directly upregulating central cognitive mechanism of movement control.

The speakers explained how PoNS™ neuromodulation occurs by leveraging neural processes different than the processes that the brain engages for the physiological control of movement and coordination. PoNS™ stimulation aims at compensating for the impairment of the deficient canonical processes of gait control by restructuring, through the neuroplastic process, mechanisms and pathways that deliver the functional input from the brain to the skeletomuscular system – a process that is not associated with the transmission of pain signals or regulation of pain to achieve its therapeutic effect. They stated that TENS devices, even though they stimulate peripheral fibers that transmit pain signals to the brain, do not directly elicit, nor modulate/regulate, activity in brain areas that control response to pain.

The speakers also discussed how the controller is not comparable to TENS devices when comparing the two devices with the components listed at 42 CFR 414.238: physical components; mechanical components; electrical components; function and intended use; and additional attributes and features.

First, the speakers stated that the physical components of TENS devices are not comparable because the controller is a highly unique, lightweight, wearable flexible plastic yoke (i.e., U-shape) with a clear plastic display developed after years of intense research and investment to function under the conditions in which it is used (e.g., during exercise).

The speakers also discussed how the controller is not comparable to the electrical components of TENS devices because it is more complex and contains a microprocessor, two memory types for device firmware and for storage of system status data and patient utilization data, an accelerometer to monitor controller motion, and device status monitoring circuitry with internal error code logging along with two encryption devices for secure mouthpiece cable signaling and for secure uploading of device and patient utilization data to the cloud.

The speakers explained how the controller is not comparable to the mechanical components of TENS devices because the controller contains an accelerometer which monitors and records motion of the controller. This enables a determination regarding patient compliance with a therapeutic regimen, beyond only knowing if the device has been turned on or off.

The speakers also explained that the controller is not comparable to TENS with regards to function and intended use, as TENS devices do not have a similar intended use. The PoNS™ device is for use as a short-term treatment of gait deficit due to mild to moderate symptoms from multiple sclerosis and is to be used as an adjunct to a supervised therapeutic exercise program in patients 22 years of age and over by prescription only. The PoNS™ device provides pulses in a complex pattern across the surface of the tongue that results in modulated brain activity, while TENS devices impose neural stimulation to block sensory nerve pain signals on peripheral sensory nerves.

The speakers discussed how the controller is not comparable to TENS with regards to additional aspects and features because unlike TENS devices, the controller is configured to provide real-time feedback to patients during use (e.g., start/stop/pause, proper function, Mouthpiece position on the tongue, stimulation level selection, session completion, battery status, etc.) and records that data for upload to the cloud for review by a care provider.

The speakers also provided prior examples of CMS determining an item was not comparable to any existing items, such as an item CMS determined to not be comparable to TENS, and how CMS then determined the price of these items through gap-filling. For example, the speakers discussed how CMS previously determined that another device named the Cala kIQ™ (formerly the CalaTrio™) was comparable to TENS in its preliminary payment determination but determined in the final determination that it was not comparable to TENS because of the special componentry and patterned stimulation produced by the device. As the PoNS™ controller similarly has special componentry and differences in stimulation than TENS, the speakers expressed that this warrants a change to the preliminary determination for the controller to find it is not comparable to TENS devices.

For all these reasons, the speakers requested that CMS gap-fill the controller with the starting point being in the range of $16,416 to $16,554 for the controller, with payments made on a capped rental basis.

Final Medicare Payment Determination

CMS is finalizing the preliminary determination to establish the fee schedule amounts for HCPCS Level II code A4593 based on existing fee schedule amounts for comparable items described by HCPCS Level II code E0730 (“transcutaneous electrical nerve stimulation (TENS) device, four or more leads, for multiple nerve stimulation”), before applying any fee schedule adjustments as per regulations at 42 CFR 414.210(g). Although TENS devices and the PoNS™ controller differ in design and functionality, there are key similarities that make the devices comparable.

Both categories of devices rely on similar mechanisms for applying electrical current in that they feature a housing unit through which electrical stimulation is delivered and regulated. Both work on the same basic principle of using electrical stimulation to influence neural activity. Furthermore, the distinctions between TENS devices and the PoNS™ controller highlighted by the speaker during the public meeting, such as the shape of the devices, do not represent significant differences in the two types of electrical stimulation equipment. There have been many different shapes and sizes of electrical stimulation equipment, such as TENS devices, over the years.

The speaker highlighted differences between TENS electrodes and the PoNS™ mouthpiece in the public meeting. We agree that while TENS devices apply electrical impulses through electrodes placed on the skin to stimulate nerves, the PoNS™ system takes a novel approach by applying electrical stimulation to the tongue through the PoNS™ mouthpiece, which has direct neural connections to the brain. This method allows for more targeted and potentially more effective stimulation of brain activity.

The speaker also noted that the PoNS™ system improves balance and/or gait by directly upregulating central cognitive mechanism of movement control rather than overriding nerve signals. This key difference however lies in the location and method of stimulation via the

separately coded PoNS™ mouthpiece rather than the PoNS™ controller. CMS already concluded that the PoNS™ mouthpiece and TENS electrodes are not comparable and already established a payment determination for the mouthpiece based on that conclusion in the First Biannual 2024 HCPCS Coding Cycle. The attributes of the PoNS™ mouthpiece are therefore not factored into the payment determination for the PoNS™ controller, or to the comparison of the PoNS™ electrical stimulation equipment (i.e., controller) to the TENS electrical stimulation equipment. In another decision, CMS concluded that the Cala kIQ™ electrical stimulator (formerly Cala Trio™) cannot be compared to a TENS device due to its use of Transcutaneous Afferent Patterned Stimulation (TAPS) to produce patterned electrical stimulation. The speaker for the PoNS™ controller stated that CMS should reach a similar conclusion because of the distinct features of the PoNS™ controller, including its unique shape and materials. However, the PoNS™ controller does not use TAPS.

We note the inclusion of an accelerometer in the PoNS™ controller, but this is not a unique feature, as several TENS devices on the market also utilize accelerometers or similar motion-sensing technology. Both the PoNS™ and TENS devices combine electrical stimulation with the principles of neuroplasticity. The PoNS™ device uses electrical stimulation applied to the tongue, activating cranial nerves and stimulating brain areas associated with motor and sensory functions to promote healing and functional recovery. The TENS unit applies electrical stimulation to modulate pain and potentially encourage neuroplastic changes over time.

The use of an accelerometer has become a more common element in modern TENS and electrical muscle stimulation (EMS) devices, where it helps improve the user experience by automatically adjusting stimulation intensity based on movement or physical activity. While the presence of this technology may enhance the effectiveness and personalization of the device, it is no longer a distinguishing characteristic, as many other products in the market incorporate similar features to optimize pain relief and muscle recovery. For instance, the Omron Pain Relief Pro TENS device, although not explicitly marketed with an accelerometer, adjusts stimulation intensity based on activity levels, and some models are compatible with mobile apps that monitor movement. Similarly, the PowerDot 2.0, a smart TENS and EMS device, along with the iReliev TENS + EMS device, combines both therapies and integrates with apps to adjust settings based on user movement or physical feedback. The Quell Pain Relief Device employs sensor technology to detect activity changes and automatically modulate stimulation, making it particularly effective for users seeking pain relief during everyday activities. All of these devices utilize accelerometers or comparable technologies to dynamically adjust therapy based on the user's physical activity, offering a more tailored and effective approach to pain relief and muscle recovery.

As noted in the preliminary payment determination, previous cycles have involved consideration of a variety of multi-component devices, including stimulators and controllers, that CMS has classified as comparable to HCPCS Level II codes E0720 and E0730. These devices share a common purpose: to deliver electrical pulses for the stimulation of different nerves throughout the body. By stimulating the specific nerve fibers, these devices modulate neural pathways, influencing pain perception and other bodily functions. One example of such a device is the Monarch eTNS System®, which employs transcutaneous electrical nerve stimulation (eTNS) to achieve therapeutic effects.

Per this final determination that the PoNS™ controller is electrical stimulation equipment comparable to TENS electrical stimulation equipment, the 2025 fee schedule amounts for

new HCPCS Level II code A4593 will be based on the unadjusted purchase fee schedule amounts for HCPCS Level II code E0730 of approximately $506.91. As the purchase price for this item is greater than $150 in the base period, payment will be made on a capped rental basis in accordance with our regulations at 42 CFR 414.229, with the capped rental fee schedule amounts for months 1 thru 3 based on 10 percent of the purchase price and months 4 thru 13 based on 7.5 percent of the purchase price. Therefore, the monthly capped rental fee schedule amount for new HCPCS Level II code A4593 will be approximately $50.69 on average for months 1 through 3, and approximately $38.02 on average for months 4 through 13, resulting in a total capped payment of $532.27 should there be 13 months of continuous use. Fee schedules are updated annually.

Pricing Indicator = 36

VRTX - HCP240625VDHC7

Topic/Issue

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

The applicant did not submit any suggested language.

Summary of Applicant's Submission

Aspen Medical Products submitted a request to establish a new HCPCS Level II code to identify VRTX. The VRTX is a class I device, exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The VRTX cervical-thoracic-lumbar-sacral-orthoses (CTLSO) is an adjustable and customizable CTLSO used to immediately treat medical spinal conditions requiring therapeutic stability and immobilization. Specifically, this non-invasive spinal orthosis is a CTLSO, cervical, multiple post collar, occipital/mandibular supports, adjustable cervical bars, thoracic-lumbar-sacral orthosis with triplanar control, modular segmented system, rigid plastic shells, posterior panel extends from sacrococcygeal junction and terminates just inferior to scapular spine and connects to occipital supports, rigid anterior connects to mandibular supports, soft liner interface, restricts gross trunk motion in sagittal, coronal, and transverse planes, lateral strength is provided by overlapping plastic and stabilizing compressive closures, flexible provides trunk support, produces intracavitary pressure to reduce load on the intervertebral disks, lateral strength provided by rigid lateral frame/panels, includes straps, closures, may include padding, shoulder straps, pendulous abdomen design, prefabricated item that can be bent, molded, assembled, or otherwise customized to fit a specific individual by an individual with expertise.

CMS Preliminary HCPCS Coding Recommendation

Establish a new HCPCS Level II code LXXXX, “Cervical-thoracic-lumbar-sacral-orthoses (ctlso), adult size, anterior-posterior-lateral control, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise” to describe VRTX.

VRTX is a non-invasive spinal orthosis that is a prefabricated customizable device that can be adjustable across the four spinal segments (cervical-thoracic-lumbar-sacral).

Preliminary Medicare Benefit Category Determination

Back Brace.

The application supports a preliminary benefit category determination that the VRTX Cervical to Spinal Orthosis (CTLSO) is used as a brace. Section 130 of Chapter 15 of the Medicare Benefit Policy Manual (CMS Pub. 100-02) defines a brace as a rigid or semi-rigid device used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body. VRTX cervical to spinal orthosis (CTLSO) is a rigid device that is used to provide spinal support.

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 LXXXX is to use the existing fee schedule amounts for comparable items described by HCPCS Level II code L0464 (“Tlso, triplanar control, modular segmented spinal system, four rigid plastic shells, posterior extends from sacrococcygeal junction and terminates just inferior to scapular spine, anterior extends from symphysis pubis to the sternal notch, soft liner, restricts gross trunk motion in sagittal, coronal, and transverse planes, lateral strength is provided by overlapping plastic and stabilizing closures, includes straps and closures, prefabricated, includes fitting and adjustment”) for the thoracic lumbar sacral orthosis portion of the CTLSO and HCPCS Level II code L0180 ("Cervical, multiple post collar, occipital/mandibular supports, adjustable") to account for the cervical collar portion of the CTLSO.

CMS has compared the two HCPCS Level II codes to the VRTX cervical to spinal orthosis as shown in the below comparability table and finds them comparable for pricing purposes.

	VRTX CTLSO	**L0180**	**L0464**
Physical Components	Cervical Thoracis Lumbar Sacral Orthosis made of: Cervical collar (back panel with pads) Front panel with pads Chin piece Thoracic lumbar sacral orthosis (two piece bivalved design; anterior and posterior panels, Under arm straps)	Cervical collar made of: Back panel with pads Front panel with pads Chin piece	Thoracic lumbar sacral orthosis made of: Two piece bivalved design (anterior and posterior panels) Under arm straps
Mechanical Components	NA	NA	NA
Electrical Components	NA	NA	NA

Function and Intended Use	Provides therapeutic motion restriction, to improve posture, to reduce muscle spasm, and for optimal motion stability in trauma and post operative individuals Intended Use: For multilevel spinal support	Provides therapeutic motion restriction, to improve posture, and to reduce muscle spasm. Intended Use: For acute cervical trauma, post-op, and optimized occipital support.	Provides optimal motion stability in trauma and post operative individuals Intended Use: For acute thoracolumbar spine trauma and post-operative individuals.
Additional Aspects and Features	Ability to step down to a TLSO or LSO based on the individual's needs. Anterior tightening and adjustments allow for more efficient clinician application.	Automatically adjusts to individual neutral head position. Ability to step up to CTLSO (with upgrade kit)	One size fits most Anterior tightening and adjustments allow for more efficient clinician application.

As described above, the preliminary payment determination is to use the sum of the pricing for HCPCS Level II codes L0464 and L0180 to account for the cervical to spinal support of the VRTX CTLSO. Therefore, the preliminary payment determination for HCPCS Level II code LXXXX using comparable items is calculated using the following formula: LXXXX= L0464 + L0180.

The 2024 average purchase fee schedule amount for HCPCS Level II code LXXXX would be approximately $2,201.41. 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

Aspen Medical Products agreed with CMS' published preliminary recommendations. However, the speaker suggested that CMS should revise the proposed code descriptor by removing the language "adult size" because the VRTX CTLSO is offered in three different sizes, which includes adolescent sizes. As such, removing "adult size" from the proposed code descriptor language would reduce confusion and provide clarity in determining the appropriate brace for the individual.

CMS Final HCPCS Coding Decision

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

and finalizing the decision to:

Establish a new HCPCS Level II code L0720, “Cervical-thoracic-lumbar-sacral-orthoses (ctlso), anterior-posterior-lateral control, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise” to describe VRTX.

CMS agreed with the applicant to remove the language “adult size” from the code language

Final Medicare Benefit Category Determination

Back Brace.

Final Medicare Payment Determination

The fee schedule amount for L0720 will be established based on the sum of the pricing for HCPCS Level II codes L0464 and L0180, as discussed in the preliminary determination.

Therefore, the final payment determination for HCPCS Level II code L0720 using comparable items is calculated using the following formula: L0720 = L0464 + L0180. The 2025 purchase fee schedule amount is approximately $2,254.25 on average.

Pricing Indicator = 38

Swedo-Step Smart Brace (2007.115) - HCP211020NP3A5

Topic/Issue

Request to revise an existing CMS HCPCS Level II final coding determination from 2007 for Swedo-Step Smart Brace.

The applicant did not submit any suggested language.

Summary of Applicant's Submission

Palmetto GBA submitted a request to revise CMS' final coding determination from 2007 for application 07.115 for Swedo-Step Smart Brace. CMS concluded a coding determination for Swedo-Step Smart Brace to bill existing HCPCS Level II codes L1971, "Ankle foot orthosis, plastic or other material with ankle joint, prefabricated" and L2210, "Addition to lower extremity, dorsiflexion assist (plantar flexion resist), each joint." HCPCS Level II code L2210 is an 'addition to' a custom fabricated device, while L1971 describes a prefabricated device. The Swedo-Step Smart Brace is a prefabricated ankle foot orthosis which includes a posterior designed ankle joint, designed to provide ankle motion swing phase control to control drop foot and to mitigate shock absorption dynamics at the initial contact and loading response of stance phase. A prefabricated orthosis is one, which is manufactured in quantity without a specific individual in mind. A prefabricated orthosis may be considered an off-the-shelf or a custom fitted device that may be trimmed, bent, molded (with or without heat), or otherwise modified for use by a specific individual. An orthosis that is assembled from prefabricated components is considered prefabricated. It is inherent in the definition of prefabricated that a particular item is complete. A custom-fabricated orthosis is one which is individually made for a specific individual starting with basic materials including, but not limited to, plastic, metal, leather, or cloth in the form of sheets, bars, etc. It involves substantial work such as cutting, bending, molding, sewing, etc. It may involve the incorporation of some prefabricated components. It involves more than trimming, bending, or making other modifications to a substantially prefabricated item. Custom-fabricated additions are appropriate only for custom-fabricated base orthotics and should not be billed with prefabricated base orthotics.

CMS Preliminary HCPCS Coding Recommendation

CMS' prior final determination for Swedo-Step Smart Brace from 2007 indicated that HCPCS Level II code L1971, "Ankle foot orthosis, plastic or other material with ankle joint, prefabricated" in conjunction with HCPCS Level II code L2210, "Addition to lower extremity, dorsiflexion assist (plantar flexion resist), each joint" describes Swedo-Step Smart Brace. However, the Medicare fee schedule amounts for HCPCS Level II code L1971 include payment for the dorsiflexion assist feature; therefore, this determination was incorrect. The fee schedule amounts for HCPCS Level II code L1971 were established using 2003 retail prices for the Dream Brace & Joint product made by Scott Orthotic Labs Inc., which includes the dorsiflexion assist feature and a similar brace made by J.E. Hanger. As such, CMS is proposing to:

Revise existing HCPCS Level II code L1971, "Ankle foot orthosis, plastic or other material with ankle joint, prefabricated, includes fitting and adjustment" to instead read "Ankle foot

orthosis, plastic or other material with ankle joint, with or without dorsiflexion assist, prefabricated, includes fitting and adjustment."

Revised HCPCS Level II code L1971 would be used to describe Swedo-Step Smart Brace.

HCPCS Level II code L2210, "Addition to lower extremity, dorsiflexion assist (plantar flexion resist), each joint" should not be used in combination with HCPCS Level II code L1971 for any item, including Swedo-Step Smart Brace.

Preliminary Medicare Benefit Category Determination

Leg Brace.

The application supports a preliminary benefit category determination that the Swedo-Step Smart Brace is used as a lower extremity brace and would fall under the Medicare benefit for leg 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. This definition is also in Medicare regulations at 42 CFR 410.2. The Swedo-Step Smart Brace is a rigid device that is used to control drop foot and to mitigate shock absorption dynamics at the initial contact and loading response of stance phase.

Preliminary Medicare Payment Determination

The fee schedule amounts for HCPCS Level II code L1971 are unchanged and continue to apply for the Swedo-Step Smart Brace. The average of the 2024 fee schedule amounts for HCPCS Level II code L1971 is $548.77. Note that HCPCS Level II code L2210 should not be billed with this HCPCS Level II code.

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

A speaker disagreed with the CMS' published preliminary recommendations. The speaker recommended that the HCPCS Level II code descriptor for L1971 remains unchanged. The L-code system that has been used to describe orthoses and prostheses since its inception in the late 1970's was designed to utilize a limited set of "base" procedure codes that describe the essential features of an orthosis or prosthesis and a larger set of "addition" codes that describe unique features of an orthosis or prosthesis that are not inherent in the base procedure code. HCPCS Level II code L1971 is a base code that describes a prefabricated plastic ankle foot orthosis (AFO) incorporating a free-motion articulation at the ankle. Three common addition codes are used in conjunction with HCPCS Level II code L1971 to describe the specific level of ankle joint control that meets the specific clinical needs of the individual. CMS' preliminary recommendation to revise the code description of L1971 to include the

phrase “with or without dorsiflexion assist” eliminates the ability to use a combination of appropriate base and addition codes to describe the function of the AFO that best meets the clinical needs of each individual. The speaker stated this is a short-sighted decision that will not only impact correct coding of the Swedo-Step Smart Brace but also the current and future prefabricated AFOs that are offered.

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:

Revise existing HCPCS Level II code L1971, “Ankle foot orthosis, plastic or other material with ankle joint, prefabricated, includes fitting and adjustment” to instead read “Ankle foot orthosis, plastic or other material with ankle joint, with or without dorsiflexion assist, prefabricated, includes fitting and adjustment.”

Revised HCPCS Level II code L1971 would be used to describe Swedo-Step Smart Brace.

HCPCS Level II code L2210, “Addition to lower extremity, dorsiflexion assist (plantar flexion resist), each joint” should not be used in combination with HCPCS Level II code L1971 for any item, including Swedo-Step Smart Brace.

During the public meeting, the speaker stated that three common HCPCS Level II addition codes (L2200, L2210, and L2220), are used in conjunction with L1971, which is the base code for a prefabricated plastic AFO. These addition codes, according to the speaker, represent joint components that either limit ankle joint motion (L2200), provide dorsiflexion assistance (L2210), or offer both dorsiflexion and plantarflexion assistance (L2220). However, HCPCS Level II code L1971 describes a prefabricated AFO that is custom-fitted, not a custom-fabricated device. The addition codes cited by the speaker pertain to custom-fabricated items, not prefabricated. Custom-fabricated additions should only be billed with custom-fabricated base orthotics, and not with prefabricated base orthotics like L1971.

A custom-fabricated item is a device created based on clinically derived measurements, tracings, or castings of the individuals body part (including X-rays or other images). This process typically involves basic materials such as plastic, metal, leather, or cloth, which are shaped or formed using techniques like vacuum forming, molding, cutting, bending, sewing, and finishing before being fitted on the individual. In contrast, prefabricated orthotics, such as those described by L1971, do not undergo this level of individualized fabrication. Based on this distinction, CMS has finalized its preliminary recommendation, concluding that the addition codes in question should not be used in conjunction with L1971, as they pertain to custom-fabricated items and not prefabricated devices.

Final Medicare Benefit Category Determination

Leg Brace.

Final Medicare Payment Determination

The fee schedule amounts for HCPCS Level II code L1971 are unchanged and continue to apply for the Swedo-Step Smart Brace. The average of the 2025 fee schedule amounts for HCPCS Level II code L1971 is $561.94. Note that HCPCS Level II code L2210 should not be billed with this HCPCS Level II code.

The average fee schedule amount is the average of the 2025 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

Power Knee™ - HCP2406216Y4P8

Topic/Issue

Request to establish a new HCPCS Level II code to identify Power Knee's™ features.

Applicant's suggested language: LXXXX, "Addition, endoskeletal knee-shin system, single axis, electromechanical swing and stance phase control, with or without shock absorption and stance extension dampening"

Summary of Applicant's Submission

Palmetto GBA submitted a request to establish a new HCPCS Level II code to describe Ossur Americas, Inc.'s Power Knee™. CMS' final coding determination from 2012 for Power Knee™ (application 12.067) included utilizing multiple codes, including HCPCS Level II codes L5828, "Addition, endoskeletal knee-shin system, single axis, fluid swing and stance phase control" and L5848, "Addition to endoskeletal knee-shin system, fluid stance extension, dampening feature, with or without adjustability." The term "fluid" in the long description of HCPCS Level II codes (L5828 and L5848) is intended to describe a mechanism located in a prosthetic knee joint, which includes a physical medium in one or more contained chambers that regulates the flow of pressurized fluid by valves to dampen forces acting on the knee unit. The intent of a fluid knee joint design is to enable the individual to walk comfortably at different speeds. Ossur Americas responded to the question in 2012 "Why Existing Code Categories are Inadequate to Describe the Item?" and replied that the Power Knee™ controls all phases of the gait cycle by an electromechanical actuator and indicated that their product does not include a fluid control mechanism; therefore, it is not accurate to describe the Power Knee™ with HCPCS Level II codes L5828 or L5848. Therefore, there must be a 'base knee code' used to describe the Power Knee™ with any additional knee feature codes.

CMS Preliminary HCPCS Coding Recommendation

The Power Knee™ is a motorized prosthetic knee that controls all phases of the gait cycle using an electromechanical actuator. The Power Knee™ is currently described by HCPCS Level II codes L5859, L5856, L5828, L5845, and L5848. HCPCS Level II codes L5828 and L5848 describe a fluid control mechanism rather than the electromechanical control found in the Power Knee™. As such, CMS is proposing to:

Establish a new HCPCS Level II code LXXXX, "Endoskeletal knee-shin system, single axis, electromechanical swing and stance phase control, with or without shock absorption and stance extension damping" to be used in conjunction with existing HCPCS Level II codes L5859 and L5856 to describe the Power Knee™.

Preliminary Medicare Benefit Category Determination

Artificial Leg.

The application supports a preliminary benefit category determination that the Ossur Power Knee is used as a replacement for the natural knee joint that has been lost and therefore is a prosthetic limb.

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.

The Ossur Americas Power Knee™ is a motorized prosthetic knee that controls all phases of the gait cycle using an electromechanical actuator. The Power Knee™ is currently described by the combination of HCPCS Level II codes L5859 + L5856 + L5828 + L5845 + L5848. HCPCS Level II codes L5828 and L5848 describe a fluid control mechanism rather than the electromechanical control found in the Power Knee™. However, we believe the base characteristics of the fluid-based codes HCPCS Level II codes L5828 and L5848, as well as L5845, are comparable to the electromechanical actuator motor-based properties of the Power Knee™ for pricing purposes. The fee schedule amounts for HCPCS Level II codes L5828 and L5848 have been added to the fees for HCPCS Level II code L5845 to establish a fee for HCPCS Level II code LXXXX, "addition, endoskeletal knee-shin system, single axis, electromechanical swing and stance phase control, with or without shock absorption and stance extension dampening." Features of the Power Knee™ were compared against HCPCS Level II codes L5828, L5845 and L5848 as shown in the below comparability table.

Power Knee™	L5828	L5845	L5848
Physical Components			
Single axis	X		
Mechanical Components			
Programmable stance and swing control	NA	NA	NA
Stance phase control: stance flexion		X	
Shock absorption			X
Stance extension dampening			X
Electrical Components			
Microprocessor control	NA	NA	NA
Function and Intended Use			
Transfemoral and hip disarticulation level	X	X	X
Lower extremity device/component	X	X	X
Additional Aspects and Features	NA	NA	NA

Based on this preliminary determination, the average 2024 fee schedule amount for HCPCS Level II code LXXXX would be based on the sum of the purchase fee schedule amounts for

HCPCS Level II codes L5828, L5845 and L5848 of approximately $7,072.52 on average. As stated in the CMS Preliminary HCPCS Coding Recommendation, LXXXX would be used in conjunction with existing HCPCS Level II codes L5859 and L5856 to describe the Power Knee™.

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 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:

Establish a new HCPCS Level II code L5827, "Endoskeletal knee-shin system, single axis, electromechanical swing and stance phase control, with or without shock absorption and stance extension damping" to be used in conjunction with existing HCPCS Level II codes L5859 and L5856 to describe the Power Knee™.

Final Medicare Benefit Category Determination

Artificial Leg.

Final Medicare Payment Determination

The fee schedule amounts will be established as discussed in the preliminary payment determination. The average 2025 fee schedule amount for HCPCS Level II code L5827 will be based on the sum of the purchase fee schedule amounts for HCPCS Level II codes L5828, L5845 and L5848 of approximately $7,242.27 on average. Fee schedules are updated annually.

Pricing Indicator = 38

Static Progressive Stretching Finger Device - HCP220222U1GRE

Topic/Issue

Request to establish a new HCPCS Level II code to identify a static progressive stretching device for the fingers.

Applicant's suggested language: EXXXX, “Static progressive stretch finger device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories”

Summary of Applicant's Submission

Palmetto GBA submitted a request to establish a new HCPCS Level II code to identify static progressive joint stretch device for the fingers. Static progressive joint stretching devices are included in the existing array of joint stiffness/contracture management devices described in HCPCS Level II code range E1800-E1841. The static progressive joint stretching codes include language for various anatomical joints; however, there is not a code to describe a device which includes a static progressive finger joint stretching device.

CMS Preliminary HCPCS Coding Recommendation

We agree with Palmetto GBA that the current HCPCS Level II code set for a static progressive stretching devices is lacking a code to describe the anatomical location of the finger. As such, CMS is proposing to:

Establish HCPCS Level II code EXXXX, “Static progressive stretch finger device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories” to describe a static progressive joint stretch device for the fingers.

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.

We believe that there is currently one product that would fall under new HCPCS Level II code EXXXX and that is the EZ Turnbuckle Finger Orthosis, which is manufactured by Joint Active Systems (JAS) Inc. The Pricing, Data Analysis and Coding (PDAC) contractor has

code verified this product under HCPCS Level II code E1399. Our preliminary HCPCS coding recommendation would assign this product to newly established HCPCS Level II code EXXXX.

As the intended use of the EZ Turnbuckle Finger Orthosis is for therapeutic stretching of the finger, this would not fall under the Medicare braces benefit category. We discussed this policy in CMS-1780-F (88 FR 77838), in which we said that dynamic adjustable extension/flexion devices and static progressive stretch devices are used to stretch an arm or leg or other part of the body to treat contractures and increase range of motion. While these devices may look similar to a brace, they are used for the purpose of treating contractures and are not 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. As a result, dynamic adjustable extension/flexion devices and static progressive stretch devices do not fall under the definition of brace in accordance with Section 130 of Chapter 15 of the Medicare Benefit Policy Manual (Pub. 100-02) but do fit within the Medicare DME benefit category.

Although JAS may market their EZ Turnbuckle Finger Orthosis as a single-patient use device, we believe that the custom fitted cuffs can be removed and replaced. Therefore, the device can be used by multiple patients, especially if fitting is required to use the device.

With regard to the device's durability, our assessment of the JAS's EZ product line is that its features and functions are similar/same to the JAS's original SPS line, which have met our 3-year minimum lifetime requirement. The JAS EZ product line is made of a thermoplastic alternative to that of a metal frame design. Based on our understanding of thermoplastics, and the rigidity of the devices themselves, they are durable and exceed the 3-year minimum lifetime requirement.[7]

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.

We have concluded that newly established HCPCS Level II code EXXXX is comparable to HCPCS Level II code E1831 ("static progressive stretch toe device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories") with respect to its function and intended use, and additional attributes and features.

Although they have different designs and mechanisms of action, both devices promote the extension and flexion of joints, whether they are for fingers or toes. Essentially, both provide a stretching effect on the phalanges of the toes and fingers. While their features may differ, their functions are quite similar. This comparability is also supported by the fact that the dynamic splint fee schedule amounts for the finger (HCPCS Level II code E1825) and toe (HCPCS Level II code E1830) devices are the same.

[7] Alexander Chudnovsky, Zhenwen Zhou, Haiying Zhang, Kalyan Sehanobish, Lifetime assessment of engineering thermoplastics, International Journal of Engineering Science, Volume 59, 2012, Pages 108-139, ISSN 0020-7225, https://doi.org/10.1016/j.ijengsci.2012.03.016.

While the JAS EZ Turnbuckle Finger Orthosis and the Ermi MPJ Extender (E1831) differ in their physical components, we find them comparable as they share common goals and applications. Both devices are made from rigid or semi-rigid materials that maintain the finger or toe in a fixed or adjustable position. The JAS EZ Turnbuckle Finger Orthosis uses a turnbuckle system to precisely control the tension and positioning of the finger joint, allowing for accurate adjustment of extension or flexion. In contrast, the Ermi MPJ Extender employs an air bladder system to support and adjust the extension of the metacarpophalangeal joint (MPJ), with inflation or deflation to achieve the desired support and positioning. Although they use different adjustment methods, both devices are designed to be adjusted to meet individual patient needs and can be adapted to various finger and toe sizes and shapes. Functionally, both devices aim to correct or maintain the alignment of similar sized finger and toe joints. The JAS EZ Turnbuckle Finger Orthosis is focused on finger joints, while the Ermi MPJ Extender targets the great toe joint. Despite their different areas of focus, both devices address joint-specific issues such as stiffness, reduced range of motion, or post-traumatic effects. Also, another aspect of their comparability is their adjustability and customization to accommodate individual patient needs.

HCPCS Level II code E1831 is for a joint distinct from the fingers, specifically the metacarpophalangeal joint (MPJ) of the great toe. Anatomically, the MPJ is more comparable to the proximal interphalangeal (PIP) joint of the finger, which is the focus of the JAS EZ Turnbuckle Finger Orthosis. While the PIP joint enables flexion and extension of the fingers, the MPJ supports similar movements for the big toe. These joints are more comparable to each other than to joints such as the elbow, knee, or ankle.

In summary, despite differences in design, both the JAS EZ Turnbuckle Finger Orthosis and the Ermi MPJ Extender share similar features aimed at supporting and managing joint conditions, aiding in rehabilitation, and improving patient outcomes in clinical settings for similar size joints/anatomy. Therefore, we find JAS EZ Turnbuckle Finger Orthosis and the Ermi MPJ Extender comparable.

The preliminary payment determination is to establish the fee schedule amounts using existing fee schedule amounts for comparable items described by HCPCS Level II code E1831. See below table.

	EXXXX	**E1831**
Physical Components	Hand and finger splint (frame) Turnbuckle Cuffs Straps	Air bag Straps Rigid frame
Mechanical Components	NA	Air bladder
Electrical Components	NA	NA
Function and Intended Use	Maintains proper alignment of all four digits	Improves range of motion for toes

	EXXXX	E1831
	Device applies low- to high-level load to the joint to achieve maximal total end range time Treats individuals with PIP (proximal interphalangeal) contracture, fractures, dislocations, tendon/ligament repairs, and volar plate injuries	Individual applies a high intensity force using an air bag mechanism Designed for dorsiflexion and plantarflexion
Additional Aspects and Features	To promote both extension and flexion of PIP joint of fingers Single patient use Three thirty minutes session/day Dynamic splint fee schedule amounts for the finger (HCPCS Level II code E1825) and toe (HCPCS Level II code E1830) devices are the same.	To promote both extension and flexion of MP (metatarsophalangeal) joint of toes Fifteen minutes session for 4 to 8 training/day Stretching from 1 to 5 mins followed by a recovery of equal length of time Dynamic splint fee schedule amounts for the finger (HCPCS Level II code E1825) and toe (HCPCS Level II code E1830) devices are the same.

The payment rules and pricing associated with the existing HCPCS Level II code E1831 apply to this product, if covered. Payment for existing HCPCS Level II code E1831 is made on a capped rental basis. Therefore, the monthly capped rental fee schedule amount for new HCPCS Level II code EXXXX would be approximately $88.94 on average for months 1 through 3, and approximately $66.71 on average for months 4 through 13, resulting in a total capped payment of $933.92 should there be 13 months of continuous use. Fee schedules are updated annually.

Pricing Indicator = 36

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:

Establish HCPCS Level II code E1832, "Static progressive stretch finger device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories" to describe a static progressive joint stretch device for the fingers.

Final Medicare Benefit Category Determination

Durable Medical Equipment.

Final 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.

We concluded in the preliminary payment determination that newly established HCPCS Level II code E1832 is comparable to HCPCS Level II code E1831 ("static progressive stretch toe device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories") with respect to its function and intended use, and additional attributes and features. We will be finalizing our preliminary payment determination and will establish the fee schedule amounts using existing fee schedule amounts for comparable items described by HCPCS Level II code E1831.

The payment rules and pricing associated with the existing HCPCS Level II code E1831 apply to this product, if covered. Payment for existing HCPCS Level II code E1831 is made on a capped rental basis. Therefore, the 2025 monthly capped rental fee schedule amount for new HCPCS Level II code E1832 would be approximately $91.07 on average for months 1 through 3, and approximately $68.31 on average for months 4 through 13, resulting in a total capped payment of $956.31 should there be 13 months of continuous use. Fee schedules are updated annually.

Pricing Indicator = 36

Partial Hand and Finger Prostheses - HCP240701W4N75

Topic/Issue

Request to revise existing HCPCS Level II codes L6380, L6400, L6680, L6687, L6694, L6695, L6696, L6697, L6698, L6883, L7400, and L7403 to include the description related to partial hand and finger prostheses.

Applicant's suggested language:

1. L6380, “Immediate post-surgical or early fitting, application of initial rigid dressing, including fitting alignment and suspension of components, and one cast change, finger, partial hand, wrist disarticulation, or below elbow”

2. L6400, “Partial hand, below elbow, molded socket, endoskeletal system, including soft prosthetic tissue shaping”

3. L6680, “Upper extremity addition, test socket, partial hand, wrist disarticulation or below elbow”

4. L6687, “Upper extremity addition, frame type socket, partial hand, below elbow or wrist disarticulation”

5. L6694, “Addition to upper extremity prosthesis, partial hand, below elbow/above elbow, custom fabricated from existing mold or prefabricated, socket insert, silicone gel, elastomeric or equal, for use with locking mechanism”

6. L6695, “Addition to upper extremity prosthesis, partial hand, below elbow/above elbow, custom fabricated from existing mold or prefabricated, socket insert, silicone gel, elastomeric or equal, not for use with locking mechanism”

7. L6696, “Addition to upper extremity prosthesis, partial hand, below elbow/above elbow, custom fabricated socket insert for congenital or atypical traumatic amputee, silicone gel, elastomeric or equal, for use with or without locking mechanism, initial only (for other than initial, use code L6694 or L6695)”

8. L6697, “Addition to upper extremity prosthesis, partial hand, below elbow/above elbow, custom fabricated socket insert for other than congenital or atypical traumatic amputee, silicone gel, elastomeric or equal, for use with or without locking mechanism, initial only (for other than initial, use code L6694 or L6695)”

9. L6698, “Addition to upper extremity prosthesis, partial hand, below elbow/above elbow, lock mechanism, excludes socket insert”

10. L6883, “Replacement socket, partial hand/below elbow/wrist disarticulation, molded to patient model, for use with or without external power”

11. L7400, “Addition to upper extremity prosthesis, partial hand, below elbow/wrist disarticulation, ultralight material (titanium, carbon fiber or equal)”

12. L7403, “Addition to upper extremity prosthesis, partial hand, below elbow/wrist disarticulation, acrylic material”

Summary of Applicant's Submission

The Upper Limb Prosthetics Society of the American Academy of Orthotists and Prosthetists submitted a request to revise the existing HCPCS Level II codes L6380, L6400, L6680, L6687, L6694, L6695, L6696, L6697, L6698, L6883, L7400, and L7403, by adding partial hand and finger to their code descriptions. Each of the items for which a revision is requested describes a socket, sub-component of a socket, or an item that helps create a socket, and are classified as class I devices by the Food and Drug Administration (FDA). Partial hand and finger prostheses are critical for individuals who have undergone partial hand and/or finger amputations, and they require specialized components and fitting processes to achieve optimal prosthetic performance, comfort, and durability. Each of the codes listed describes a component of the prosthetic socket, whether the socket itself, a material sub-component, or a test socket which allows the clinician to get to a well-fitting, clinically viable prosthesis that is functional for the user. The codes currently include descriptors for below elbow and wrist disarticulation prosthetic sockets, but they do not specify partial hand and finger prosthetic sockets. The purpose of a prosthetic socket is to serve as the interface between the individual and the prosthetic components. It must be properly suspended from the limb for the individual to be able to hold and grasp objects. For partial hand, the socket often serves as the interface for operation of the prosthesis as well. The amount of clinical care, expertise, time, and materials required to address the unique functional needs of individuals with partial hand or finger loss are equivalent to what is required to provide the corresponding services to more proximal levels of upper limb difference such as wrist disarticulation and below elbow.

CMS Preliminary HCPCS Coding Recommendation

We agree with the American Academy of Orthotists and Prosthetists assessment that the current HCPCS Level II code set for partial hand prostheses does not adequately represent the evolving clinical practices in this field. We recognize the recommendation to revise 12 existing HCPCS Level II codes to better describe and categorize partial hand prostheses; however, CMS has determined that, due to advancements in technology and clinical practice, it is more appropriate to create new, distinct HCPCS Level II codes for partial hands and fingers. As such, CMS is proposing to establish the following seven new HCPCS Level II codes:

1. LXXX1, “Immediate post-surgical or early fitting, application of initial rigid dressing, including fitting alignment and suspension of components, and one cast change, finger, partial hand”

2. LXXX2, “Partial hand, flexible inner socket, endoskeletal system, molded to patient model, for use with or without external power”

3. LXXX3, “Upper extremity addition, test socket, partial hand”

4. LXXX4, “Upper extremity addition, frame type socket, partial hand”

5. LXXX5, “Replacement socket, partial hand, molded to patient model, for use with or without external power”

6. LXXX6, “Addition to upper extremity prosthesis, partial hand, ultralight material (titanium, carbon fiber or equal)”

7. LXXX7, “Addition to upper extremity prosthesis, partial hand, acrylic material”

CMS is proposing to establish a set of seven new codes, rather than 12, to help address the distinct needs of partial hand and finger prostheses. Partial hands and fingers do not require all of the same HCPCS Level II codes that are currently applied to the below-elbow and wrist disarticulation prostheses. For example, the codes for socket inserts (silicone gel, elastomeric, etc.) are not necessary for partial hand and finger prostheses, which do not rely on suspension mechanisms in the same way.

Current partial hand and finger prostheses do not have a standardized socket interface comparable to those used in lower limb prostheses or other upper limb prostheses, such as below-the-elbow, above-the-elbow, or wrist disarticulation prostheses. We recommend distinct codes for the socket interface to address different aspects of flexible inner socket fabrication for partial hand and finger prostheses. HCPCS Level II code LXXX1 is for the creation of the initial flexible inner socket, which is essential for the proper fitting and function of the prosthesis. HCPCS Level II code LXXX2 should be used when the existing flexible inner socket needs to be replaced due to damage or wear. The replacement socket will be fabricated based on the specifications of the original socket. HCPCS Level II code LXXX3 is designated for the test socket, a temporary component used during the fitting process. Creating a test socket is a standard practice for various types of prostheses, allowing for adjustments and refinements before finalizing the permanent socket.

The Department of Veterans Affairs (VA) and Department of Defense (DOD) has shown that various laboratories have developed different methods to create effective interfaces for the limb, using basic materials like silicone sheets. To address this, CMS has reviewed the existing market for partial hand and finger prostheses and is recommending a new code specifically for flexible inner sockets made from materials like silicone. For partial hand and finger prostheses, the interface for the individual functions similarly to a flexible inner socket found in the lower limb prostheses or other upper limb prostheses, such as below-the-elbow, above-the-elbow, or wrist disarticulation prostheses. This flexible inner socket is typically crafted from materials like silicone. By updating the code language to specify "flexible inner socket," CMS aims to streamline the process and eliminate the need for separate liners. Currently, the interface for partial hand and finger prostheses serves a dual purpose, acting as both a socket and a socket insert (also known as a liner). These seven proposed HCPCS Level II codes reflect the variety of approaches and materials employed to ensure a proper fit and function for prosthetic limbs.

Considering the potential changes for billing and the development of a payment determination, as discussed below, we also seek comment on when these codes should take effect.

Preliminary Medicare Benefit Category Determination

Artificial Arm.

The application supports a preliminary benefit category determination that new HCPCS Level II codes that encompass partial hand and finger prostheses would fall under the Medicare benefit category for artificial arms.

Preliminary Medicare Payment Determination

No determination.

We welcome information from the applicant and other interested parties to submit further information to CMS that would be beneficial for establishing Medicare payment corresponding to each of the preliminary new and revised HCPCS Level II codes.

Summary of Public Feedback

The Upper Limb Prosthetics Society of the American Academy of Orthotists and Prosthetists expressed general appreciation with CMS' efforts to establish a contemporary code set to describe upper limb prostheses but disagreed with some aspects of the preliminary coding recommendations as well as the preliminary payment recommendation.

The speakers disagreed with CMS' preliminary recommendation regarding HCPCS Level II code LXXX1, "Immediate post-surgical or early fitting, application of initial rigid dressing, including fitting alignment and suspension of components, and one cast change, finger, partial hand," and LXXX2, "Partial hand, flexible inner socket, endoskeletal system, molded to patient model, for use with or without external power," due to the proposed combination of socket insert codes into these codes. Since LXXX1 was proposed as an initial flexible inner socket, the speakers suggested the descriptor language for LXXX1 be updated and adapted from the language in HCPCS Level II code L6380, "Immediate post surgical or early fitting, application of initial rigid dressing, including fitting alignment and suspension of components, and one cast change, wrist disarticulation or below elbow." The speakers suggested that LXXX2 be completely withdrawn because it was proposed as the code used to replace the initial socket due to damage or wear and the language was mostly adapted from HCPCS Level II code L6400.

The speakers generally agreed with CMS' preliminary recommendations regarding HCPCS Level II codes LXXX3 through LXXX7, but suggested the descriptor language for these codes should also include the phrase "partial hand and/or finger."

The speakers expressed a need to be able to provide and bill for socket inserts and liners as separate and standalone items, therefore suggested that two additional HCPCS Level II codes LXXX8 and LXXX9 be established to describe partial hand socket inserts similar to HCPCS Level II code L6697, "Addition to upper extremity prosthesis, below elbow/above elbow, custom fabricated socket insert for other than congenital or atypical traumatic amputee, silicone gel, elastomeric or equal, for use with or without locking mechanism, initial only (for other than initial, use code l6694 or l6695)," and HCPCS Level II code L6695, "Addition to upper extremity prosthesis, below elbow/above elbow, custom fabricated from existing mold or prefabricated, socket insert, silicone gel, elastomeric or equal, not for use with locking mechanism".

The speakers also requested that HCPCS Level II code L6698, "Addition to upper extremity prosthesis, below elbow/above elbow, lock mechanism, excludes socket insert," be updated to not be level specific.

Finally, the speakers emphasized the need for CMS to assign an adequate reimbursement value for each new code because the same level of clinical time, technical time, and fabrication cost necessary to perform the transradial/wrist disarticulation services described by the existing codes similarly applies to the newly-proposed partial hand and finger prosthetic codes. While addressing smaller anatomical areas, the effort to design and fit partial hand prostheses can be equivalent to or more complex than for larger limb prostheses. Another commenter noted that the Department of Veterans Affairs (VA) has unique purchasing and clinical evaluation power as well as internal processes for price negotiations that are not attainable in the non-VA sector.

The speakers noted that they plan to submit additional applications for base codes in a subsequent biannual coding cycle.

CMS Final HCPCS Coding Decision

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

1. Establish new HCPCS Level II code L6037, "Immediate post-surgical or early fitting, application of initial rigid dressing, including fitting alignment and suspension of components, and one cast change, partial hand including fingers"

2. Establish new HCPCS Level II code L6028, "Partial hand including fingers, flexible or non-flexible interface, endoskeletal system, molded to patient model, for use without external power, not including inserts described by L6692"

3. Establish new HCPCS Level II code L6029, "Upper extremity addition, test socket/interface, partial hand including fingers"

4. Establish new HCPCS Level II code L6030, "Upper extremity addition, external frame, partial hand including fingers"

5. Establish new HCPCS Level II code L6031, "Replacement socket/interface, partial hand including fingers, molded to patient model, for use with or without external power"

6. Establish new HCPCS Level II code L6032, "Addition to upper extremity prosthesis, partial hand including fingers, ultralight material (titanium, carbon fiber or equal)"

7. Establish new HCPCS Level II code L6033, "Addition to upper extremity prosthesis, partial hand including fingers, acrylic material"

8. Revise HCPCS Level II code L6692, “Upper extremity addition, silicone gel insert or equal, each” to instead read, “Upper extremity addition, silicone gel insert or equal, with or without locking mechanism, each”

9. Revise HCPCS Level II code L6698, “Addition to upper extremity prosthesis, below elbow/above elbow, lock mechanism, excludes socket insert” to instead read “Addition to upper extremity prosthesis, lock mechanism, excludes socket insert”

These new and revised HCPCS Level II codes are intended to ensure that partial hand and finger prosthetics are properly represented in the HCPCS coding system with clear and accurate language that reflects current practices and technologies.

CMS agrees with the public comments regarding the preliminary coding recommendation for HCPCS Level II code L6037, especially the objection to the inclusion of flexible inner socket codes within this code language. It is important to note that the intention behind establishing this code is not to encompass flexible inner socket components, rather it is specifically designed for the application of initial rigid dressings and fittings during the early post-surgical phase for partial hands. This code is not intended to serve as a base for flexible inner sockets or interfaces, and CMS does not consider it applicable in this context.

CMS also agrees with the comments suggesting more clarification by adding the phrase “including fingers” to the language for the HCPCS Level II codes L6029 through L6033. This clarification is also applied to the language for HCPCS Level II codes L6037 and L6028.

CMS disagrees with the comments suggesting the withdrawal of the preliminary coding recommendation for HCPCS Level II code L6028, specifically with the assertion that this it is derived from HCPCS Level II code L6400, “Below elbow, molded socket, endoskeletal system, including soft prosthetic tissue shaping.” HCPCS Level II code L6400 applies to prostheses for below-elbow amputations and includes a post-surgical socket system, primarily intended for use in the immediate post-operative period that does not include any additional components such as pylons, cables, etc. In contrast, HCPCS Level II code L6028 is intended as a base code for the main interface used for partial hand and finger prosthetics, and it is not linked to HCPCS Level II code L6400. These two codes differ in their intended application and purpose, making their comparison inaccurate.

CMS has a history of incorporating flexible interfaces within base codes. For example, in 2015, HCPCS Level II code L6026, “Transcarpal/metacarpal or partial hand disarticulation prosthesis, external power, self-suspended, inner socket with removable forearm section, electrodes and cables, two batteries, charger, myoelectric control of terminal device, excludes terminal device(s)” was introduced as a base code for externally powered transradial, metacarpal, or partial hand prostheses, and it includes the flexible inner socket in its description. This precedent reinforces our position that it is appropriate to also include the flexible inner socket or interface as part of the base code for partial hand prosthetics. Therefore, we believe that HCPCS Level II code L6028 should serve as the base code for the flexible interface for partial hands and fingers, with the additional clarification that the phrase “including fingers” is added to the code description.

Furthermore, HCPCS Level II code L6028 includes language to clarify that this code applies only to non-externally powered devices, while HCPCS Level II code L6026 addresses

externally powered prostheses. CMS also recognizes that in some cases, materials other than rolled silicone may be used for the interface in partial hand and finger prosthetics. To account for this variation, CMS is adding the phrase "flexible or non-flexible" in the language for HCPCS Level II code L6028 to ensure that it covers a variety of materials used in the interface for partial hands and fingers, including but not limited to rolled silicone. The term "interface" is included in the language for HCPCS Level II code L6028 because the terms "socket," "insert," and "liner" are frequently used interchangeably in the partial hand and finger prosthetic market. Partial hand and finger prostheses do not align with the traditional definitions of "socket" and "liner/insert." For this reason, we believe that the term "interface" more precisely conveys the concept behind silicone roll technology.

In addition, CMS is updating the language of HCPCS Level II code L6030 to align with existing codes for lower-limb prosthetics, particularly HCPCS Level II code L5645, "Addition to lower extremity, below knee, flexible inner socket, external frame." This revision ensures that the external frame is defined clearly, without any confusion relating to flexible inner socket terminology, which will be addressed by HCPCS Level II code L6028. This code language better aligns with the established practices in lower-limb prosthetics, while also distinguishing partial hand and finger prosthetics from other types of devices.

CMS disagrees with the comments suggesting the creation of two additional HCPCS Level II codes LXXX8 and LXXX9 for billing purposes related to liners and socket inserts for locking and non-locking mechanisms. Unlike other prosthetic devices, which typically follow a standardized system of socket and insert interfaces, partial hand and finger prosthetics operate under different considerations. In partial hand and finger prosthetics, rigid sockets constructed from copolymers or plastics such as polypropylene and its copolymers are not generally utilized, though exceptions may apply. Partial hand prostheses typically incorporate interfaces made from silicone or similar materials, combined with external frames. These materials, including high-temperature vulcanized silicone, serve a critical role as a protective layer between the individuals' residual limb and the prosthetic frame. These designs are primarily intended to ensure that pressure is evenly distributed, protecting the skin and creating a secure fit. In contrast, prosthetic systems for lower limbs and even upper limbs use flexible inner sockets made from semi-flexible thermoplastic or polymer materials designed for strain relief and enhanced mobility. Given the significant differences in the material and functional roles of interfaces in partial hand prostheses versus lower limb prostheses, we do not see a need to establish separate codes for socket inserts and liners related to locking and non-locking mechanisms. Instead, CMS is modifying the existing HCPCS Level II code L6692, which covers silicone gel inserts for upper extremity prostheses, to explicitly include inserts with or without locking mechanisms for partial hand and finger prosthetics.

Lastly, CMS agrees with the comments requesting a revision to HCPCS Level II code L6698, "Addition to upper extremity prosthesis, below elbow/above elbow, lock mechanism, excludes socket insert," to reflect the applicability of locking mechanisms for partial hand and finger prostheses. Several manufacturers offer locking mechanisms designed specifically for partial hand amputations, including transcarpal and metacarpal levels. As such, CMS is revising the code language with the intent to ensure that locking mechanisms for partial hands and fingers are appropriately described by HCPCS Level II code L6698, without restricting the use of the code to any particular level of amputation.

Final Medicare Benefit Category Determination

Artificial Arm.

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.

Pricing Indicator = 46

Walkasins® Lower Extremity Sensory Prosthesis – HCP230630P62DH

Topic/Issue

Request for Medicare payment determination for Walkasins® lower extremity sensory prosthesis.

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 individuals 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 Final HCPCS Coding Decision

CMS established HCPCS Level II code L8720, "External lower extremity sensory prosthetic device, cutaneous stimulation of mechanoreceptors proximal to the ankle, per leg" to describe Walkasins®, effective October 1, 2024.

Medicare Benefit Category Determination

CMS determined that Walkasins® lower extremity sensory prosthesis is a Prosthetic Device, effective October 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. In determining whether the device described by this code are comparable to items with existing codes and fee schedule amounts, we undertook a detailed examination of the physical, mechanical, and electrical components along with the function and intended use, in comparison with HCPCS Level II code E0734, “external upper limb tremor stimulator of the peripheral nerves of the wrist”. See table below.

The device named Cala kIQ™ (formerly known as CalaTrio™) is coded under HCPCS Level II code E0734.We do not think that they are comparable given the significant differences in their technologies and functions. In particular, Cala kIQ™ employs transcutaneous afferent patterned stimulation (TAPS) and uses triaxial accelerometers to measure tremor. The device then adjusts the stimulation pattern based on this data. It operates on a biphasic waveform, delivering rectangular pulses at 150 Hz with a 300 μs pulse width and a 50 μs interpulse period, alternating between the median and radial nerves to match the tremor frequency. In contrast, Walkasins® uses mechanical tactile stimulation to target the plantar mechanoreceptors in the feet. It features sensors embedded in the soles to detect changes in foot pressure and maintain balance. Walkasins® operates on a monophasic waveform, providing tactile stimuli at a frequency similar to a 128 Hz tuning fork. Unlike Cala kIQ™, Walkasins® does not use triaxial accelerometers but instead focuses on replacing lost mechanoreceptor function to aid in gait and balance.

In addition, Cala kIQ™ utilizes TAPS, a non-invasive neuromodulation therapy designed for treating hand tremors in individuals with essential tremor. This FDA-cleared, wrist-worn neurostimulation device customizes stimulation based on each individual’s unique physiology, delivering alternating signals to the median and radial peripheral nerves. In contrast, Walkasins® provides afferent nerve stimulation aimed at addressing peripheral neuropathy. It focuses on replacing the ability to sense and communicate critical plantar pressure information needed for gait and balance. Unlike Cala kIQ™, Walkasins® does not alternate stimulation signals between different nerves. Instead, it aims to compensate for lost plantar mechanoreceptor function.

While both Walkasins® and Cala kIQ™ are non-invasive and use advanced technology to assist in sensorimotor control, their approaches are fundamentally different. Walkasins® is tailored to enhance lower limb sensory feedback and balance in individuals with peripheral neuropathy, whereas Cala kIQ™ is designed to modulate neural activity in the upper limbs to alleviate hand tremors associated with essential tremor.

Regarding their technology, Walkasins® utilizes pressure sensors integrated into the insoles of footwear to monitor and respond to variations in foot pressure. This setup allows the device to provide feedback that helps with balance and gait. On the other hand, Cala kIQ™ employs electrodes placed on the wrist to deliver electrical stimulation directly to the peripheral nerves, targeting tremor control.

The fundamental differences in their mechanisms, therapeutic goals, and technological approaches emphasize the necessity of a thorough evaluation when assessing their effectiveness and appropriateness for their specific conditions. Each device's unique method of intervention highlights the need for careful consideration to determine which is more suitable for addressing the distinct issues faced by their respective individual populations.

For these reasons, we have determined that no items described by HCPCS Level II codes with existing fee schedule amounts are comparable to HCPCS Level II code E0734 and it is most appropriate to determine the Medicare payment amount in accordance with the "gap filling" procedure outlined in 42 CFR 414.238(c).

	L8720	**E0734**
Physical Components	Haptic module worn around the ankle Charging adapter and cable	Stimulator AC-powered base station
Mechanical Components	-	Tri-axial accelerometer
Electrical Components	Monophasic wave Vibrotactile stimulation Lithium-Ion rechargeable battery	Biphasic waveform On-board motion sensors on the stimulator Lithium-Ion rechargeable battery
Function and Intended Use	Delivers mechanical tactile stimulation with the intent to naturally stimulate intact mechanoreceptors above the ankle while avoiding sensation adaptation effects (no numbing) To treat various types of peripheral neuropathy and gait and standing imbalance	Delivers transcutaneous afferent patterned stimulation (TAPS) for hand tremors in essential tremor individuals The Cala kIQ™ stimulator is attached to the wrist band, which includes integrated electrodes placed at appropriate intervals around the inner diameter of the band to properly target the median and radial nerves. To aid in the temporary relief of hand tremors in adults with essential tremor.
Additional Aspects and Features	10-week treatment Used as needed by the individual	2-week treatment with at least 5 sessions Used as needed by the individual

In accordance with regulations at 42 CFR 414.238(c), items and services described by new HCPCS Level II codes that do not have a fee schedule pricing history and that are not comparable to items and services with existing fee schedule amounts may be established using supplier price lists, including catalogs and other retail price lists (such as internet retail prices) that provide information on commercial pricing for the item. Potential appropriate sources for such commercial pricing information can also include payments made by Medicare Advantage plans, as well as verifiable information from supplier invoices and non-Medicare payer data. If the only available price information is from a period other than the fee schedule base period, deflation factors are applied against current pricing in order to approximate the base period price. 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 also listed in these program instructions.

The applicant has sent us several invoices for the Walkasins® Lower Extremity Sensory Prosthesis. These invoices are mainly from VA locations across the country, as well as some invoices from individuals who self-pay for the device. The median invoice price is $2,485 for

each unit (one unit being one Walkasins® Lower Extremity Sensory Prosthesis, per leg). The applicant has also informed us that the supplier retail price is $3,350 for each unit. However, we have not received any invoices from the applicant showing that this amount has been paid. Therefore, we will not be including this $3,350 amount in our median calculation.

In accordance with regulations at 42 CFR 414.238(c), $2,485 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, the 2024 payment amount for HCPCS Level II code L8720 would be approximately $1,667.29. It is our understanding that when a Walkasins® Lower Extremity Sensory Prosthesis is furnished it also includes a Walkasins® Receptor Sole. As such, HCPCS Level II code L8720 includes payment for one Walkasins® Receptor Sole.

Pricing Indicator = 38

Summary of Public Feedback

RxFunction, Inc. and others provided written and oral comments urging CMS to reevaluate the comparability of Walkasins® to Cala kIQ™. First, the speaker compared the mechanisms between the two devices and said that both devices use advanced sensor components and microprocessors to calibrate stimulation to the individual user, and to alternate stimulation between multiple nerve locations. Both devices use sensors to detect patient motion, and to pattern the stimulation to each individual patient's movement. Both devices are non-invasive, wearable nerve stimulation devices that directly provide afferent (or sensory) stimulation to peripheral nerves in the limb. The speakers then discussed how in terms of therapeutic goals, the noninvasive, precise stimulation from both devices is intended to affect the central nervous system through neuromodulation. They said that prior CMS decisions confirm that devices can be comparable even if providing noninvasive neuromodulation to different body parts. The ultimate therapeutic goal of each device is to provide afferent stimulation to improve a deficiency or limitation of involuntary motor control or response. Both devices treat debilitating symptoms of a neurological condition, for which there is otherwise no cure, to allow people to overcome limitations impacting their ability to perform activities of daily living (ADLs). Finally, the speakers stated that both devices use technological approaches that are very similar. Each system incorporates advanced sensors to provide input to a microprocessor with a complex software algorithm contained in the durable stimulator unit. The microprocessor and software algorithm process detected motion in real-time to automatically calibrate stimulation output. Both devices use multiple, noninvasive stimulation components to stimulate multiple peripheral nerves. The sensors, software algorithm, and the precise application of patterned stimulation are unique and required to achieve each device's medical outcome and improvements in that patient's motor symptoms. The speakers said that if CMS maintains that Walkasins® is not comparable to Cala kIQ™, then CMS should defer the final payment determination until RxFunction becomes accredited as a supplier.

The speakers discussed how they do not believe self-pay and Veterans Affairs (VA) pricing represent true commercial pricing. For instance, VA pricing for Walkasins® does not reflect true commercial pricing but instead reflects the reduced costs associated with VA acquisition

versus supplying items to patients enrolled in Medicare, Medicare Advantage, Medicaid, or commercial insurance plans. The speakers said the invoices CMS used for gap-filling are not "supplier" invoices, "supplier prices", or suppliers' non-Medicare payor data because RxFunction is a manufacturer and not yet a Medicare supplier. In this role, RxFunction has been serving the VA through manufacturer-direct sales to the VA system. The speakers noted that RxFunction's VA pricing amounts for the Walkasins® System and the replacement Receptor Soles reflect wholesale manufacturer prices – not retail prices or supplier prices that take account of the significant supplier costs of accreditation, enrollment, documentation, claim submission, and other activities that suppliers must incur but are not applicable to manufacturer direct VA sales. The speakers also discussed how unique circumstances prevented commercial transactions for the Walkasins®. For example, they stated that they did not have a prosthetic device miscellaneous or not otherwise classified HCPCS code, nor any defined HCPCS code, available for billing Walkasins®.

Some patients testified about the value Walkasins® has played in their lives and urged that CMS ensure access to the device. One patient spoke of how there may be people who could benefit from but cannot afford the device.

CMS asked the speakers several questions during the meeting about pricing. For one, CMS discussed how the regulations at 42 CFR 414.238(c) state that potential appropriate sources for commercial pricing information include verifiable information from supplier invoices and non-Medicare payer data. CMS asked the speaker why they believed that supplier invoices with prices paid by non-Medicare payers and self-paid customers for the Walkasins® device are not commercial prices that can be used for gap filling fee schedule amounts in accordance with the regulation. The speaker responded that VA and self-pay invoices do not carry the same service delivery expenses as commercial payers. When RxFunction established pricing to the VA in 2019, they utilized the regulation around most favored customer. The decision was made at the time that the pricing would be an absolute floor. This is because there are no billing costs, no accreditation cost, and no service delivery costs associated with doing business where claims have to be submitted. As it is a direct sale to the VA, this does not represent the commercial pricing that would be necessary to go beyond the VA system.

CMS also stated that they had received some self-pay claims for Walkasins® going back several years with a similar price as used by the VA. CMS asked how RxFunction was able to furnish the device at this price if the benefits of VA acquisition were not involved. The speaker responded that the self-pay has a little higher of a price than the VA, but the thought process when selling direct to a consumer is similar in that it is a credit card exchange, and there are no other services provided. The speaker said they priced what they felt was an appropriate price given the reduction of services and associated costs.

CMS stated that they assume that RxFunction believes the commercial prices obtained in the future will be higher than the commercial prices paid over the past 5 years. CMS then asked what is the reason for the increase in price? Why can a product no longer be furnished at the prices paid over the past 5 years? The speaker responded that it has to do with the additional costs of becoming accredited, a billing system, receiving and reviewing documentation, submitting claims, going through appeals processes if claims are not paid or not completely paid, internal support, technical support, and customer support. The speaker said they think the price will be higher because they must cover the manufacturer cost of a very sophisticated prosthetic device, and all associated costs with providing the product. The speaker also noted that they will provide education and training in the patient's home.

One commenter said based on the language of Medicare's regulation at 42 CFR 414.238(c), the payment information provided by RxFunction is not "verifiable supplier or commercial pricing" that can be used for the gap-filling process. Rather than supplier prices, all the information provided by RxFunction to date is direct sale from a manufacturer to other healthcare facilities (VA hospitals) or directly to patients. The commenter stated that no other verifiable pricing information is available, and the lack of "supplier price lists," "supplier invoices," or other verifiable retail price lists creates a deficiency in the proposed application of Medicare's gap fill-payment regulation.

Final Medicare Payment Determination

No determination. We have information that we are continuing to evaluate.

In the interim, 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 for Medicare payment determination for Walkasins® receptor sole.

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 individuals 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 Final HCPCS Coding Decision

CMS established HCPCS Level II code L8721, “Receptor sole for use with L8720, replacement, each” to describe Walkasins® receptor sole, effective October 1, 2024.

Medicare Benefit Category Determination

CMS determined that Walkasins® receptor sole is an accessory for a prosthetic device, effective October 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. In determining whether the device described by this code are comparable to items with existing codes and fee schedule amounts, we undertook a detailed examination of the physical, mechanical, and electrical components along with the function and intended use, in comparison with HCPCS Level II code A4542, "supplies and accessories for external upper limb tremor stimulator of the peripheral nerves of the wrist." See table below.

The wrist worn connector for the device named Cala kIQ™ (formerly known as CalaTrio) is coded under HCPCS Level II code A4542. In sum, the two systems are designed to trigger different types of sensory receptors, which implies that they deliver different forms of stimulation. The mechanisms for how each system delivers frequencies also differ. These variations suggest that their approaches to stimulation are not directly comparable. While both hand tremors and gait imbalance are neurological disorders, they do not necessarily require the same type of intervention or follow the same treatment protocols. For these reasons, we have determined it is most appropriate to determine the Medicare payment amount in accordance with the "gap filling" procedure outlined in 42 CFR 414.238(c).

	L8721	**A4542**
Physical Components	Plantar pressure sensor	Wrist-worn band
Mechanical Components	-	-
Electrical Components	Force Sensor resistors	Three electrodes embedded in the wrist-worn band
Function and Intended Use	Detect pressure information from the bottom of the feet that is no longer detected by the damaged plantar mechanoreceptors. This information is analyzed and transmitted via the connection between the Receptor Sole and the Haptic Module which then stimulates a different set of healthy mechanoreceptors around/above the ankle. Through a proprietary algorithm, vibration stimuli communicate the lost plantar pressure information to the central nervous system. Receptor sole is placed under the foot Indicated for individuals with lower limb sensory peripheral neuropathy who present with gait and balance impairments	Applies transcutaneous afferent patterned stimulation (TAPS) to the median and radial nerves of an individual's wrist on the wrist band The stimulation delivery and device operation are managed through the embedded firmware control. The electrode band is worn around the wrist Indicated to aid in the temporary relief of hand tremors in adults with essential tremor. Intended to properly target the median and radial nerves through integrated electrodes placed at appropriate intervals around the inner diameter of the band

	Intended to replace part of nerve function used for detection and signaling of foot pressure sensation	
Additional Aspects and Features	Disposable pressure sensors Sole receptor is available in one size	Disposable electrodes Biocompatible wrist band Wrist band is available in different sizes (small, medium, and large) Wrist bands are available in right- or left-handed version

In accordance with regulations at 42 CFR 414.238(c), items and services described by new HCPCS Level II codes that do not have a fee schedule pricing history and that are not comparable to items and services with existing fee schedule amounts may be established using supplier price lists, including catalogs and other retail price lists (such as internet retail prices) that provide information on commercial pricing for the item. Potential appropriate sources for such commercial pricing information can also include payments made by Medicare Advantage plans, as well as verifiable information from supplier invoices and non-Medicare payer data. If the only available price information is from a period other than the fee schedule base period, deflation factors are applied against current pricing in order to approximate the base period price. 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 also listed in these program instructions.

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 60739).

The applicant has sent us several invoices for the Walkasins® Receptor Sole. These invoices are mainly from VA locations across the country, as well one invoice from an individual who self-paid for the Walkasins® Receptor Sole. The median invoice price is $220 for each Walkasins® Receptor Sole.

In accordance with regulations at 42 CFR 414.238(c), $220 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, the 2024 payment amount for HCPCS Level II code L8721 would be approximately $147.59.

It is our understanding that when a Walkasins® Lower Extremity Sensory Prosthesis is furnished it also includes a Walkasins® Receptor Sole. As such, HCPCS Level II code L8721 is only for the replacement of a Walkasins® Receptor Sole.

Pricing Indicator = 38

Summary of Public Feedback

RxFunction, Inc. and others provided written and oral comments urging CMS to reevaluate the comparability of Walkasins® to Cala kIQ™. First, the speaker compared the mechanisms between the two devices and said that both devices use advanced sensor components and microprocessors to calibrate stimulation to the individual user, and to alternate stimulation between multiple nerve locations. Both devices use sensors to detect patient motion, and to pattern the stimulation to each individual patient's movement. Both devices are non-invasive, wearable nerve stimulation devices that directly provide afferent (or sensory) stimulation to peripheral nerves in the limb. The speakers then discussed how in terms of therapeutic goals, the noninvasive, precise stimulation from both devices is intended to affect the central nervous system through neuromodulation. They said that prior CMS decisions confirm that devices can be comparable even if providing noninvasive neuromodulation to different body parts. The ultimate therapeutic goal of each device is to provide afferent stimulation to improve a deficiency or limitation of involuntary motor control or response. Both devices treat debilitating symptoms of a neurological condition, for which there is otherwise no cure, to allow people to overcome limitations impacting their ability to perform activities of daily living (ADLs). Finally, the speakers stated that both devices use technological approaches that are very similar. Each system incorporates advanced sensors to provide input to a microprocessor with a complex software algorithm contained in the durable stimulator unit. The microprocessor and software algorithm process detected motion in real-time to automatically calibrate stimulation output. Both devices use multiple, noninvasive stimulation components to stimulate multiple peripheral nerves. The sensors, software algorithm, and the precise application of patterned stimulation are unique and required to achieve each device's medical outcome and improvements in that patient's motor symptoms. The speakers said that if CMS maintains that Walkasins® is not comparable to Cala kIQ™, then CMS should defer the final payment determination until RxFunction becomes accredited as a supplier.

The speakers discussed how they do not believe self-pay and Veterans Affairs (VA) pricing represent true commercial pricing. For instance, VA pricing for Walkasins® does not reflect true commercial pricing but instead reflects the reduced costs associated with VA acquisition versus supplying items to patients enrolled in Medicare, Medicare Advantage, Medicaid, or commercial insurance plans. The speakers said the invoices CMS used for gap-filling are not "supplier" invoices, "supplier prices", or suppliers' non-Medicare payor data because RxFunction is a manufacturer and not yet a Medicare supplier. In this role, RxFunction has been serving the VA through manufacturer-direct sales to the VA system. The speakers noted that RxFunction's VA pricing amounts for the Walkasins® System and the replacement Receptor Soles reflect wholesale manufacturer prices – not retail prices or supplier prices that take account of the significant supplier costs of accreditation, enrollment, documentation, claim submission, and other activities that suppliers must incur but are not applicable to manufacturer direct VA sales. The speakers also discussed how unique circumstances prevented commercial transactions for the Walkasins®. For example, they stated that they did not have a prosthetic device miscellaneous or not otherwise classified HCPCS code, nor any defined HCPCS code, available for billing Walkasins®.

Some patients testified about the value Walkasins® has played in their lives and urged that CMS ensure access to the device. One patient spoke of how there may be people who could benefit from but cannot afford the device.

CMS asked the speakers several questions during the meeting about pricing. For one, CMS discussed how the regulations at 42 CFR 414.238(c) state that potential appropriate sources for commercial pricing information include verifiable information from supplier invoices and non-Medicare payer data. CMS asked the speaker why they believed that supplier invoices with prices paid by non-Medicare payers and self-paid customers for the Walkasins® device are not commercial prices that can be used for gap filling fee schedule amounts in accordance with the regulation. The speaker responded that VA and self-pay invoices do not carry the same service delivery expenses as commercial payers. When RxFunction established pricing to the VA in 2019, they utilized the regulation around most favored customer. The decision was made at the time that the pricing would be an absolute floor. This is because there are no billing costs, no accreditation cost, and no service delivery costs associated with doing business where claims have to be submitted. As it is a direct sale to the VA, this does not represent the commercial pricing that would be necessary to go beyond the VA system.

CMS also stated that they had received some self-pay claims for Walkasins® going back several years with a similar price as used by the VA. CMS asked how RxFunction was able to furnish the device at this price if the benefits of VA acquisition were not involved. The speaker responded that the self-pay has a little higher of a price than the VA, but the thought process when selling direct to a consumer is similar in that it is a credit card exchange, and there are no other services provided. The speaker said they priced what they felt was an appropriate price given the reduction of services and associated costs.

CMS stated that they assume that RxFunction believes the commercial prices obtained in the future will be higher than the commercial prices paid over the past 5 years. CMS then asked what is the reason for the increase in price? Why can a product no longer be furnished at the prices paid over the past 5 years? The speaker responded that it has to do with the additional costs of becoming accredited, a billing system, receiving and reviewing documentation, submitting claims, going through appeals processes if claims are not paid or not completely paid, internal support, technical support, and customer support. The speaker said they think the price will be higher because they must cover the manufacturer cost of a very sophisticated prosthetic device, and all associated costs with providing the product. The speaker also noted that they will provide education and training in the patient's home.

One commenter said based on the language of Medicare's regulation at 42 CFR414.238(c), the payment information provided by RxFunction is not "verifiable supplier or commercial pricing" that can be used for the gap-filling process. Rather than supplier prices, all the information provided by RxFunction to date is direct sale from a manufacturer to other healthcare facilities (VA hospitals) or directly to patients. The commenter stated that no other verifiable pricing information is available, and the lack of "supplier price lists," "supplier invoices," or other verifiable retail price lists creates a deficiency in the proposed application of Medicare's gap fill-payment regulation.

Final Medicare Payment Determination

No determination. We have information that we are continuing to evaluate.

In the interim, 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

Breast Prosthesis, Mastectomy Sleeve - IHC2407191WHRL

Topic/Issue

Discontinue existing HCPCS Level II code L8010, “Breast prosthesis, mastectomy sleeve.”

Summary of Applicant's Submission

Medicare pays for lymphedema compression treatment items under the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) benefit for individuals with Medicare Part B. The lymphedema compression treatment items benefit category is defined in section 1861(s)(2)(JJ) of the Social Security Act, and further defined in Medicare regulations at 42 Code of Federal Regulations (CFR) 410.36(a)(4). When defining the scope of this benefit category in rulemaking (CMS-1780-F), CMS received public input suggesting deletion of HCPCS Level II code L8010, “Breast prosthesis, mastectomy sleeve” and CMS indicated that proposal would be taken into consideration at a future date.

CMS Preliminary HCPCS Coding Recommendation

After further consideration of the public input received when defining the scope of this benefit category in rulemaking (CMS-1780-F), CMS is now recommending that this code be removed from the HCPCS Level II code set. As such, CMS is proposing to:

Discontinue existing HCPCS Level II code L8010, “Breast prosthesis, mastectomy sleeve” as there are other HCPCS Level II codes that should be used in its place. Existing HCPCS Level II codes A6576, A6577, or A6578 can instead be used in place of HCPCS Level II code L8010.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

As discussed in the CMS Preliminary HCPCS Coding Recommendation, HCPCS Level II codes A6576, A6577, or A6578 can be used in place of HCPCS Level II code L8010.

The payment rules and pricing associated with existing HCPCS Level II codes A6576, A6577, and A6578 apply to this product, if covered. The current average 2024 fee schedule amount for HCPCS Level II code A6576 is $184.50. The current average 2024 fee schedule amount for HCPCS Level II code A6577 is $152.70. The current average 2024 fee schedule amount for HCPCS Level II code A6578 is $75.20.

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 = 40

Summary of Public Feedback

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

CMS Final HCPCS Coding Decision

CMS is finalizing its preliminary recommendation to:

Discontinue existing HCPCS Level II code L8010, "Breast prosthesis, mastectomy sleeve" as there are other HCPCS Level II codes that should be used in its place. Existing HCPCS Level II codes A6576, A6577, or A6578 can instead be used in place of HCPCS Level II code L8010.

Final Medicare Benefit Category Determination

For HCPCS Level II codes A6576, A6577, or A6578: Lymphedema Compression Treatment Item.

Final Medicare Payment Determination

As discussed in the CMS HCPCS Coding Decision, HCPCS Level II codes A6576, A6577, or A6578 can be used in place of HCPCS Level II code L8010.

The payment rules and pricing associated with existing HCPCS Level II codes A6576, A6577, and A6578 apply to this product, if covered. The current average 2025 fee schedule amount for HCPCS Level II code A6576 is $190.03. The current average 2025 fee schedule amount for HCPCS Level II code A6577 is $157.28. The current average 2025 fee schedule amount for HCPCS Level II code A6578 is $77.46.

The average fee schedule amount is the average of the 2025 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 = 40

Gradient Compression Nighttime Garment, Not Otherwise Specified - HCP2406275UFBP

Topic/Issue

Request to establish a new HCPCS Level II code to identify a not otherwise classified (NOC) code for a nighttime gradient compression garment.

Applicant's suggested language: XXXXX, “Gradient compression garment, not otherwise specified, padded, for nighttime use, each”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code to identify a NOC code for a nighttime gradient compression garment. Nighttime garments are manufactured to incorporate a textured surface against the skin, which is achieved in a few different formats based on current technology on the market, such as: chip foam, flat foam, channel foam, polyfill, and 3D knit structure. These garments are primarily cut or knit to size, filled with texture-based solution/knit with texture, and lastly sewn. Many of them also integrate built-in directional channeling based on the lymphatic pathways. Nighttime garments have the unique ability to maintain lymphedema safely overnight / during low activity with its lower levels of compression and containment based on medium-stretch fabric properties. Additionally, its textured surface provides a unique pressure differential on the tissue with high and low pressures designed to help stimulate the tissue, break up and soften fibrosis and support long term tissue health for lymphedema. A NOC nighttime HCPCS Level II code would allow for submission of claims for nighttime products that do not fall within the existing HCPCS Level II codes (e.g., head and neck, torso, genital). The addition of a nighttime specific NOC HCPCS Level II code would also aid in the prevention of unintentional denials or overlap with HCPCS Level II code A6549, “Gradient compression garment, not otherwise specified,” which would be utilized for daytime products. Without delineation between daytime and nighttime for NOC codes, it will be difficult to track and respond to claims for the two different quantity and replacement frequency allotments per individual.

CMS Preliminary HCPCS Coding Recommendation

The applicant has requested a new HCPCS Level II code (gradient compression garment, not otherwise specified, padded for nighttime use, each), because the existing nighttime HCPCS Level II code set is limited to codes for limbs and a bra. The applicant has explained that a not otherwise specified HCPCS Level II code is necessary to allow for submission of claims for nighttime products that do not fall within the published HCPCS Level II codes for nighttime garments (e.g., head and neck, torso, genital).

Currently, HCPCS Level II code A6549 was intended for use for daytime and nighttime garments. However, we agree with adding a new “not otherwise specified” code for nighttime gradient compression garments given that utilization limits for nighttime garments are different than for daytime garments. However, we have not included the requested word “padded” to achieve the requested effect, e.g., create a not otherwise specified code for nighttime garments to differentiate from the existing not otherwise specified code for daytime

garments. We are also revising existing HCPCS Level II code A6549 to be clear that it would not be intended for use with daytime garments. As such, CMS is proposing to:

1. Establish new HCPCS Level II code AXXXX, "Gradient compression garment, not otherwise specified, for nighttime use, each" to describe a nighttime gradient compression garment.

2. Revise HCPCS Level II code A6549, "Gradient compression garment, not otherwise specified" to instead read "Gradient compression garment, not otherwise specified, for daytime use, each" to describe a daytime gradient compression garment.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for claims submitted using HCPCS Level II "Not Otherwise Specified" codes are made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Summary of Public Feedback

See Appendix A for a summary of public feedback for the HCPCS Level II lymphedema management applications.

CMS Final HCPCS Coding Decision

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

1. Establish new HCPCS Level II code A6519, "Gradient compression garment, not otherwise specified, for nighttime use, each" to describe a nighttime gradient compression garment.

2. Revise HCPCS Level II code A6549, "Gradient compression garment, not otherwise specified" to instead read "Gradient compression garment, not otherwise specified, for daytime use, each" to describe a daytime gradient compression garment.

Final Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Final Medicare Payment Determination

The payment determination for claims submitted using HCPCS Level II "Not Otherwise Specified" codes are made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 40

Gradient Compression Wrap Below Knee - HCP240625X0PEW

Topic/Issue

Request to revise existing HCPCS Level II code A6583, “Gradient compression wrap with adjustable straps, below knee, 30-50 mmhg, each” to remove “30-50 mmhg.”

Applicant's suggested language: A6583, "Gradient compression wrap with adjustable straps, Below Knee, each"

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to revise existing HCPCS Level II code A6583 to remove “30-50 mmHg.” The current long description of existing HCPCS Level II code A6583 includes “30-50 mmhg”, however, due to the variations in levels of adjustability and to align language with the other adjustable wrap codes that do not specify mmHg, the code language should be revised. Gradient compression wraps with adjustable straps are uniquely constructed from multiple layers of textiles that are sewn, laminated or bonded together to create a fabric that has minimal stretch (inelastic) and high rigidity. The textiles may include but are not limited to nylon, foam, and textured fabric delivering the highest stiffness/containment compared to other compression garments. These garments use clasps or hook and loop closures to enable adjustability providing greater independence, adherence, and efficacy for individual management of their lymphedema symptoms. HCPCS Level II code A6583 maintained the 30-50 mmHg language from the pre-existing surgical dressing HCPCS Level II code A6545. A revised description is necessary for proper product selection to effectively manage an individual’s lymphedema and to align with the other gradient compression wrap with adjustable straps HCPCS Level II codes that do not specify mmHg.

CMS Preliminary HCPCS Coding Recommendation

CMS agrees with the request to remove the “30-50 mmhg” portion of the description for HCPCS Level II code A6583 so that it aligns with the other gradient compression wrap with adjustable wrap HCPCS Level II codes that do not specify mmHg. As such, CMS is proposing to:

Revise existing HCPCS Level II code A6583, “Gradient compression wrap with adjustable straps, below knee, 30-50 mmhg, each” to instead read “Gradient compression wrap with adjustable straps, below knee, each” to describe below knee gradient compression wraps.

Preliminary Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for HCPCS Level II code A6583 applies.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code A6583 apply to this product, if covered. Fee schedules are updated annually.

Pricing Indicator = 40

Summary of Public Feedback

See Appendix A for a summary of public feedback for the HCPCS Level II lymphedema management applications.

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:

Revise existing HCPCS Level II code A6583, "Gradient compression wrap with adjustable straps, below knee, 30-50 mmhg, each" to instead read "Gradient compression wrap with adjustable straps, below knee, each" to describe below knee gradient compression wraps.

Final Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Final Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code A6583 apply to this product, if covered. Fee schedules are updated annually.

Pricing Indicator = 40

Gradient Compression Custom Wrap Above Knee - HCP240626P6WKG

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression custom wrap for above the knee.

Applicant's suggested language: XXXXX, “Gradient compression wrap with adjustable straps, Above Knee, each, custom”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression custom wrap for above knee. The proposed code is necessary to recognize the specific textile/technology, precise anatomical location of lymphedema, and custom version of the product. Adjustable wrap items are uniquely constructed from multiple layers of textiles that are sewn, laminated or bonded together to create a fabric that has minimal stretch (inelastic) and high rigidity. The textiles may include but are not limited to nylon, foam, and textured fabric delivering the highest stiffness/containment compared to other compression garments. These garments use clasps or hook and loop closures to enable adjustability providing greater patient independence, adherence, and efficacy. The Lymphedema Treatment Act amended title XVIII of the Social Security Act to provide coverage of certain lymphedema compression treatment items under Medicare. The term ‘lymphedema compression treatment items’ means standard and custom fitted gradient compression garments determined to serve a medical purpose and for the treatment of lymphedema.

CMS Preliminary HCPCS Coding Recommendation

CMS has generally created custom made and corresponding non-custom-made codes for lymphedema compression treatment items in the HCPCS Level II code set. We understand that lymphedema compression treatment items can come in both standard and custom-fitted form, and that there are distinct differences between the two. CMS described these differences in the Background section of the 2023 Lymphedema Compression Treatment Items Rule (88 FR 77812), “Standard compression garments are also referred to as ready-made or ready-to wear and are widely available pre-made, off-the-shelf and in a range of standard sizes;” and, “Custom-fit gradient compression garments are garments that are uniquely sized, shaped, and custom made to fit the exact dimensions of the affected extremity (circumferential measurements are every 1 and a half to 2 inches) and provide more accurate and consistent gradient compression to manage the individual’s symptoms.” Given these distinct differences CMS agrees with the request to create a new HCPCS Level II code. This code request is for a custom-made equivalent code to correspond with the non-custom HCPCS Level II code A6585. As such, CMS is proposing to:

Establish a new HCPCS Level II code AXXXX, “Gradient compression wrap with adjustable straps, above knee, each, custom” to describe custom above knee gradient compression wraps.

In addition, we would revise the description for HCPCS Level II code A6585 to replace the word “pressure” with “compression” so that the description is more consistent with the

HCPCS Level II code descriptions used for lymphedema compression treatment items. CMS is also proposing to:

Revise existing HCPCS Level II code A6585, “Gradient pressure wrap with adjustable straps, above knee, each” to instead read “Gradient compression wrap with adjustable straps, above knee, each” to describe above knee gradient compression wraps.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

Section 1834(z)(1) of the Social Security Act mandates an appropriate payment basis for lymphedema compression treatment items defined in section 1861(mmm) of the Act and specifically identifies payment rates from other government and private sector payers that may be taken into account in establishing the payment basis for these items. These sources include payment rates used by Medicaid state plans, the Veterans Health Administration (VHA), group health plans, and health insurance coverage (as defined in section 2791 of the Public Health Service Act). Section 1834(z)(1) of the Act also indicates that other information determined to be appropriate may be taken into account in establishing the payment basis for lymphedema compression treatment items.

In accordance with 42 CFR 414.1650(b), and as discussed in our CY 2024 rule (88 FR 77831), where Medicaid state plan payment amounts are available for a lymphedema compression treatment item, we set payment amounts at 120 percent of the average of the Medicaid payment amounts for the lymphedema compression treatment item. Where Medicaid payment amounts are not available for an item, we set payment amounts at 100 percent of the average of internet retail prices and payment amounts for that item from TRICARE. Where payment amounts are not available from Medicaid state plans or TRICARE for a given lymphedema compression treatment item, we base payment amounts based on 100 percent of average internet retail prices for that item.

We discussed in our CY 2024 rule (88 FR 77832) that when new items are added to this Lymphedema Compression Treatment Item benefit category, the data sources (Medicaid, TRICARE, VHA, or internet prices) may not initially be available for establishing an appropriate payment amount. We said that in this situation, until the data necessary for establishing the payment amount becomes available, the DME MACs would consider what an appropriate payment amount would be for each item on an individual, claim-by-claim basis and may consider using pricing for similar items that already have established payment amounts.

We have not been able to identify payment amounts from any of the data sources (Medicaid, TRICARE, VHA, or internet prices). As such, claims for new HCPCS Level II code AXXXX will be priced by the DME MACs on a claim-by-claim basis.

Pricing Indicator = 46

Summary of Public Feedback

See Appendix A for a summary of public feedback for the HCPCS Level II lymphedema management applications.

CMS Final HCPCS Coding Decision

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

1. Establish a new HCPCS Level II code A6611, "Gradient compression wrap with adjustable straps, above knee, each, custom" to describe custom above knee gradient compression wraps.

2. Revise existing HCPCS Level II code A6585, "Gradient pressure wrap with adjustable straps, above knee, each" to instead read "Gradient compression wrap with adjustable straps, above knee, each" to describe above knee gradient compression wraps.

Final Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Final Medicare Payment Determination

As stated in the preliminary determination, we have not been able to identify payment amounts from any of the data sources (Medicaid, TRICARE, VHA, or internet prices) in order to establish a national fee schedule amount. As such, we are finalizing the preliminary determination and claims for new HCPCS Level II code A6611 will be priced by the DME MACs on a claim-by-claim basis.

Pricing Indicator = 40

Gradient Compression Custom Wrap Arm - HCP240626R5DGX

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression custom wrap for the arm.

Applicant's suggested language: XXXXX, “Gradient compression wrap with adjustable straps, Arm, each, custom”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression custom wrap for the arm. The proposed code is necessary to recognize the specific textile/technology, precise anatomical location of lymphedema, and specification of customization. Adjustable wrap items are uniquely constructed from multiple layers of textiles that are sewn, laminated or bonded together to create a fabric that has minimal stretch (inelastic) and high rigidity. The textiles may include but are not limited to nylon, foam, and textured fabric delivering the highest stiffness/containment compared to other compression garments. These garments use clasps and hook and loop closures to enable adjustability providing greater patient independence, adherence, and efficacy. The Lymphedema Treatment Act amended title XVIII of the Social Security Act to provide coverage of certain lymphedema compression treatment items under Medicare. The term ‘lymphedema compression treatment items’ means standard and custom fitted gradient compression garments determined to serve a medical purpose and for the treatment of lymphedema.

CMS Preliminary HCPCS Coding Recommendation

CMS has generally created custom made and corresponding non-custom-made codes for lymphedema compression treatment items in the HCPCS Level II code set. We understand that lymphedema compression treatment items can come in both standard and custom-fitted form, and that there are distinct differences between the two. CMS described these differences in the Background section of the 2023 Lymphedema Compression Treatment Items Rule (88 FR 77812), “Standard compression garments are also referred to as ready-made or ready-to wear and are widely available pre-made, off-the-shelf and in a range of standard sizes;” and, “Custom-fit gradient compression garments are garments that are uniquely sized, shaped, and custom made to fit the exact dimensions of the affected extremity (circumferential measurements are every 1 and a half to 2 inches) and provide more accurate and consistent gradient compression to manage the individual’s symptoms.” Given these distinct differences CMS agrees with the request to create a new HCPCS Level II code. This code request is for a custom-made equivalent code to correspond with the non-custom HCPCS Level II code A6588. As such, CMS is proposing to:

Establish a new HCPCS Level II code AXXXX, “Gradient compression wrap with adjustable straps, arm, each, custom” to describe custom arm gradient compression wraps.

In addition, we would revise the description for HCPCS Level II code A6588 to replace the word “pressure” with “compression” so that the description is more consistent with the

HCPCS Level II code descriptions used for lymphedema compression treatment items. CMS is also proposing to:

Revise existing HCPCS Level II code A6588, “Gradient pressure wrap with adjustable straps, arm, each” to instead read “Gradient compression wrap with adjustable straps, arm, each” describe arm gradient compression wraps.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

Section 1834(z)(1) of the Social Security Act mandates an appropriate payment basis for lymphedema compression treatment items defined in section 1861(mmm) of the Act and specifically identifies payment rates from other government and private sector payers that may be taken into account in establishing the payment basis for these items. These sources include payment rates used by Medicaid state plans, the Veterans Health Administration (VHA), group health plans, and health insurance coverage (as defined in section 2791 of the Public Health Service Act). Section 1834(z)(1) of the Act also indicates that other information determined to be appropriate may be taken into account in establishing the payment basis for lymphedema compression treatment items.

In accordance with 42 CFR 414.1650(b), and as discussed in our CY 2024 rule (88 FR 77831), where Medicaid state plan payment amounts are available for a lymphedema compression treatment item, we set payment amounts at 120 percent of the average of the Medicaid payment amounts for the lymphedema compression treatment item. Where Medicaid payment amounts are not available for an item, we set payment amounts at 100 percent of the average of internet retail prices and payment amounts for that item from TRICARE. Where payment amounts are not available from Medicaid state plans or TRICARE for a given lymphedema compression treatment item, we base payment amounts based on 100 percent of average internet retail prices for that item.

We discussed in our CY 2024 rule (88 FR 77832) that when new items are added to this Lymphedema Compression Treatment Item benefit category, the data sources (Medicaid, TRICARE, VHA, or internet prices) may not initially be available for establishing an appropriate payment amount. We said that in this situation, until the data necessary for establishing the payment amount becomes available, the DME MACs would consider what an appropriate payment amount would be for each item on an individual, claim-by-claim basis and may consider using pricing for similar items that already have established payment amounts.

We have not been able to identify payment amounts from any of the data sources (Medicaid, TRICARE, VHA, or internet prices). As such, claims for new HCPCS Level II code AXXXX will be priced by the DME MACs on a claim-by-claim basis.

Pricing Indicator = 46

Summary of Public Feedback

See Appendix A for a summary of public feedback for the HCPCS Level II lymphedema management applications.

CMS Final HCPCS Coding Decision

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

1. Establish a new HCPCS Level II code A6518, "Gradient compression wrap with adjustable straps, arm, each, custom" to describe custom arm gradient compression wraps.

2. Revise existing HCPCS Level II code A6588, "Gradient pressure wrap with adjustable straps, arm, each" to instead read "Gradient compression wrap with adjustable straps, arm, each" describe arm gradient compression wraps.

Final Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Final Medicare Payment Determination

As stated in the preliminary determination, we have not been able to identify payment amounts from any of the data sources (Medicaid, TRICARE, VHA, or internet prices) in order to establish a national fee schedule amount. As such, we are finalizing the preliminary determination and claims for new HCPCS Level II code A6518 will be priced by the DME MACs on a claim-by-claim basis.

Pricing Indicator = 40

Gradient Compression Custom Wrap Below Knee - HCP240626KQ3P4

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression custom wrap for below the knee.

Applicant's suggested language: XXXXX, “Gradient compression wrap with adjustable straps, Below Knee, each, custom”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression custom wrap for below the knee. The proposed code is necessary to recognize the specific textile/technology, precise anatomical location of lymphedema, and custom version of the product. Adjustable wrap items are uniquely constructed from multiple layers of textiles that are sewn, laminated or bonded together to create a fabric that has minimal stretch (inelastic) and high rigidity. The textiles may include but are not limited to nylon, foam, and textured fabric delivering the highest stiffness/containment compared to other compression garments. These garments use clasps or hook and loop closures to enable adjustability providing greater patient independence, adherence, and efficacy. The Lymphedema Treatment Act amended title XVIII of the Social Security Act to provide coverage of certain lymphedema compression treatment items under Medicare. The term ‘lymphedema compression treatment items’ means standard and custom fitted gradient compression garments determined to serve a medical purpose and for the treatment of lymphedema.

CMS Preliminary HCPCS Coding Recommendation

CMS has generally created custom made and corresponding non-custom-made codes for lymphedema compression treatment items in the HCPCS Level II code set. We understand that lymphedema compression treatment items can come in both standard and custom-fitted form, and that there are distinct differences between the two. CMS described these differences in the Background section of the 2023 Lymphedema Compression Treatment Items Rule (88 FR 77812), “Standard compression garments are also referred to as ready-made or ready-to wear and are widely available pre-made, off-the-shelf and in a range of standard sizes;” and, “Custom-fit gradient compression garments are garments that are uniquely sized, shaped, and custom made to fit the exact dimensions of the affected extremity (circumferential measurements are every 1 and a half to 2 inches) and provide more accurate and consistent gradient compression to manage the individual’s symptoms.” Given these distinct differences CMS agrees with the request to create a new HCPCS Level II code. This code request is for a custom-made equivalent code to correspond with the non-custom HCPCS Level II code A6583. As such, CMS is proposing to:

Establish a new HCPCS Level II code AXXXX, “Gradient compression wrap with adjustable straps, below knee, each, custom” to describe custom below knee gradient compression wraps.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

Section 1834(z)(1) of the Social Security Act mandates an appropriate payment basis for lymphedema compression treatment items defined in section 1861(mmm) of the Act and specifically identifies payment rates from other government and private sector payers that may be taken into account in establishing the payment basis for these items. These sources include payment rates used by Medicaid state plans, the Veterans Health Administration (VHA), group health plans, and health insurance coverage (as defined in section 2791 of the Public Health Service Act). Section 1834(z)(1) of the Act also indicates that other information determined to be appropriate may be taken into account in establishing the payment basis for lymphedema compression treatment items.

In accordance with 42 CFR 414.1650(b), and as discussed in our CY 2024 rule (88 FR 77831), where Medicaid state plan payment amounts are available for a lymphedema compression treatment item, we set payment amounts at 120 percent of the average of the Medicaid payment amounts for the lymphedema compression treatment item. Where Medicaid payment amounts are not available for an item, we set payment amounts at 100 percent of the average of internet retail prices and payment amounts for that item from TRICARE. Where payment amounts are not available from Medicaid state plans or TRICARE for a given lymphedema compression treatment item, we base payment amounts based on 100 percent of average internet retail prices for that item.

We discussed in our CY 2024 rule (88 FR 77832) that when new items are added to this Lymphedema Compression Treatment Item benefit category, the data sources (Medicaid, TRICARE, VHA, or internet prices) may not initially be available for establishing an appropriate payment amount. We said that in this situation, until the data necessary for establishing the payment amount becomes available, the DME MACs would consider what an appropriate payment amount would be for each item on an individual, claim-by-claim basis and may consider using pricing for similar items that already have established payment amounts.

We have not been able to identify payment amounts from any of the data sources (Medicaid, TRICARE, VHA, or internet prices). As such, claims for new HCPCS Level II code AXXXX will be priced by the DME MACs on a claim-by-claim basis.

Pricing Indicator = 46

Summary of Public Feedback

See Appendix A for a summary of public feedback for the HCPCS Level II lymphedema management applications.

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 A6517, “Gradient compression wrap with adjustable straps, below knee, each, custom” to describe custom below knee gradient compression wraps.

Final Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Final Medicare Payment Determination

As stated in the preliminary determination, we have not been able to identify payment amounts from any of the data sources (Medicaid, TRICARE, VHA, or internet prices) in order to establish a national fee schedule amount. As such, we are finalizing the preliminary determination and claims for new HCPCS Level II code A6517 will be priced by the DME MACs on a claim-by-claim basis.

Pricing Indicator = 40

Gradient Compression Custom Wrap Foot - HCP240626K1QT5

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression custom wrap for the foot.

Applicant's suggested language: XXXXX, “Gradient compression wrap with adjustable straps, Foot, each, custom”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression custom wrap for the foot. The proposed code is necessary to recognize the specific textile/technology, precise anatomical location of lymphedema, and custom version of the product. Adjustable wrap items are uniquely constructed from multiple layers of textiles that are sewn, laminated or bonded together to create a fabric that has minimal stretch (inelastic) and high rigidity. The textiles may include but are not limited to nylon, foam, and textured fabric delivering the highest stiffness/containment compared to other compression garments. These garments use clasps or hook and loop closures to enable adjustability providing greater patient independence, adherence, and efficacy. The Lymphedema Treatment Act amended title XVIII of the Social Security Act to provide coverage of certain lymphedema compression treatment items under Medicare. The term ‘lymphedema compression treatment items’ means standard and custom fitted gradient compression garments determined to serve a medical purpose and for the treatment of lymphedema.

CMS Preliminary HCPCS Coding Recommendation

CMS has generally created custom made and corresponding non-custom-made codes for lymphedema compression treatment items in the HCPCS Level II code set. We understand that lymphedema compression treatment items can come in both standard and custom-fitted form, and that there are distinct differences between the two. CMS described these differences in the Background section of the 2023 Lymphedema Compression Treatment Items Rule (88 FR 77812), “Standard compression garments are also referred to as ready-made or ready-to wear and are widely available pre-made, off-the-shelf and in a range of standard sizes;” and, “Custom-fit gradient compression garments are garments that are uniquely sized, shaped, and custom made to fit the exact dimensions of the affected extremity (circumferential measurements are every 1 and a half to 2 inches) and provide more accurate and consistent gradient compression to manage the individual’s symptoms.” Given these distinct differences CMS agrees with the request to create a new HCPCS Level II code. This code request is for a custom-made equivalent code to correspond with the non-custom HCPCS Level II code A6587. As such, CMS is proposing to:

Establish a new HCPCS Level II code AXXXX, “Gradient compression wrap with adjustable straps, foot, each, custom” to describe custom foot gradient compression wraps.

In addition, we would revise the description for HCPCS Level II code A6587 to replace the word “pressure” with “compression” so that the description is more consistent with the

HCPCS Level II code descriptions used for lymphedema compression treatment items. CMS is also proposing to:

Revise existing HCPCS Level II code A6587, "Gradient pressure wrap with adjustable straps, foot, each" to instead read "Gradient compression wrap with adjustable straps, foot, each" to describe foot gradient compression wraps.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

Section 1834(z)(1) of the Social Security Act mandates an appropriate payment basis for lymphedema compression treatment items defined in section 1861(mmm) of the Act and specifically identifies payment rates from other government and private sector payers that may be taken into account in establishing the payment basis for these items. These sources include payment rates used by Medicaid state plans, the Veterans Health Administration (VHA), group health plans, and health insurance coverage (as defined in section 2791 of the Public Health Service Act). Section 1834(z)(1) of the Act also indicates that other information determined to be appropriate may be taken into account in establishing the payment basis for lymphedema compression treatment items.

In accordance with 42 CFR 414.1650(b), and as discussed in our CY 2024 rule (88 FR 77831), where Medicaid state plan payment amounts are available for a lymphedema compression treatment item, we set payment amounts at 120 percent of the average of the Medicaid payment amounts for the lymphedema compression treatment item. Where Medicaid payment amounts are not available for an item, we set payment amounts at 100 percent of the average of internet retail prices and payment amounts for that item from TRICARE. Where payment amounts are not available from Medicaid state plans or TRICARE for a given lymphedema compression treatment item, we base payment amounts based on 100 percent of average internet retail prices for that item.

We discussed in our CY 2024 rule (88 FR 77832) that when new items are added to this Lymphedema Compression Treatment Item benefit category, the data sources (Medicaid, TRICARE, VHA, or internet prices) may not initially be available for establishing an appropriate payment amount. We said that in this situation, until the data necessary for establishing the payment amount becomes available, the DME MACs would consider what an appropriate payment amount would be for each item on an individual, claim-by-claim basis and may consider using pricing for similar items that already have established payment amounts.

We have not been able to identify payment amounts from any of the data sources (Medicaid, TRICARE, VHA, or internet prices). As such, claims for new HCPCS Level II code AXXXX will be priced by the DME MACs on a claim-by-claim basis.

Pricing Indicator = 46

Summary of Public Feedback

See Appendix A for a summary of public feedback for the HCPCS Level II lymphedema management applications.

CMS Final HCPCS Coding Decision

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

1. Establish a new HCPCS Level II code A6516, "Gradient compression wrap with adjustable straps, foot, each, custom" to describe custom foot gradient compression wraps.

2. Revise existing HCPCS Level II code A6587, "Gradient pressure wrap with adjustable straps, foot, each" to instead read "Gradient compression wrap with adjustable straps, foot, each" to describe foot gradient compression wraps.

Final Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Final Medicare Payment Determination

As stated in the preliminary determination, we have not been able to identify payment amounts from any of the data sources (Medicaid, TRICARE, VHA, or internet prices) in order to establish a national fee schedule amount. As such, we are finalizing the preliminary determination and claims for new HCPCS Level II code A6516 will be priced by the DME MACs on a claim-by-claim basis.

Pricing Indicator = 40

Gradient Compression Custom Wrap Full Leg - HCP2406263JJDM

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression custom wrap for the full leg.

Applicant's suggested language: XXXXX, “Gradient pressure wrap with adjustable straps, full leg, each, custom”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression custom wrap for the full leg. The proposed code is necessary to recognize the specific textile/technology, precise anatomical location of lymphedema, and custom version of the product. Adjustable wrap items are uniquely constructed from multiple layers of textiles that are sewn, laminated or bonded together to create a fabric that has minimal stretch (inelastic) and high rigidity. The textiles may include but are not limited to nylon, foam, and textured fabric delivering the highest stiffness/containment compared to other compression garments. These garments use clasps or hook and loop closures to enable adjustability providing greater patient independence, adherence, and efficacy. The Lymphedema Treatment Act amended title XVIII of the Social Security Act to provide coverage of certain lymphedema compression treatment items under Medicare. The term ‘lymphedema compression treatment items’ means standard and custom fitted gradient compression garments determined to serve a medical purpose and for the treatment of lymphedema.

CMS Preliminary HCPCS Coding Recommendation

CMS has generally created custom made and non-custom-made (“standard”) codes for lymphedema compression treatment items in the HCPCS Level II code set. We understand that lymphedema compression treatment items can come in both standard and custom-fitted form, and that there are distinct differences between the two. CMS described these differences in the Background section of the 2023 Lymphedema Compression Treatment Items Rule (88 FR 77812), “Standard compression garments are also referred to as ready-made or ready-to wear and are widely available pre-made, off-the-shelf and in a range of standard sizes;” and, “Custom-fit gradient compression garments are garments that are uniquely sized, shaped, and custom made to fit the exact dimensions of the affected extremity (circumferential measurements are every 1 and a half to 2 inches) and provide more accurate and consistent gradient compression to manage the individual’s symptoms.” Given these distinct differences CMS agrees with the request to create a new HCPCS Level II code. However, we would revise the requested description to replace the word “pressure” with “compression” so that the description is more consistent with the HCPCS Level II code descriptions used for lymphedema compression treatment items. This code request is for a custom-made equivalent code to correspond with the non-custom HCPCS Level II code A6586. As such, CMS is proposing to:

Establish a new HCPCS Level II code AXXXX, “Gradient compression wrap with adjustable straps, full leg, each, custom” to describe custom full leg gradient compression wraps.

In addition, we would revise the description for HCPCS Level II code A6586 to replace the word “pressure” with “compression” so that the description is more consistent with the HCPCS Level II code descriptions used for lymphedema compression treatment items. CMS is also proposing to:

Revise existing HCPCS Level II code A6586, “Gradient pressure wrap with adjustable straps, full leg, each” to instead read “Gradient compression wrap with adjustable straps, full leg, each” to describe full leg gradient compression wraps.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

Section 1834(z)(1) of the Social Security Act mandates an appropriate payment basis for lymphedema compression treatment items defined in section 1861(mmm) of the Act and specifically identifies payment rates from other government and private sector payers that may be taken into account in establishing the payment basis for these items. These sources include payment rates used by Medicaid state plans, the Veterans Health Administration (VHA), group health plans, and health insurance coverage (as defined in section 2791 of the Public Health Service Act). Section 1834(z)(1) of the Act also indicates that other information determined to be appropriate may be taken into account in establishing the payment basis for lymphedema compression treatment items.

In accordance with 42 CFR 414.1650(b), and as discussed in our CY 2024 rule (88 FR 77831), where Medicaid state plan payment amounts are available for a lymphedema compression treatment item, we set payment amounts at 120 percent of the average of the Medicaid payment amounts for the lymphedema compression treatment item. Where Medicaid payment amounts are not available for an item, we set payment amounts at 100 percent of the average of internet retail prices and payment amounts for that item from TRICARE. Where payment amounts are not available from Medicaid state plans or TRICARE for a given lymphedema compression treatment item, we base payment amounts based on 100 percent of average internet retail prices for that item.

We discussed in our CY 2024 rule (88 FR 77832) that when new items are added to this Lymphedema Compression Treatment Item benefit category, the data sources (Medicaid, TRICARE, VHA, or internet prices) may not initially be available for establishing an appropriate payment amount. We said that in this situation, until the data necessary for establishing the payment amount becomes available, the DME MACs would consider what an appropriate payment amount would be for each item on an individual, claim-by-claim basis and may consider using pricing for similar items that already have established payment amounts.

We have not been able to identify payment amounts from any of the data sources (Medicaid, TRICARE, VHA, or internet prices). As such, claims for new HCPCS Level II code AXXXX will be priced by the DME MACs on a claim-by-claim basis.

Pricing Indicator = 46

Summary of Public Feedback

See Appendix A for a summary of public feedback for the HCPCS Level II lymphedema management applications.

CMS Final HCPCS Coding Decision

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

1. Establish a new HCPCS Level II code A6515, "Gradient compression wrap with adjustable straps, full leg, each, custom" to describe custom full leg gradient compression wraps.

2. Revise existing HCPCS Level II code A6586, "Gradient pressure wrap with adjustable straps, full leg, each" to instead read "Gradient compression wrap with adjustable straps, full leg, each" to describe full leg gradient compression wraps.

Final Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Final Medicare Payment Determination

As stated in the preliminary determination, we have not been able to identify payment amounts from any of the data sources (Medicaid, TRICARE, VHA, or internet prices) in order to establish a national fee schedule amount. As such, we are finalizing the preliminary determination and claims for new HCPCS Level II code A6515 will be priced by the DME MACs on a claim-by-claim basis.

Pricing Indicator = 40

Gradient Compression Below Knee Bandage Liner - HCP2407019YVJC

Topic/Issue

Request to revise existing HCPCS Level II code A6594, “Gradient compression bandaging supply, bandage liner, lower extremity, any size or length, each” and to expand the HCPCS Level II code to also specify anatomical segments for foot, knee and thigh, and full leg bandage liners.

Applicant's suggested language: A6594, “Gradient compression accessory - bandage liner, below knee, any size or length, each”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to revise existing HCPCS Level II code A6594 to expand the HCPCS Level II code to also specify anatomical segments for foot, knee and thigh, and full leg bandage liners. The more specific anatomical locations are necessary to address the individual’s clinical characteristics and any unique individual shapes which require adaptation in targeted segments. The request is to also expand the HCPCS Level II code set to include four distinct codes for lower extremity bandage liners: foot, below knee, knee and thigh, and a full leg. Additionally, the January 2024 DMEPOS Fee Schedule published on December 19, 2023, lists a price of $33.14. The published national payment amount is not reflective of a true bandage liner and a reconsideration is requested as it is possible that incorrect products were selected for the initial review. There are no previous Medicaid fee schedules for bandage liners, and a review of internet pricing reveals substantially higher costs.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code A6594, “Gradient compression bandaging supply, bandage liner, lower extremity, any size or length, each” describes gradient compression bandage liners and supplies for the lower extremities.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

In accordance with 42 CFR 414.1650(b), and as discussed in our CY 2024 Home Health (HH) Prospective Payment System final rule (88 FR 77831), where Medicaid state plan payment amounts are available for a lymphedema compression treatment item, we set payment amounts at 120 percent of the average of the Medicaid payment amounts for the lymphedema compression treatment item. Where Medicaid payment amounts are not available for an item, we set payment amounts at 100 percent of the average of internet retail prices and payment amounts for that item from TRICARE. Where payment amounts are not available from Medicaid state plans or TRICARE for a given lymphedema compression treatment item, we base payment amounts based on 100 percent of average internet retail prices for that item.

When originally determining the payment amount for HCPCS Level II code A6594, we followed the process outlined in 42 CFR 414.1650(b) and since there was no Medicaid or TRICARE pricing available, took 100 percent of the average of average internet retail prices. After finding several internet retail prices for lower extremity bandage liners, the average price was $33.14. The applicant has sent us internet retail pricing for items they believe should have been included in this average calculation. We can confirm that we already included one of these products and its price in the average calculation. Although there may be products with a higher price than $33.14, the average still reflects the spectrum of pricing on the internet. We noted in the CY 2024 HH Prospective Payment System final rule that when collecting internet retail prices for use in any such averages, we only consider prices for items that meet the requirements for payment under each code in question (88 FR 77833). As such, we can confirm that the products included in this average are indeed bandage liners.

The payment rules and pricing associated with the existing HCPCS Level II code A6594 apply to this product, if covered. Fee schedules are updated annually.

Pricing Indicator = 40

Summary of Public Feedback

See Appendix A for a summary of public feedback for the HCPCS Level II lymphedema management applications.

CMS Final HCPCS Coding Decision

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

Existing HCPCS Level II code A6594, "Gradient compression bandaging supply, bandage liner, lower extremity, any size or length, each" describes gradient compression bandage liners and supplies for the lower extremities.

Given the low volume of claims submitted using HCPCS Level II code A6594 since the new Medicare benefit for Lymphedema Compression Treatment Items began on January 1, 2024, more time is needed to determine what codes are needed for claims processing purposes for the various gradient compression bandaging supplies.

Final Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Final Medicare Payment Determination

In accordance with 42 CFR 414.1650(b), and as discussed in our CY 2024 Home Health (HH) Prospective Payment System final rule (88 FR 77831), where Medicaid state plan payment amounts are available for a lymphedema compression treatment item, we set payment amounts at 120 percent of the average of the Medicaid payment amounts for the lymphedema compression treatment item. Where Medicaid payment amounts are not

available for an item, we set payment amounts at 100 percent of the average of internet retail prices and payment amounts for that item from TRICARE. Where payment amounts are not available from Medicaid state plans or TRICARE for a given lymphedema compression treatment item, we base payment amounts based on 100 percent of average internet retail prices for that item. When originally determining the payment amount for HCPCS Level II code A6594, we followed the process outlined in 42 CFR 414.1650(b) and since there was no Medicaid or TRICARE pricing available, took 100 percent of the average of average internet retail prices.

The applicant expressed concerns that we may have included certain inappropriate items in the calculation of the average internet retail price used for our payment determination; additionally, the applicant sent several examples of items that should be included in the payment calculation for HCPCS Level II code A6594. We can confirm that we did not include any of the inappropriate items cited by the applicant in the original calculation of our average internet retail price. Furthermore, as we mentioned in our preliminary determination, at least one of the specific items mentioned as an example was included, together with other similar items. Therefore, we confirm that the average price of $33.14 for items that would be classified in this code was calculated in accordance with our procedures. We would like to reiterate that although there may be products with a higher price than $33.14, the average still reflects the spectrum of pricing on the internet. Suppliers are expected to dispense the item prescribed. We noted in the CY 2024 HH Prospective Payment System final rule that when collecting internet retail prices for use in any such averages, we only consider prices for items that meet the requirements for payment under each code in question (88 FR 77833). As such, we can confirm that the products included in this average are indeed bandage liners.

We can also confirm that we have consulted with the appropriate experts for this and other determinations. In the CY 2022 DMEPOS final rule, we noted that CMS has years of experience making such determinations and our initial and final determinations are formulated in conjunction with experts such as medical officers, certified orthotists and prosthetists, nurses and other allied health professionals, and biomedical engineers (86 FR 73894). We also noted in the CY 2024 HH Prospective Payment System final rule that we intend to closely monitor access to lymphedema compression treatment items and related services necessary for the effective use of these items to ensure that the Medicare payments for these items are appropriate (86 FR 77820). Thus far, we have not detected access issues in our claims monitoring data.

The payment rules and pricing associated with the existing HCPCS Level II code A6594 apply to this product, if covered. Fee schedules are updated annually.

Pricing Indicator = 40

Gradient Compression Bra Bandage Liner - HCP240701KEDHA

Topic/Issue

Request to establish a new HCPCS Level II code to identify a bra bandage liner.

Applicant's suggested language: XXXXX, “Gradient compression bandaging supply, bandage liner, bra, any size or length, each”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a bra bandage liner. The existing codes acknowledge upper and lower extremity bandage areas, and do not include a bra version. It is necessary to identify this anatomical location for individuals with lymphedema to the chest/breast area who utilize the prescribed compression bandage system.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. Existing HCPCS Level II code A6609, “Gradient compression bandaging supply, not otherwise specified” is used when submitting claims for this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II “Not Otherwise Specified” codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Summary of Public Feedback

See Appendix A for a summary of public feedback for the HCPCS Level II lymphedema management applications.

CMS Final HCPCS Coding Decision

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

Existing HCPCS Level II code A6609, “Gradient compression bandaging supply, not otherwise specified” when submitting claims for the ‘Gradient Compression Bra Bandage Liner’.

Given the low volume of claims submitted using HCPCS Level II code A6609 since the new Medicare benefit for Lymphedema Compression Treatment Items began on January 1, 2024, more time is needed to determine what codes are needed for claims processing purposes for the various gradient compression bandaging supplies.

Final Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Final Medicare Payment Determination

The payment determination for HCPCS Level II “Not Otherwise Specified” codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 40

Gradient Compression Arm Bandage Liner - HCP240701FWP0N

Topic/Issue

Request to revise existing HCPCS Level II code A6595, “Gradient compression bandaging supply, bandage liner, upper extremity, any size or length, each” to include more specific anatomical locations.

Applicant's suggested language: A6595, “Gradient compression accessory - bandage liner, arm, any size or length, each” to specify wrist to axilla coverage and expand the HCPCS code set to also specify anatomical segments for hand and an arm & hand combination bandage liner.

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to revise existing HCPCS Level II code A6595 to include more specific anatomical locations. The existing code description generalizes the product as upper extremity, but more specific anatomical locations are necessary to address the individual’s clinical characteristics and any unique individual shapes which require adaptation in targeted segments. The request is to expand the HCPCS Level II code set to include three distinct codes for the arm, hand, and a combination of arm and hand. Additionally, the January 2024 DMEPOS Fee Schedule published on December 19, 2023 lists a price of $32.59. The published national payment amount is not reflective of a true bandage liner and a reconsideration is requested as it is possible that incorrect products were selected for the initial review. There are no previous Medicaid fee schedules for bandage liners, and a review of internet pricing reveals substantially higher costs.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code A6595, “Gradient compression bandaging supply, bandage liner, upper extremity, any size or length, each” describes gradient compression bandage liners and supplies for the upper extremities.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

In accordance with 42 CFR 414.1650(b), and as discussed in our CY 2024 Home Health (HH) Prospective Payment System final rule (88 FR 77831), where Medicaid state plan payment amounts are available for a lymphedema compression treatment item, we set payment amounts at 120 percent of the average of the Medicaid payment amounts for the lymphedema compression treatment item. Where Medicaid payment amounts are not available for an item, we set payment amounts at 100 percent of the average of internet retail prices and payment amounts for that item from TRICARE. Where payment amounts are not available from Medicaid state plans or TRICARE for a given lymphedema compression treatment item, we base payment amounts based on 100 percent of average internet retail prices for that item. When originally determining the payment amount for HCPCS Level II code A6595, we followed the process outlined in 42 CFR 414.1650(b) and since there was no

Medicaid or TRICARE pricing available, took 100 percent of the average of average internet retail prices. After finding several internet retail prices for lower extremity bandage liners, the average price was $32.59. The applicant has sent us internet retail pricing for items they believe should have been included in this average calculation. We can confirm that we already included one of these products and its price in the average calculation. Although there may be products with a higher price than $32.59, the average still reflects the spectrum of pricing on the internet. We noted in the CY 2024 Home Health (HH) Prospective Payment System final rule that when collecting internet retail prices for use in any such averages, we only consider prices for items that meet the requirements for payment under each code in question (88 FR 77833). As such, we can confirm that the products included in this average are indeed bandage liners.

The payment rules and pricing associated with the existing HCPCS Level II code A6595 apply to this product, if covered. Fee schedules are updated annually.

Pricing Indicator = 40

Summary of Public Feedback

See Appendix A for a summary of public feedback for the HCPCS Level II lymphedema management applications.

CMS Final HCPCS Coding Decision

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

Existing HCPCS Level II code A6595, "Gradient compression bandaging supply, bandage liner, upper extremity, any size or length, each" describes gradient compression bandage liners and supplies for the upper extremities.

Given the low volume of claims submitted using HCPCS Level II code A6595 since the new Medicare benefit for Lymphedema Compression Treatment Items began on January 1, 2024, more time is needed to determine what codes are needed for claims processing purposes for the various gradient compression bandaging supplies.

Final Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Final Medicare Payment Determination

In accordance with 42 CFR 414.1650(b), and as discussed in our CY 2024 Home Health (HH) Prospective Payment System final rule (88 FR 77831), where Medicaid state plan payment amounts are available for a lymphedema compression treatment item, we set payment amounts at 120 percent of the average of the Medicaid payment amounts for the lymphedema compression treatment item. Where Medicaid payment amounts are not available for an item, we set payment amounts at 100 percent of the average of internet retail

prices and payment amounts for that item from TRICARE. Where payment amounts are not available from Medicaid state plans or TRICARE for a given lymphedema compression treatment item, we base payment amounts based on 100 percent of average internet retail prices for that item.

When originally determining the payment amount for HCPCS Level II code A6595, we followed the process outlined in 42 CFR 414.1650(b) and since there was no Medicaid or TRICARE pricing available, took 100 percent of the average of average internet retail prices. After finding several internet retail prices for lower extremity bandage liners, the average price was $32.59. We would like to reiterate that although there may be products with a higher price than $32.59, the average still reflects the spectrum of pricing on the internet. Suppliers are expected to dispense the item prescribed. We noted in the CY 2024 HH Prospective Payment System final rule that when collecting internet retail prices for use in any such averages, we only consider prices for items that meet the requirements for payment under each code in question (88 FR 77833). As such, we can confirm that the products included in this average are indeed bandage liners.

We can also confirm that we have consulted with the appropriate experts for this and other determinations. In the CY 2022 DMEPOS final rule, we noted that CMS has years of experience making such determinations and our initial and final determinations are formulated in conjunction with experts such as medical officers, certified orthotists and prosthetists, nurses and other allied health professionals, and biomedical engineers (86 FR 73894). We also noted in the CY 2024 HH Prospective Payment System final rule that we intend to closely monitor access to lymphedema compression treatment items and related services necessary for the effective use of these items to ensure that the Medicare payments for these items are appropriate (86 FR 77820). Thus far, we have not detected access issues in our claims monitoring data.

The payment rules and pricing associated with the existing HCPCS Level II code A6595 apply to this product, if covered. Fee schedules are updated annually.

Pricing Indicator = 40

Gradient Compression Custom Padded Nighttime Garment, Torso/Abdomen - HCP240627LVYYT

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression custom padded nighttime garment for the torso/abdomen.

Applicant's suggested language: XXXXX, “Gradient compression garment, torso - abdomen, padded, for nighttime use, each, custom”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression custom padded nighttime garment for the torso/abdomen. This is a medical gradient compression garment for the treatment of lymphedema. The proposed code language is necessary to recognize the specific textile/technology and anatomical location of lymphedema. Nighttime garments are manufactured to incorporate a textured surface against the skin, which is achieved in a few different formats based on current technology on the market, such as chip foam, flat foam, channel foam, polyfill, and 3D knit structure. These garments are primarily cut or knit to size, filled with texture-based solution/knit with texture, and lastly sewn. Many of them also integrate built-in directional channeling based on the lymphatic pathways. Nighttime garments have the unique ability to maintain lymphedema safely overnight/during low activity with its lower levels of compression and containment based on medium-stretch fabric properties. Additionally, its textured surface provides a unique pressure differential on the tissue with high and low pressures designed to help stimulate the tissue, break up and soften fibrosis and support long term tissue health for lymphedema. Additional HCPCS Level II codes for abdomen are necessary for proper identification and product selection to effectively manage lymphedema overnight or during periods of low activity.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. CMS is proposing (in our CMS Preliminary HCPCS Coding Recommendation, see application HCP2406275UFBP) to revise HCPCS Level II code A6549, “Gradient compression garment, not otherwise specified” to instead read “Gradient compression garment, not otherwise specified, for daytime use, each” to describe this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Note that in our CMS Preliminary HCPCS Coding Recommendation, we are proposing establishment of new HCPCS Level II code AXXXX, “Gradient compression garment, not otherwise specified, for nighttime use, each” to describe nighttime gradient compression garments (see application HCP2406275UFBP). If this code is established, suppliers would begin using this new code when submitting claims for this nighttime garment.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II "Not Otherwise Specified" codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Summary of Public Feedback

See Appendix A for a summary of public feedback for the HCPCS Level II lymphedema management applications.

CMS Final HCPCS Coding Decision

This application is being deferred for additional consideration in a subsequent biannual coding cycle. CMS will continue to monitor the lymphedema compression treatment item benefit category, claims processing data, and health outcomes to assess the need to develop additional HCPCS Level II codes.

In the meantime, claims for these items should be billed using existing HCPCS Level II code A6549, "Gradient compression garment, not otherwise specified" through March 2025. Beginning April 1, 2025, claims for these items should be billed using new HCPCS Level II code A6519, "Gradient compression garment, not otherwise specified, for nighttime use, each".

Final Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Final Medicare Payment Determination

The payment determination for HCPCS Level II "Not Otherwise Specified" codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 40

Gradient Compression Custom Padded Nighttime Garment, Arm Sleeve and Glove - HCP2406264KDYN

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression custom padded nighttime garment for the combination of the arm sleeve and glove.

Applicant's suggested language: XXXXX, “Gradient compression garment, arm sleeve and glove combination, padded, for nighttime use, each, custom”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression custom padded nighttime garment for the combination of the arm sleeve and glove. This is a medical gradient compression garment for the treatment of lymphedema. The proposed code language is necessary to recognize the specific textile/technology and combined anatomical locations of lymphedema. Nighttime garments are manufactured to incorporate a textured surface against the skin, which is achieved in a few different formats based on current technology on the market, such as chip foam, flat foam, channel foam, polyfill, and 3D knit structure. These garments are primarily cut or knit to size, filled with texture-based solution/knit with texture, and lastly sewn. Many of them also integrate built-in directional channeling based on the lymphatic pathways. Nighttime garments have the unique ability to maintain lymphedema safely overnight/during low activity with its lower levels of compression and containment based on medium-stretch fabric properties. Additionally, its textured surface provides a unique pressure differential on the tissue with high and low pressures designed to help stimulate the tissue, break up and soften fibrosis and support long term tissue health for lymphedema. Additional codes are necessary for proper identification and product selection to effectively manage lymphedema overnight or during periods of low activity.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. CMS is proposing (in our CMS Preliminary HCPCS Coding Recommendation, see application HCP2406275UFBP) to revise HCPCS Level II code A6549, “Gradient compression garment, not otherwise specified” to instead read “Gradient compression garment, not otherwise specified, for daytime use, each” to describe this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Note that in our CMS Preliminary HCPCS Coding Recommendation, we are proposing establishment of new HCPCS Level II code AXXXX, “Gradient compression garment, not otherwise specified, for nighttime use, each” to describe nighttime gradient compression garments (see application HCP2406275UFBP). If this code is established, suppliers would begin using this new code when submitting claims for this nighttime garment.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II "Not Otherwise Specified" codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Summary of Public Feedback

See Appendix A for a summary of public feedback for the HCPCS Level II lymphedema management applications.

CMS Final HCPCS Coding Decision

This application is being deferred for additional consideration in a subsequent biannual coding cycle. CMS will continue to monitor the lymphedema compression treatment item benefit category, claims processing data, and health outcomes to assess the need to develop additional HCPCS Level II codes.

In the meantime, claims for these items should be billed using existing HCPCS Level II code A6549, "Gradient compression garment, not otherwise specified" through March 2025. Beginning April 1, 2025, claims for these items should be billed using new HCPCS Level II code A6519, "Gradient compression garment, not otherwise specified, for nighttime use, each".

Final Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Final Medicare Payment Determination

The payment determination for HCPCS Level II "Not Otherwise Specified" codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 40

Gradient Compression Padded Nighttime Garment, Arm Sleeve and Glove - HCP240626N5LFM

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression padded nighttime garment for the combination of the arm sleeve and glove.

Applicant's suggested language: XXXXX, “Gradient compression garment, arm sleeve and glove combination, padded, for nighttime use, each”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression padded nighttime garment for the combination of the arm sleeve and glove. The item is a medical gradient compression garment for the treatment of lymphedema. The proposed code language is necessary to recognize the specific textile/technology and combined anatomical locations of lymphedema. Nighttime garments are manufactured to incorporate a textured surface against the skin, which is achieved in a few different formats based on current technology on the market, such as chip foam, flat foam, channel foam, polyfill, and 3D knit structure. These garments are primarily cut or knit to size, filled with texture-based solution/knit with texture, and lastly sewn. Many of them also integrate built-in directional channeling based on the lymphatic pathways. Nighttime garments have the unique ability to maintain lymphedema safely overnight/during low activity with its lower levels of compression and containment based on medium-stretch fabric properties. Additionally, its textured surface provides a unique pressure differential on the tissue with high and low pressures designed to help stimulate the tissue, break up and soften fibrosis and support long term tissue health for lymphedema. Additional codes are necessary for proper identification and product selection to effectively manage lymphedema overnight or during periods of low activity.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. CMS is proposing (in our CMS Preliminary HCPCS Coding Recommendation, see application HCP2406275UFBP) to revise HCPCS Level II code A6549, “Gradient compression garment, not otherwise specified” to instead read “Gradient compression garment, not otherwise specified, for daytime use, each” to describe this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Note that in our CMS Preliminary HCPCS Coding Recommendation we are proposing establishment of new HCPCS Level II code AXXXX, “Gradient compression garment, not otherwise specified, for nighttime use, each” to describe nighttime gradient compression garments (see application HCP2406275UFBP). If this code is established, suppliers would begin using this new code when submitting claims for this nighttime garment.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II "Not Otherwise Specified" codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Summary of Public Feedback

See Appendix A for a summary of public feedback for the HCPCS Level II lymphedema management applications.

CMS Final HCPCS Coding Decision

This application is being deferred for additional consideration in a subsequent biannual coding cycle. CMS will continue to monitor the lymphedema compression treatment item benefit category, claims processing data, and health outcomes to assess the need to develop additional HCPCS Level II codes.

In the meantime, claims for these items should be billed using existing HCPCS Level II code A6549, "Gradient compression garment, not otherwise specified" through March 2025. Beginning April 1, 2025, claims for these items should be billed using new HCPCS Level II code A6519, "Gradient compression garment, not otherwise specified, for nighttime use, each".

Final Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Final Medicare Payment Determination

The payment determination for HCPCS Level II "Not Otherwise Specified" codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 40

Gradient Compression Custom Padded Nighttime Garment, Body Suit - HCP240627PCD0U

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression custom padded nighttime garment body suit.

Applicant's suggested language: XXXXX, “Gradient compression garment, body suit, padded, for nighttime use, each, custom”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression custom padded nighttime garment body suit. The item is a medical gradient compression garment for the treatment of lymphedema. The proposed code language is necessary to recognize the specific textile/technology and combined anatomical locations of lymphedema. Nighttime garments are manufactured to incorporate a textured surface against the skin, which is achieved in a few different formats based on current technology on the market, such as chip foam, flat foam, channel foam, polyfill, and 3D knit structure. These garments are primarily cut or knit to size, filled with texture-based solution/knit with texture, and lastly sewn. Many of them also integrate built-in directional channeling based on the lymphatic pathways. Nighttime garments have the unique ability to maintain lymphedema safely overnight/during low activity with its lower levels of compression and containment based on medium-stretch fabric properties. Additionally, its textured surface provides a unique pressure differential on the tissue with high and low pressures designed to help stimulate the tissue, break up and soften fibrosis and support long term tissue health for lymphedema. Additional HCPCS Level II code for a custom nighttime body suit is needed for comprehensive coverage to effectively manage multiple body parts lymphedema overnight or during periods of low activity.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. CMS is proposing (in our CMS Preliminary HCPCS Coding Recommendation, see application HCP2406275UFBP) to revise HCPCS Level II code A6549, “Gradient compression garment, not otherwise specified” to instead read “Gradient compression garment, not otherwise specified, for daytime use, each” to describe this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Note that in our CMS Preliminary HCPCS Coding Recommendation we are proposing establishment of new HCPCS Level II code AXXXX, “Gradient compression garment, not otherwise specified, for nighttime use, each” to describe nighttime gradient compression garments (see application HCP2406275UFBP). If this code is established, suppliers would begin using this new code when submitting claims for this nighttime garment.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II "Not Otherwise Specified" codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Summary of Public Feedback

See Appendix A for a summary of public feedback for the HCPCS Level II lymphedema management applications.

CMS Final HCPCS Coding Decision

This application is being deferred for additional consideration in a subsequent biannual coding cycle. CMS will continue to monitor the lymphedema compression treatment item benefit category, claims processing data, and health outcomes to assess the need to develop additional HCPCS Level II codes.

In the meantime, claims for these items should be billed using existing HCPCS Level II code A6549, "Gradient compression garment, not otherwise specified" through March 2025. Beginning April 1, 2025, claims for these items should be billed using new HCPCS Level II code A6519, "Gradient compression garment, not otherwise specified, for nighttime use, each".

Final Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Final Medicare Payment Determination

The payment determination for HCPCS Level II "Not Otherwise Specified" codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 40

Gradient Compression Padded Nighttime Garment, Genital/Capri - HCP2406276225W

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression padded nighttime garment for genital/capri.

Applicant's suggested language: XXXXX, “Gradient compression garment, genital - capri, padded, for nighttime use, each”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression padded nighttime garment for genital/capri. The item is a medical gradient compression garment for the treatment of lymphedema. The proposed code language is necessary to recognize the specific textile/technology and anatomical locations of lymphedema. Nighttime garments are manufactured to incorporate a textured surface against the skin, which is achieved in a few different formats based on current technology on the market, such as chip foam, flat foam, channel foam, polyfill, and 3D knit structure. These garments are primarily cut or knit to size, filled with texture-based solution/knit with texture, and lastly sewn. Many of them also integrate built-in directional channeling based on the lymphatic pathways. Nighttime garments have the unique ability to maintain lymphedema safely overnight/during low activity with its lower levels of compression and containment based on medium-stretch fabric properties. Additionally, its textured surface provides a unique pressure differential on the tissue with high and low pressures designed to help stimulate the tissue, break up and soften fibrosis and support long term tissue health for lymphedema. Additional HCPCS Level II code for a nighttime capri is needed for comprehensive coverage to effectively manage multiple body parts lymphedema (e.g., genital, torso, lower extremities) overnight or during periods of low activity.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. CMS is proposing (in our CMS Preliminary HCPCS Coding Recommendation, see application HCP2406275UFBP) to revise HCPCS Level II code A6549, “Gradient compression garment, not otherwise specified” to instead read “Gradient compression garment, not otherwise specified, for daytime use, each” to describe this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Note that in our CMS Preliminary HCPCS Coding Recommendation we are proposing establishment of new HCPCS Level II code AXXXX, “Gradient compression garment, not otherwise specified, for nighttime use, each” to describe nighttime gradient compression garments (see application HCP2406275UFBP). If this code is established, suppliers would begin using this new code when submitting claims for this nighttime garment.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II "Not Otherwise Specified" codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Summary of Public Feedback

See Appendix A for a summary of public feedback for the HCPCS Level II lymphedema management applications.

CMS Final HCPCS Coding Decision

This application is being deferred for additional consideration in a subsequent biannual coding cycle. CMS will continue to monitor the lymphedema compression treatment item benefit category, claims processing data, and health outcomes to assess the need to develop additional HCPCS Level II codes.

In the meantime, claims for these items should be billed using existing HCPCS Level II code A6549, "Gradient compression garment, not otherwise specified" through March 2025. Beginning April 1, 2025, claims for these items should be billed using new HCPCS Level II code A6519, "Gradient compression garment, not otherwise specified, for nighttime use, each".

Final Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Final Medicare Payment Determination

The payment determination for HCPCS Level II "Not Otherwise Specified" codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 40

Gradient Compression Custom Padded Nighttime Garment, Foot - HCP240626FGCQC

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression custom padded nighttime garment for the foot.

Applicant's suggested language: XXXXX, “Gradient compression garment, foot, padded, for nighttime use, custom, each”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression custom padded nighttime garment for the foot. This is a medical gradient compression garment for the treatment of lymphedema. The proposed code language is necessary to recognize the specific textile/technology and anatomical location of lymphedema. Nighttime garments are manufactured to incorporate a textured surface against the skin, which is achieved in a few different formats based on current technology on the market, such as chip foam, flat foam, channel foam, polyfill, and 3D knit structure. These garments are primarily cut or knit to size, filled with texture-based solution/knit with texture, and lastly sewn. Many of them also integrate built-in directional channeling based on the lymphatic pathways. Nighttime garments have the unique ability to maintain lymphedema safely overnight/during low activity with its lower levels of compression and containment based on medium-stretch fabric properties. Additionally, its textured surface provides a unique pressure differential on the tissue with high and low pressures designed to help stimulate the tissue, break up and soften fibrosis and support long term tissue health for lymphedema. Additional codes are necessary for proper identification and product selection to effectively manage lymphedema overnight or during periods of low activity.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. CMS is proposing (in our CMS Preliminary HCPCS Coding Recommendation, see application HCP2406275UFBP) to revise HCPCS Level II code A6549, “Gradient compression garment, not otherwise specified” to instead read “Gradient compression garment, not otherwise specified, for daytime use, each” to describe this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Note that in our CMS Preliminary HCPCS Coding Recommendation we are proposing establishment of new HCPCS Level II code AXXXX, “Gradient compression garment, not otherwise specified, for nighttime use, each” to describe nighttime gradient compression garments (see application HCP2406275UFBP). If this code is established, suppliers would begin using this new code when submitting claims for this nighttime garment.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II "Not Otherwise Specified" codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Summary of Public Feedback

See Appendix A for a summary of public feedback for the HCPCS Level II lymphedema management applications.

CMS Final HCPCS Coding Decision

This application is being deferred for additional consideration in a subsequent biannual coding cycle. CMS will continue to monitor the lymphedema compression treatment item benefit category, claims processing data, and health outcomes to assess the need to develop additional HCPCS Level II codes.

In the meantime, claims for these items should be billed using existing HCPCS Level II code A6549, "Gradient compression garment, not otherwise specified" through March 2025. Beginning April 1, 2025, claims for these items should be billed using new HCPCS Level II code A6519, "Gradient compression garment, not otherwise specified, for nighttime use, each".

Final Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Final Medicare Payment Determination

The payment determination for HCPCS Level II "Not Otherwise Specified" codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 40

Gradient Compression Padded Nighttime Garment, Foot - HCP2406275H7WW

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression padded nighttime garment for the foot.

Applicant's suggested language: XXXXX, “Gradient compression garment, foot, padded, for nighttime use, each”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression padded nighttime garment for the foot. The item is a medical gradient compression garment for the treatment of lymphedema. The proposed code language is necessary to recognize the specific textile/technology and anatomical location of lymphedema. Nighttime garments are manufactured to incorporate a textured surface against the skin, which is achieved in a few different formats based on current technology on the market, such as chip foam, flat foam, channel foam, polyfill, and 3D knit structure. These garments are primarily cut or knit to size, filled with texture-based solution/knit with texture, and lastly sewn. Many of them also integrate built-in directional channeling based on the lymphatic pathways. Nighttime garments have the unique ability to maintain lymphedema safely overnight/during low activity with its lower levels of compression and containment based on medium-stretch fabric properties. Additionally, its textured surface provides a unique pressure differential on the tissue with high and low pressures designed to help stimulate the tissue, break up and soften fibrosis and support long term tissue health for lymphedema. Additional codes are necessary for proper identification and product selection to effectively manage lymphedema overnight or during periods of low activity.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. CMS is proposing (in our CMS Preliminary HCPCS Coding Recommendation, see application HCP2406275UFBP) to revise HCPCS Level II code A6549, “Gradient compression garment, not otherwise specified” to instead read “Gradient compression garment, not otherwise specified, for daytime use, each” to describe this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Note that in our CMS Preliminary HCPCS Coding Recommendation we are proposing establishment of new HCPCS Level II code AXXXX, “Gradient compression garment, not otherwise specified, for nighttime use, each” to describe nighttime gradient compression garments (see application HCP2406275UFBP). If this code is established, suppliers would begin using this new code when submitting claims for this nighttime garment.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II "Not Otherwise Specified" codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Summary of Public Feedback

See Appendix A for a summary of public feedback for the HCPCS Level II lymphedema management applications.

CMS Final HCPCS Coding Decision

This application is being deferred for additional consideration in a subsequent biannual coding cycle. CMS will continue to monitor the lymphedema compression treatment item benefit category, claims processing data, and health outcomes to assess the need to develop additional HCPCS Level II codes.

In the meantime, claims for these items should be billed using existing HCPCS Level II code A6549, "Gradient compression garment, not otherwise specified" through March 2025. Beginning April 1, 2025, claims for these items should be billed using new HCPCS Level II code A6519, "Gradient compression garment, not otherwise specified, for nighttime use, each".

Final Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Final Medicare Payment Determination

The payment determination for HCPCS Level II "Not Otherwise Specified" codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 40

Gradient Compression Custom Padded Nighttime Garment, Gauntlet - HCP240626GHYEP

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression custom padded nighttime garment for gauntlet.

Applicant's suggested language: XXXXX, “Gradient compression garment, gauntlet, padded, for nighttime use, each, custom”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression custom padded nighttime garment for gauntlet. This is a medical gradient compression garment for the treatment of lymphedema. The proposed code language is necessary to recognize the specific textile/technology and anatomical location of lymphedema. Nighttime garments are manufactured to incorporate a textured surface against the skin, which is achieved in a few different formats based on current technology on the market, such as chip foam, flat foam, channel foam, polyfill, and 3D knit structure. These garments are primarily cut or knit to size, filled with texture-based solution/knit with texture, and lastly sewn. Many of them also integrate built-in directional channeling based on the lymphatic pathways. Nighttime garments have the unique ability to maintain lymphedema safely overnight/during low activity with its lower levels of compression and containment based on medium-stretch fabric properties. Additionally, its textured surface provides a unique pressure differential on the tissue with high and low pressures designed to help stimulate the tissue, break up and soften fibrosis and support long term tissue health for lymphedema. The existing HCPCS Level II codes in the nighttime category are limited to an "arm", and there are no HCPCS Level II codes for segmented anatomical locations and their custom counterparts. Additional codes are necessary for proper identification and product selection to effectively manage lymphedema overnight or during periods of low activity.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. CMS is proposing (in our CMS Preliminary HCPCS Coding Recommendation, see application HCP2406275UFBP) to revise HCPCS Level II code A6549, “Gradient compression garment, not otherwise specified” to instead read “Gradient compression garment, not otherwise specified, for daytime use, each” to describe this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Note that in our CMS Preliminary HCPCS Coding Recommendation we are proposing establishment of new HCPCS Level II code AXXXX, “Gradient compression garment, not otherwise specified, for nighttime use, each” to describe nighttime gradient compression garments (see application HCP2406275UFBP). If this code is established, suppliers would begin using this new code when submitting claims for this nighttime garment.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II "Not Otherwise Specified" codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Summary of Public Feedback

See Appendix A for a summary of public feedback for the HCPCS Level II lymphedema management applications.

CMS Final HCPCS Coding Decision

This application is being deferred for additional consideration in a subsequent biannual coding cycle. CMS will continue to monitor the lymphedema compression treatment item benefit category, claims processing data, and health outcomes to assess the need to develop additional HCPCS Level II codes.

In the meantime, claims for these items should be billed using existing HCPCS Level II code A6549, "Gradient compression garment, not otherwise specified" through March 2025. Beginning April 1, 2025, claims for these items should be billed using new HCPCS Level II code A6519, "Gradient compression garment, not otherwise specified, for nighttime use, each".

Final Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Final Medicare Payment Determination

The payment determination for HCPCS Level II "Not Otherwise Specified" codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 40

Gradient Compression Padded Nighttime Garment, Gauntlet - HCP240627PWHRD

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression padded nighttime garment for gauntlet.

Applicant's suggested language: XXXXX, “Gradient compression garment, gauntlet, padded, for nighttime use, each”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression padded nighttime garment for gauntlet. This is a medical gradient compression garment for the treatment of lymphedema. The proposed code language is necessary to recognize the specific textile/technology and anatomical location of lymphedema. Nighttime garments are manufactured to incorporate a textured surface against the skin, which is achieved in a few different formats based on current technology on the market, such as chip foam, flat foam, channel foam, polyfill, and 3D knit structure. These garments are primarily cut or knit to size, filled with texture-based solution/knit with texture, and lastly sewn. Many of them also integrate built-in directional channeling based on the lymphatic pathways. Nighttime garments have the unique ability to maintain lymphedema safely overnight/during low activity with its lower levels of compression and containment based on medium-stretch fabric properties. Additionally, its textured surface provides a unique pressure differential on the tissue with high and low pressures designed to help stimulate the tissue, break up and soften fibrosis and support long term tissue health for lymphedema. The existing HCPCS Level II codes in the nighttime category are limited to an "arm", and there are no HCPCS Level II codes for segmented anatomical locations and their custom counterparts. Additional codes are necessary for proper identification and product selection to effectively manage lymphedema overnight or during periods of low activity.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. CMS is proposing (in our CMS Preliminary HCPCS Coding Recommendation, see application HCP2406275UFBP) to revise HCPCS Level II code A6549, “Gradient compression garment, not otherwise specified” to instead read “Gradient compression garment, not otherwise specified, for daytime use, each” to describe this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Note that in our CMS Preliminary HCPCS Coding Recommendation we are proposing establishment of new HCPCS Level II code AXXXX, “Gradient compression garment, not otherwise specified, for nighttime use, each” to describe nighttime gradient compression garments (see application HCP2406275UFBP). If this code is established, suppliers would begin using this new code when submitting claims for this nighttime garment.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II "Not Otherwise Specified" codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Summary of Public Feedback

See Appendix A for a summary of public feedback for the HCPCS Level II lymphedema management applications.

CMS Final HCPCS Coding Decision

This application is being deferred for additional consideration in a subsequent biannual coding cycle. CMS will continue to monitor the lymphedema compression treatment item benefit category, claims processing data, and health outcomes to assess the need to develop additional HCPCS Level II codes.

In the meantime, claims for these items should be billed using existing HCPCS Level II code A6549, "Gradient compression garment, not otherwise specified" through March 2025. Beginning April 1, 2025, claims for these items should be billed using new HCPCS Level II code A6519, "Gradient compression garment, not otherwise specified, for nighttime use, each".

Final Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Final Medicare Payment Determination

The payment determination for HCPCS Level II "Not Otherwise Specified" codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 40

Gradient Compression Padded Nighttime Garment, Head and Neck - HCP240626Y4RCN

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression padded nighttime garment for the head and neck.

Applicant's suggested language: XXXXX, “Gradient compression garment, head and neck, padded, for nighttime use, each”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression padded nighttime garment for the head and neck. The item is a medical gradient compression garment for the treatment of lymphedema. The proposed code language is necessary to recognize the specific textile/technology and anatomical location of lymphedema. Nighttime garments are manufactured to incorporate a textured surface against the skin, which is achieved in a few different formats based on current technology on the market, such as chip foam, flat foam, channel foam, polyfill, and 3D knit structure. These garments are primarily cut or knit to size, filled with texture-based solution/knit with texture, and lastly sewn. Many of them also integrate built-in directional channeling based on the lymphatic pathways. Nighttime garments have the unique ability to maintain lymphedema safely overnight/during low activity with its lower levels of compression and containment based on medium-stretch fabric properties. Additionally, its textured surface provides a unique pressure differential on the tissue with high and low pressures designed to help stimulate the tissue, break up and soften fibrosis and support long term tissue health for lymphedema. The existing HCPCS Level II codes in the nighttime category are limited as there are no HCPCS Level II codes for several anatomical locations and their custom counterparts. Specifically, there are no codes for a head and neck garment which is especially important as head and neck swelling is worse in the morning, even when individuals sleep with their head and neck well supported and elevated. Additional codes are necessary for proper identification and product selection to effectively manage lymphedema overnight or during periods of low activity.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. CMS is proposing (in our CMS Preliminary HCPCS Coding Recommendation, see application HCP2406275UFBP) to revise HCPCS Level II code A6549, “Gradient compression garment, not otherwise specified” to instead read “Gradient compression garment, not otherwise specified, for daytime use, each” to describe this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Note that in our CMS Preliminary HCPCS Coding Recommendation we are proposing establishment of new HCPCS Level II code AXXXX, “Gradient compression garment, not otherwise specified, for nighttime use, each” to describe nighttime gradient compression garments (see application HCP2406275UFBP). If this code is established, suppliers would begin using this new code when submitting claims for this nighttime garment.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II "Not Otherwise Specified" codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Summary of Public Feedback

See Appendix A for a summary of public feedback for the HCPCS Level II lymphedema management applications.

CMS Final HCPCS Coding Decision

This application is being deferred for additional consideration in a subsequent biannual coding cycle. CMS will continue to monitor the lymphedema compression treatment item benefit category, claims processing data, and health outcomes to assess the need to develop additional HCPCS Level II codes.

In the meantime, claims for these items should be billed using existing HCPCS Level II code A6549, "Gradient compression garment, not otherwise specified" through March 2025. Beginning April 1, 2025, claims for these items should be billed using new HCPCS Level II code A6519, "Gradient compression garment, not otherwise specified, for nighttime use, each".

Final Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Final Medicare Payment Determination

The payment determination for HCPCS Level II "Not Otherwise Specified" codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 40

Gradient Compression Custom Padded Nighttime Garment, Head and Neck - HCP240627X41TJ

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression custom padded nighttime garment for the head and neck.

Applicant's suggested language: XXXXX, “Gradient compression garment, head and neck, padded, for nighttime use, each, custom”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression custom padded nighttime garment for the head and neck. This is a medical gradient compression garment for the treatment of lymphedema. The proposed code language is necessary to recognize the specific textile/technology and anatomical location of lymphedema. Nighttime garments are manufactured to incorporate a textured surface against the skin, which is achieved in a few different formats based on current technology on the market, such as chip foam, flat foam, channel foam, polyfill, and 3D knit structure. These garments are primarily cut or knit to size, filled with texture-based solution/knit with texture, and lastly sewn. Many of them also integrate built-in directional channeling based on the lymphatic pathways. Nighttime garments have the unique ability to maintain lymphedema safely overnight/during low activity with its lower levels of compression and containment based on medium-stretch fabric properties. Additionally, its textured surface provides a unique pressure differential on the tissue with high and low pressures designed to help stimulate the tissue, break up and soften fibrosis and support long term tissue health for lymphedema. The existing HCPCS Level II codes in the nighttime category are limited as there are no HCPCS Level II codes for several anatomical locations and their custom counterparts. Specifically, there are no codes for a head and neck garment which is especially important as head and neck swelling is worse in the morning, even when individuals sleep with their head and neck well supported and elevated. Additional codes are necessary for proper identification and product selection to effectively manage lymphedema overnight or during periods of low activity.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. CMS is proposing (in our CMS Preliminary HCPCS Coding Recommendation, see application HCP2406275UFBP) to revise HCPCS Level II code A6549, “Gradient compression garment, not otherwise specified” to instead read “Gradient compression garment, not otherwise specified, for daytime use, each” to describe this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Note that in our CMS Preliminary HCPCS Coding Recommendation we are proposing establishment of new HCPCS Level II code AXXXX, “Gradient compression garment, not otherwise specified, for nighttime use, each” to describe nighttime gradient compression garments (see application HCP2406275UFBP). If this code is established, suppliers would begin using this new code when submitting claims for this nighttime garment.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II "Not Otherwise Specified" codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Summary of Public Feedback

See Appendix A for a summary of public feedback for the HCPCS Level II lymphedema management applications.

CMS Final HCPCS Coding Decision

This application is being deferred for additional consideration in a subsequent biannual coding cycle. CMS will continue to monitor the lymphedema compression treatment item benefit category, claims processing data, and health outcomes to assess the need to develop additional HCPCS Level II codes.

In the meantime, claims for these items should be billed using existing HCPCS Level II code A6549, "Gradient compression garment, not otherwise specified" through March 2025. Beginning April 1, 2025, claims for these items should be billed using new HCPCS Level II code A6519, "Gradient compression garment, not otherwise specified, for nighttime use, each".

Final Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Final Medicare Payment Determination

The payment determination for HCPCS Level II "Not Otherwise Specified" codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 40

Gradient Compression Custom Padded Nighttime Garment, Torso and Arm, Long Sleeve Shirt - HCP240627W1DEW

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression custom padded nighttime garment, long sleeve shirt, for the torso and arm.

Applicant's suggested language: XXXXX, “Gradient compression garment, torso and arm, long sleeve shirt, padded, for nighttime use, each, custom”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression custom padded nighttime garment, long sleeve shirt, for the torso and arm. The item is a medical gradient compression garment for the treatment of lymphedema. The proposed code language is necessary to recognize the specific textile/technology and combined anatomical locations of lymphedema. Nighttime garments are manufactured to incorporate a textured surface against the skin, which is achieved in a few different formats based on current technology on the market, such as chip foam, flat foam, channel foam, polyfill, and 3D knit structure. These garments are primarily cut or knit to size, filled with texture-based solution/knit with texture, and lastly sewn. Many of them also integrate built-in directional channeling based on the lymphatic pathways. Nighttime garments have the unique ability to maintain lymphedema safely overnight/during low activity with its lower levels of compression and containment based on medium-stretch fabric properties. Additionally, its textured surface provides a unique pressure differential on the tissue with high and low pressures designed to help stimulate the tissue, break up and soften fibrosis and support long term tissue health for lymphedema. Additional HCPCS Level II code for a custom nighttime long sleeve shirt is needed for comprehensive coverage to effectively manage multiple body parts lymphedema overnight or during periods of low activity.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. CMS is proposing (in our CMS Preliminary HCPCS Coding Recommendation, see application HCP2406275UFBP) to revise HCPCS Level II code A6549, “Gradient compression garment, not otherwise specified” to instead read “Gradient compression garment, not otherwise specified, for daytime use, each” to describe this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Note that in our CMS Preliminary HCPCS Coding Recommendation we are proposing establishment of new HCPCS Level II code AXXXX, “Gradient compression garment, not otherwise specified, for nighttime use, each” to describe nighttime gradient compression garments (see application HCP2406275UFBP). If this code is established, suppliers would begin using this new code when submitting claims for this nighttime garment.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II "Not Otherwise Specified" codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Summary of Public Feedback

See Appendix A for a summary of public feedback for the HCPCS Level II lymphedema management applications.

CMS Final HCPCS Coding Decision

This application is being deferred for additional consideration in a subsequent biannual coding cycle. CMS will continue to monitor the lymphedema compression treatment item benefit category, claims processing data, and health outcomes to assess the need to develop additional HCPCS Level II codes.

In the meantime, claims for these items should be billed using existing HCPCS Level II code A6549, "Gradient compression garment, not otherwise specified" through March 2025. Beginning April 1, 2025, claims for these items should be billed using new HCPCS Level II code A6519, "Gradient compression garment, not otherwise specified, for nighttime use, each".

Final Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Final Medicare Payment Determination

The payment determination for HCPCS Level II "Not Otherwise Specified" codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 40

Gradient Compression Custom Padded Nighttime Garment, Genital, Shorts - HCP240627RKU6Y

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression custom padded nighttime garment shorts for the torso.

Applicant's suggested language: XXXXX, “Gradient compression garment, torso - shorts, padded, for nighttime use, custom, each”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression custom padded nighttime garment shorts for the torso. The item is a medical gradient compression garment for the treatment of lymphedema. The proposed code language is necessary to recognize the specific textile/technology and anatomical locations of lymphedema. Nighttime garments are manufactured to incorporate a textured surface against the skin, which is achieved in a few different formats based on current technology on the market, such as: chip foam, flat foam, channel foam, polyfill, and 3D knit structure. These garments are primarily cut or knit to size, filled with texture-based solution/knit with texture, and lastly sewn. Many of them also integrate built-in directional channeling based on the lymphatic pathways. Nighttime garments have the unique ability to maintain lymphedema safely overnight/during low activity with its lower levels of compression and containment based on medium-stretch fabric properties. Additionally, its textured surface provides a unique pressure differential on the tissue with high and low pressures designed to help stimulate the tissue, break up and soften fibrosis and support long term tissue health for lymphedema. Additional HCPCS Level II codes are necessary for comprehensive coverage to effectively manage multiple body parts lymphedema (e.g., genital, torso) overnight or during periods of low activity.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. CMS is proposing (in our CMS Preliminary HCPCS Coding Recommendation, see application HCP2406275UFBP) to revise HCPCS Level II code A6549, “Gradient compression garment, not otherwise specified” to instead read “Gradient compression garment, not otherwise specified, for daytime use, each” to describe this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Note that in our CMS Preliminary HCPCS Coding Recommendation we are proposing establishment of new HCPCS Level II code AXXXX, “Gradient compression garment, not otherwise specified, for nighttime use, each” to describe nighttime gradient compression garments (see application HCP2406275UFBP). If this code is established, suppliers would begin using this new code when submitting claims for this nighttime garment.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II "Not Otherwise Specified" codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Summary of Public Feedback

See Appendix A for a summary of public feedback for the HCPCS Level II lymphedema management applications.

CMS Final HCPCS Coding Decision

This application is being deferred for additional consideration in a subsequent biannual coding cycle. CMS will continue to monitor the lymphedema compression treatment item benefit category, claims processing data, and health outcomes to assess the need to develop additional HCPCS Level II codes.

In the meantime, claims for these items should be billed using existing HCPCS Level II code A6549, "Gradient compression garment, not otherwise specified" through March 2025. Beginning April 1, 2025, claims for these items should be billed using new HCPCS Level II code A6519, "Gradient compression garment, not otherwise specified, for nighttime use, each".

Final Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Final Medicare Payment Determination

The payment determination for HCPCS Level II "Not Otherwise Specified" codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 40

Gradient Compression Custom Padded Nighttime Garment, Torso and Shoulder, Short Sleeve Shirt - HCP240627U11R3

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression custom padded nighttime garment short sleeve shirt for the torso and shoulder.

Applicant's suggested language: XXXXX, “Gradient compression garment, torso and shoulder, short sleeve shirt, padded, for nighttime use, each, custom”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression custom padded nighttime garment short sleeve shirt for the torso and shoulder. This is a medical gradient compression garment for the treatment of lymphedema. The proposed code language is necessary to recognize the specific textile/technology and combined anatomical locations of lymphedema. Nighttime garments are manufactured to incorporate a textured surface against the skin, which is achieved in a few different formats based on current technology on the market, such as chip foam, flat foam, channel foam, polyfill, and 3D knit structure. These garments are primarily cut or knit to size, filled with texture-based solution/knit with texture, and lastly sewn. Many of them also integrate built-in directional channeling based on the lymphatic pathways. Nighttime garments have the unique ability to maintain lymphedema safely overnight / during low activity with its lower levels of compression and containment based on medium-stretch fabric properties. Additionally, its textured surface provides a unique pressure differential on the tissue with high and low pressures designed to help stimulate the tissue, break up and soften fibrosis and support long term tissue health for lymphedema. Additional HCPCS Level II code for a nighttime custom short sleeve shirt is needed for comprehensive coverage to effectively manage multiple body parts lymphedema.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. CMS is proposing (in our CMS Preliminary HCPCS Coding Recommendation, see application HCP2406275UFBP) to revise HCPCS Level II code A6549, “Gradient compression garment, not otherwise specified” to instead read “Gradient compression garment, not otherwise specified, for daytime use, each” to describe this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Note that in our CMS Preliminary HCPCS Coding Recommendation we are proposing establishment of new HCPCS Level II code AXXXX, “Gradient compression garment, not otherwise specified, for nighttime use, each” to describe nighttime gradient compression garments (see application HCP2406275UFBP). If this code is established, suppliers would begin using this new code when submitting claims for this nighttime garment.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II "Not Otherwise Specified" codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Summary of Public Feedback

See Appendix A for a summary of public feedback for the HCPCS Level II lymphedema management applications.

CMS Final HCPCS Coding Decision

This application is being deferred for additional consideration in a subsequent biannual coding cycle. CMS will continue to monitor the lymphedema compression treatment item benefit category, claims processing data, and health outcomes to assess the need to develop additional HCPCS Level II codes.

In the meantime, claims for these items should be billed using existing HCPCS Level II code A6549, "Gradient compression garment, not otherwise specified" through March 2025. Beginning April 1, 2025, claims for these items should be billed using new HCPCS Level II code A6519, "Gradient compression garment, not otherwise specified, for nighttime use, each".

Final Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Final Medicare Payment Determination

The payment determination for HCPCS Level II "Not Otherwise Specified" codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 40

Gradient Compression Padded Nighttime Garment, Upper Leg - HCP240626MJV5R

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression padded nighttime garment for the upper leg.

Applicant's suggested language: XXXXX, “Gradient compression garment, upper leg, padded, for nighttime use, each”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression padded nighttime garment for the upper leg. This is a medical gradient compression garment for the treatment of lymphedema. The proposed code language is necessary to recognize the specific textile/technology and anatomical location of lymphedema. Nighttime garments are manufactured to incorporate a textured surface against the skin, which is achieved in a few different formats based on current technology on the market, such as: chip foam, flat foam, channel foam, polyfill, and 3D knit structure. These garments are primarily cut or knit to size, filled with texture-based solution/knit with texture, and lastly sewn. Many of them also integrate built-in directional channeling based on the lymphatic pathways. Nighttime garments have the unique ability to maintain lymphedema safely overnight / during low activity with its lower levels of compression and containment based on medium-stretch fabric properties. Additionally, its textured surface provides a unique pressure differential on the tissue with high and low pressures designed to help stimulate the tissue, break up and soften fibrosis and support long term tissue health for lymphedema. The existing HCPCS Level II codes in the nighttime category are limited as there no HCPCS Level II codes for several anatomical locations and their custom counterparts. Additional codes are necessary for proper identification and product selection to effectively manage lymphedema overnight or during periods of low activity.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. CMS is proposing (in our CMS Preliminary HCPCS Coding Recommendation, see application HCP2406275UFBP) to revise HCPCS Level II code A6549, “Gradient compression garment, not otherwise specified” to instead read “Gradient compression garment, not otherwise specified, for daytime use, each” to describe this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Note that in our CMS Preliminary HCPCS Coding Recommendation we are proposing establishment of new HCPCS Level II code AXXXX, “Gradient compression garment, not otherwise specified, for nighttime use, each” to describe nighttime gradient compression garments (see application HCP2406275UFBP). If this code is established, suppliers would begin using this new code when submitting claims for this nighttime garment.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II "Not Otherwise Specified" codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Summary of Public Feedback

See Appendix A for a summary of public feedback for the HCPCS Level II lymphedema management applications.

CMS Final HCPCS Coding Decision

This application is being deferred for additional consideration in a subsequent biannual coding cycle. CMS will continue to monitor the lymphedema compression treatment item benefit category, claims processing data, and health outcomes to assess the need to develop additional HCPCS Level II codes.

In the meantime, claims for these items should be billed using existing HCPCS Level II code A6549, "Gradient compression garment, not otherwise specified" through March 2025. Beginning April 1, 2025, claims for these items should be billed using new HCPCS Level II code A6519, "Gradient compression garment, not otherwise specified, for nighttime use, each".

Final Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Final Medicare Payment Determination

The payment determination for HCPCS Level II "Not Otherwise Specified" codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 40

Gradient Compression Custom Nighttime Garment, Upper Leg - HCP240626VPRN2

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression custom nighttime garment for the upper leg.

Applicant's suggested language: XXXXX, “Gradient compression garment, upper leg, for nighttime use, each, custom”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression custom nighttime garment for the upper leg. This is a medical gradient compression garment for the treatment of lymphedema. The proposed code language is necessary to recognize the specific textile/technology and anatomical location of lymphedema. Nighttime garments are manufactured to incorporate a textured surface against the skin, which is achieved in a few different formats based on current technology on the market, such as chip foam, flat foam, channel foam, polyfill, and 3D knit structure. These garments are primarily cut or knit to size, filled with texture-based solution/knit with texture, and lastly sewn. Many of them also integrate built-in directional channeling based on the lymphatic pathways. Nighttime garments have the unique ability to maintain lymphedema safely overnight/during low activity with its lower levels of compression and containment based on medium-stretch fabric properties. Additionally, its textured surface provides a unique pressure differential on the tissue with high and low pressures designed to help stimulate the tissue, break up and soften fibrosis and support long term tissue health for lymphedema. The existing HCPCS Level II codes in the nighttime category are limited as there are no HCPCS Level II codes for several anatomical locations and their custom counterparts. Additional codes are necessary for proper identification and product selection to effectively manage lymphedema overnight or during periods of low activity.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. CMS is proposing (in our CMS Preliminary HCPCS Coding Recommendation, see application HCP2406275UFBP) to revise HCPCS Level II code A6549, “Gradient compression garment, not otherwise specified” to instead read “Gradient compression garment, not otherwise specified, for daytime use, each” to describe this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Note that in our CMS Preliminary HCPCS Coding Recommendation we are proposing establishment of new HCPCS Level II code AXXXX, “Gradient compression garment, not otherwise specified, for nighttime use, each” to describe nighttime gradient compression garments (see application HCP2406275UFBP). If this code is established, suppliers would begin using this new code when submitting claims for this nighttime garment.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II "Not Otherwise Specified" codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Summary of Public Feedback

See Appendix A for a summary of public feedback for the HCPCS Level II lymphedema management applications.

CMS Final HCPCS Coding Decision

This application is being deferred for additional consideration in a subsequent biannual coding cycle. CMS will continue to monitor the lymphedema compression treatment item benefit category, claims processing data, and health outcomes to assess the need to develop additional HCPCS Level II codes.

In the meantime, claims for these items should be billed using existing HCPCS Level II code A6549, "Gradient compression garment, not otherwise specified" through March 2025. Beginning April 1, 2025, claims for these items should be billed using new HCPCS Level II code A6519, "Gradient compression garment, not otherwise specified, for nighttime use, each".

Final Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Final Medicare Payment Determination

The payment determination for HCPCS Level II "Not Otherwise Specified" codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 40

Gradient Compression Custom Padded Nighttime Garment, Torso, Vest - HCP2406277F2M1

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression custom padded nighttime garment vest for the torso.

Applicant's suggested language: XXXXX, “Gradient compression garment, torso - vest, padded, for nighttime use, each, custom”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression custom padded nighttime garment vest for the torso. This is a medical gradient compression garment for the treatment of lymphedema. The proposed code language is necessary to recognize the specific textile/technology and anatomical locations of lymphedema. Nighttime garments are manufactured to incorporate a textured surface against the skin, which is achieved in a few different formats based on current technology on the market, such as: chip foam, flat foam, channel foam, polyfill, and 3D knit structure. These garments are primarily cut or knit to size, filled with texture-based solution/knit with texture, and lastly sewn. Many of them also integrate built-in directional channeling based on the lymphatic pathways. Nighttime garments have the unique ability to maintain lymphedema safely overnight/during low activity with its lower levels of compression and containment based on medium-stretch fabric properties. Additionally, its textured surface provides a unique pressure differential on the tissue with high and low pressures designed to help stimulate the tissue, break up and soften fibrosis and support long term tissue health for lymphedema. Additional HCPCS codes are necessary for comprehensive coverage to effectively manage multiple body parts lymphedema (e.g., chest and abdomen) overnight or during periods of low activity.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. CMS is proposing (in our CMS Preliminary HCPCS Coding Recommendation, see application HCP2406275UFBP) to revise HCPCS Level II code A6549, “Gradient compression garment, not otherwise specified” to instead read “Gradient compression garment, not otherwise specified, for daytime use, each” to describe this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Note that in our CMS Preliminary HCPCS Coding Recommendation we are proposing establishment of new HCPCS Level II code AXXXX, “Gradient compression garment, not otherwise specified, for nighttime use, each” to describe nighttime gradient compression garments (see application HCP2406275UFBP). If this code is established, suppliers would begin using this new code when submitting claims for this nighttime garment.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II "Not Otherwise Specified" codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Summary of Public Feedback

See Appendix A for a summary of public feedback for the HCPCS Level II lymphedema management applications.

CMS Final HCPCS Coding Decision

This application is being deferred for additional consideration in a subsequent biannual coding cycle. CMS will continue to monitor the lymphedema compression treatment item benefit category, claims processing data, and health outcomes to assess the need to develop additional HCPCS Level II codes.

In the meantime, claims for these items should be billed using existing HCPCS Level II code A6549, "Gradient compression garment, not otherwise specified" through March 2025. Beginning April 1, 2025, claims for these items should be billed using new HCPCS Level II code A6519, "Gradient compression garment, not otherwise specified, for nighttime use, each".

Final Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Final Medicare Payment Determination

The payment determination for HCPCS Level II "Not Otherwise Specified" codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 40

Gradient Compression Garment with Adjustable Straps, Hand Gauntlet - HCP240625LVHRC

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression garment with adjustable straps for a hand gauntlet.

Applicant's suggested language: XXXXX, “Gradient compression wrap with adjustable straps, hand gauntlet, each”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression garment with adjustable straps for a hand gauntlet. The proposed code is necessary to recognize the specific textile/technology, and precise anatomical location of lymphedema. Adjustable wrap items are uniquely constructed from multiple layers of textiles that are sewn, laminated or bonded together to create a fabric that has minimal stretch (inelastic) and high rigidity. The textiles may include but are not limited to nylon, foam, and textured fabric delivering the highest stiffness/containment compared to other compression garments. These garments use clasps or hook and loop closures to enable adjustability providing greater patient independence, adherence, and efficacy. The Lymphedema Treatment Act amended title XVIII of the Social Security Act to provide coverage of certain lymphedema compression treatment items under the Medicare Program. The term “lymphedema compression treatment items” means standard and custom fitted gradient compression garments determined to serve a medical purpose and for the treatment of lymphedema. The newly published HCPCS Level II codes are limited in its description of adjustable wrap items as there are no custom HCPCS Level II codes and no codes for several anatomical locations.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. Existing HCPCS Level II code A6584, “Gradient compression wrap with adjustable straps, not otherwise specified” is used when submitting claims for this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II “Not Otherwise Specified” codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Summary of Public Feedback

See Appendix A for a summary of public feedback for the HCPCS Level II lymphedema management applications.

CMS Final HCPCS Coding Decision

This application is being deferred for additional consideration in a subsequent biannual coding cycle. CMS will continue to monitor the lymphedema compression treatment item benefit category, claims processing data, and health outcomes to assess the need to develop additional HCPCS Level II codes.

Claims for these items should be billed using existing HCPCS Level II code A6584, "Gradient compression wrap with adjustable straps, not otherwise specified".

Final Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Final Medicare Payment Determination

The payment determination for HCPCS Level II "Not Otherwise Specified" codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 40

Gradient Compression Custom Garment with Adjustable Straps, Hand Gauntlet - HCP2406267T4RF

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression custom garment with adjustable straps for a hand gauntlet.

Applicant's suggested language: XXXXX, “Gradient compression wrap with adjustable straps, hand gauntlet, each, custom”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression custom garment with adjustable straps for a hand gauntlet. The proposed code is necessary to recognize the specific textile/technology, precise anatomical location of lymphedema, and custom version of the product. Adjustable wrap items are uniquely constructed from multiple layers of textiles that are sewn, laminated or bonded together to create a fabric that has minimal stretch (inelastic) and high rigidity. The textiles may include but are not limited to nylon, foam, and textured fabric delivering the highest stiffness/containment compared to other compression garments. These garments use clasps or hook and loop closures to enable adjustability providing greater patient independence, adherence, and efficacy. The Lymphedema Treatment Act amended title XVIII of the Social Security Act to provide coverage of certain lymphedema compression treatment items under the Medicare Program. The term “lymphedema compression treatment items” means standard and custom fitted gradient compression garments determined to serve a medical purpose and for the treatment of lymphedema. The newly published HCPCS Level II codes are limited in its description of adjustable wrap items as there are no custom HCPCS Level II codes and no codes for several anatomical locations.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. Existing HCPCS Level II code A6584, “Gradient compression wrap with adjustable straps, not otherwise specified” is used when submitting claims for this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II “Not Otherwise Specified” codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Summary of Public Feedback

See Appendix A for a summary of public feedback for the HCPCS Level II lymphedema management applications.

CMS Final HCPCS Coding Decision

This application is being deferred for additional consideration in a subsequent biannual coding cycle. CMS will continue to monitor the lymphedema compression treatment item benefit category, claims processing data, and health outcomes to assess the need to develop additional HCPCS Level II codes.

Claims for these items should be billed using existing HCPCS Level II code A6584, "Gradient compression wrap with adjustable straps, not otherwise specified".

Final Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Final Medicare Payment Determination

The payment determination for HCPCS Level II "Not Otherwise Specified" codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 40

Gradient Compression Garment with Adjustable Straps, Hand Glove - HCP240625HTAQK

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression wrap with adjustable straps for a hand glove.

Applicant's suggested language: XXXXX, “Gradient compression wrap with adjustable straps, hand glove, each”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression wrap with adjustable straps for a hand glove. The proposed code is necessary to recognize the specific textile/technology, and precise anatomical location of lymphedema. Adjustable wrap items are uniquely constructed from multiple layers of textiles that are sewn, laminated or bonded together to create a fabric that has minimal stretch (inelastic) and high rigidity. The textiles may include but are not limited to nylon, foam, and textured fabric delivering the highest stiffness/containment compared to other compression garments. These garments use clasps or hook and loop closures to enable adjustability providing greater patient independence, adherence, and efficacy. The Lymphedema Treatment Act amended title XVIII of the Social Security Act to provide coverage of certain lymphedema compression treatment items under the Medicare Program. The term “lymphedema compression treatment items” means standard and custom fitted gradient compression garments determined to serve a medical purpose and for the treatment of lymphedema. The newly published HCPCS Level II codes are limited in its description of adjustable wrap items as there are no custom HCPCS Level II codes and no codes for several anatomical locations.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. Existing HCPCS Level II code A6584, “Gradient compression wrap with adjustable straps, not otherwise specified” is used when submitting claims for this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II “Not Otherwise Specified” codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Summary of Public Feedback

See Appendix A for a summary of public feedback for the HCPCS Level II lymphedema management applications.

CMS Final HCPCS Coding Decision

This application is being deferred for additional consideration in a subsequent biannual coding cycle. CMS will continue to monitor the lymphedema compression treatment item benefit category, claims processing data, and health outcomes to assess the need to develop additional HCPCS Level II codes.

Claims for these items should be billed using existing HCPCS Level II code A6584, "Gradient compression wrap with adjustable straps, not otherwise specified".

Final Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Final Medicare Payment Determination

The payment determination for HCPCS Level II "Not Otherwise Specified" codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 40

Gradient Compression Custom Garment with Adjustable Straps, Hand Glove - HCP240626CP3CR

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression custom garment with adjustable straps for a hand glove.

Applicant's suggested language: XXXXX, “Gradient compression wrap with adjustable straps, hand glove, each, custom”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression custom garment with adjustable straps for a hand glove. The proposed code is necessary to recognize the specific textile/technology, precise anatomical location of lymphedema, and custom version of the product. Adjustable wrap items are uniquely constructed from multiple layers of textiles that are sewn, laminated or bonded together to create a fabric that has minimal stretch (inelastic) and high rigidity. The textiles may include but are not limited to nylon, foam, and textured fabric delivering the highest stiffness/containment compared to other compression garments. These garments use clasps or hook and loop closures to enable adjustability providing greater patient independence, adherence, and efficacy. The Lymphedema Treatment Act amended title XVIII of the Social Security Act to provide coverage of certain lymphedema compression treatment items under the Medicare Program. The term “lymphedema compression treatment items" means standard and custom fitted gradient compression garments determined to serve a medical purpose and for the treatment of lymphedema. The newly published HCPCS Level II codes are limited in its description of adjustable wrap items as there are no custom HCPCS Level II codes and no codes for several anatomical locations.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. Existing HCPCS Level II code A6584, “Gradient compression wrap with adjustable straps, not otherwise specified” is used when submitting claims for this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II “Not Otherwise Specified” codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Summary of Public Feedback

See Appendix A for a summary of public feedback for the HCPCS Level II lymphedema management applications.

CMS Final HCPCS Coding Decision

This application is being deferred for additional consideration in a subsequent biannual coding cycle. CMS will continue to monitor the lymphedema compression treatment item benefit category, claims processing data, and health outcomes to assess the need to develop additional HCPCS Level II codes.

Claims for these items should be billed using existing HCPCS Level II code A6584, "Gradient compression wrap with adjustable straps, not otherwise specified".

Final Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Final Medicare Payment Determination

The payment determination for HCPCS Level II "Not Otherwise Specified" codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 40

Gradient Compression Garment with Adjustable Straps, Knee - HCP240625YVAET

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression garment with adjustable straps for the knee.

Applicant's suggested language: XXXXX, “Gradient compression wrap with adjustable straps, knee, each”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression wrap with adjustable straps for the knee. The proposed code is necessary to recognize the specific textile/technology, and precise anatomical location of lymphedema. Adjustable wrap items are uniquely constructed from multiple layers of textiles that are sewn, laminated or bonded together to create a fabric that has minimal stretch (inelastic) and high rigidity. The textiles may include but are not limited to nylon, foam, and textured fabric delivering the highest stiffness/containment compared to other compression garments. These garments use clasps or hook and loop closures to enable adjustability providing greater patient independence, adherence, and efficacy. The Lymphedema Treatment Act amended title XVIII of the Social Security Act to provide coverage of certain lymphedema compression treatment items under the Medicare Program. The term “lymphedema compression treatment items” means standard and custom fitted gradient compression garments determined to serve a medical purpose and for the treatment of lymphedema. The newly published HCPCS Level II codes are limited in its description of adjustable wrap items as there are no custom HCPCS Level II codes and no codes for several anatomical locations. Unique HCPCS Level II code for a knee wrap is needed to build a full leg, modular coverage with adjustable wraps to effectively manage lymphedema.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. Existing HCPCS Level II code A6584, “Gradient compression wrap with adjustable straps, not otherwise specified” is used when submitting claims for this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II “Not Otherwise Specified” codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Summary of Public Feedback

See Appendix A for a summary of public feedback for the HCPCS Level II lymphedema management applications.

CMS Final HCPCS Coding Decision

This application is being deferred for additional consideration in a subsequent biannual coding cycle. CMS will continue to monitor the lymphedema compression treatment item benefit category, claims processing data, and health outcomes to assess the need to develop additional HCPCS Level II codes.

Claims for these items should be billed using existing HCPCS Level II code A6584, "Gradient compression wrap with adjustable straps, not otherwise specified".

Final Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Final Medicare Payment Determination

The payment determination for HCPCS Level II "Not Otherwise Specified" codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 40

Gradient Compression Custom Garment with Adjustable Straps, Knee - HCP240626ACU0W

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression custom garment with adjustable straps for the knee.

Applicant's suggested language: XXXXX, “Gradient compression wrap with adjustable straps, knee, each, custom”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression custom garment with adjustable straps for the knee. The proposed code is necessary to recognize the specific textile/technology, precise anatomical location of lymphedema, and custom version of the product. Adjustable wrap items are uniquely constructed from multiple layers of textiles that are sewn, laminated or bonded together to create a fabric that has minimal stretch (inelastic) and high rigidity. The textiles may include but are not limited to nylon, foam, and textured fabric delivering the highest stiffness/containment compared to other compression garments. These garments use clasps or hook and loop closures to enable adjustability providing greater patient independence, adherence, and efficacy. The Lymphedema Treatment Act amended title XVIII of the Social Security Act to provide coverage of certain lymphedema compression treatment items under the Medicare Program. The term “lymphedema compression treatment items” means standard and custom fitted gradient compression garments determined to serve a medical purpose and for the treatment of lymphedema. The newly published HCPCS Level II codes are limited in its description of adjustable wrap items as there are no custom HCPCS Level II codes and no codes for several anatomical locations.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. Existing HCPCS Level II code A6584, “Gradient compression wrap with adjustable straps, not otherwise specified” is used when submitting claims for this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II “Not Otherwise Specified” codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Summary of Public Feedback

See Appendix A for a summary of public feedback for the HCPCS Level II lymphedema management applications.

CMS Final HCPCS Coding Decision

This application is being deferred for additional consideration in a subsequent biannual coding cycle. CMS will continue to monitor the lymphedema compression treatment item benefit category, claims processing data, and health outcomes to assess the need to develop additional HCPCS Level II codes.

Claims for these items should be billed using existing HCPCS Level II code A6584, "Gradient compression wrap with adjustable straps, not otherwise specified".

Final Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Final Medicare Payment Determination

The payment determination for HCPCS Level II "Not Otherwise Specified" codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 40

Gradient Compression Garment with Adjustable Straps, Lobe - HCP240625AGT7L

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression garment with adjustable straps for the lobe.

Applicant's suggested language: XXXXX, “Gradient compression wrap with adjustable straps, lobe, each”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression garment with adjustable straps for the lobe. The proposed code is necessary to recognize the specific textile/technology, and precise anatomical location of lymphedema. Adjustable wrap items are uniquely constructed from multiple layers of textiles that are sewn, laminated or bonded together to create a fabric that has minimal stretch (inelastic) and high rigidity. The textiles may include but are not limited to nylon, foam, and textured fabric delivering the highest stiffness/containment compared to other compression garments. These garments use clasps or hook and loop closures to enable adjustability providing greater patient independence, adherence, and efficacy. The Lymphedema Treatment Act amended title XVIII of the Social Security Act to provide coverage of certain lymphedema compression treatment items under the Medicare Program. The term “lymphedema compression treatment items” means standard and custom fitted gradient compression garments determined to serve a medical purpose and for the treatment of lymphedema. The newly published HCPCS Level II codes are limited in its description of adjustable wrap items as there are no custom HCPCS Level II codes and no codes for several anatomical locations.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. Existing HCPCS Level II code A6584, “Gradient compression wrap with adjustable straps, not otherwise specified” is used when submitting claims for this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II “Not Otherwise Specified” codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Summary of Public Feedback

See Appendix A for a summary of public feedback for the HCPCS Level II lymphedema management applications.

CMS Final HCPCS Coding Decision

This application is being deferred for additional consideration in a subsequent biannual coding cycle. CMS will continue to monitor the lymphedema compression treatment item benefit category, claims processing data, and health outcomes to assess the need to develop additional HCPCS Level II codes.

Claims for these items should be billed using existing HCPCS Level II code A6584, "Gradient compression wrap with adjustable straps, not otherwise specified".

Final Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Final Medicare Payment Determination

The payment determination for HCPCS Level II "Not Otherwise Specified" codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 40

Gradient Compression Custom Garment with Adjustable Straps, Lobe - HCP240626J6KD6

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression custom garment with adjustable straps for the lobe.

Applicant's suggested language: XXXXX, “Gradient compression wrap with adjustable straps, lobe, each, custom”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression custom garment with adjustable straps for the lobe. The proposed code is necessary to recognize the specific textile/technology, precise anatomical location of lymphedema, and custom version of the product. Adjustable wrap items are uniquely constructed from multiple layers of textiles that are sewn, laminated or bonded together to create a fabric that has minimal stretch (inelastic) and high rigidity. The textiles may include but are not limited to nylon, foam, and textured fabric delivering the highest stiffness/containment compared to other compression garments. These garments use clasps or hook and loop closures to enable adjustability providing greater patient independence, adherence, and efficacy. The Lymphedema Treatment Act amended title XVIII of the Social Security Act to provide coverage of certain lymphedema compression treatment items under the Medicare Program. The term “lymphedema compression treatment items” means standard and custom fitted gradient compression garments determined to serve a medical purpose and for the treatment of lymphedema. The newly published HCPCS Level II codes are limited in its description of adjustable wrap items as there are no custom HCPCS Level II codes and no codes for several anatomical locations.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. Existing HCPCS Level II code A6584, “Gradient compression wrap with adjustable straps, not otherwise specified” is used when submitting claims for this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II “Not Otherwise Specified” codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Summary of Public Feedback

See Appendix A for a summary of public feedback for the HCPCS Level II lymphedema management applications.

CMS Final HCPCS Coding Decision

This application is being deferred for additional consideration in a subsequent biannual coding cycle. CMS will continue to monitor the lymphedema compression treatment item benefit category, claims processing data, and health outcomes to assess the need to develop additional HCPCS Level II codes.

Claims for these items should be billed using existing HCPCS Level II code A6584, "Gradient compression wrap with adjustable straps, not otherwise specified".

Final Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Final Medicare Payment Determination

The payment determination for HCPCS Level II "Not Otherwise Specified" codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 40

Gradient Compression Garment with Adjustable Straps, Toe - HCP240625462HD

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression garment with adjustable straps for the toe.

Applicant's suggested language: XXXXX, “Gradient compression wrap with adjustable straps, toe, each”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression garment with adjustable straps for the toe. The proposed code is necessary to recognize the specific textile/technology, and precise anatomical location of lymphedema. Adjustable wrap items are uniquely constructed from multiple layers of textiles that are sewn, laminated or bonded together to create a fabric that has minimal stretch (inelastic) and high rigidity. The textiles may include but are not limited to nylon, foam, and textured fabric delivering the highest stiffness/containment compared to other compression garments. These garments use clasps or hook and loop closures to enable adjustability providing greater patient independence, adherence, and efficacy. The Lymphedema Treatment Act amended title XVIII of the Social Security Act to provide coverage of certain lymphedema compression treatment items under the Medicare Program. The term “lymphedema compression treatment items” means standard and custom fitted gradient compression garments determined to serve a medical purpose and for the treatment of lymphedema. The newly published HCPCS Level II codes are limited in its description of adjustable wrap items as there are no custom HCPCS Level II codes and no codes for several anatomical locations.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. Existing HCPCS Level II code A6584, “Gradient compression wrap with adjustable straps, not otherwise specified” is used when submitting claims for this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II “Not Otherwise Specified” codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Summary of Public Feedback

See Appendix A for a summary of public feedback for the HCPCS Level II lymphedema management applications.

CMS Final HCPCS Coding Decision

This application is being deferred for additional consideration in a subsequent biannual coding cycle. CMS will continue to monitor the lymphedema compression treatment item benefit category, claims processing data, and health outcomes to assess the need to develop additional HCPCS Level II codes.

Claims for these items should be billed using existing HCPCS Level II code A6584, "Gradient compression wrap with adjustable straps, not otherwise specified".

Final Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Final Medicare Payment Determination

The payment determination for HCPCS Level II "Not Otherwise Specified" codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 40

Gradient Compression Custom Garment with Adjustable Straps, Toe - HCP240626HQRC0

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression custom garment with adjustable straps for the toe.

Applicant's suggested language: XXXXX, “Gradient compression wrap with adjustable straps, toe, each, custom”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression custom garment with adjustable straps for the toe. The proposed code is necessary to recognize the specific textile/technology, precise anatomical location of lymphedema, and custom version of the product. Adjustable wrap items are uniquely constructed from multiple layers of textiles that are sewn, laminated or bonded together to create a fabric that has minimal stretch (inelastic) and high rigidity. The textiles may include but are not limited to nylon, foam, and textured fabric delivering the highest stiffness/containment compared to other compression garments. These garments use clasps or hook and loop closures to enable adjustability providing greater patient independence, adherence, and efficacy. The Lymphedema Treatment Act amended title XVIII of the Social Security Act to provide coverage of certain lymphedema compression treatment items under the Medicare Program. The term “lymphedema compression treatment items" means standard and custom fitted gradient compression garments determined to serve a medical purpose and for the treatment of lymphedema. The newly published HCPCS Level II codes are limited in its description of adjustable wrap items as there are no custom HCPCS Level II codes and no codes for several anatomical locations.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. Existing HCPCS Level II code A6584, “Gradient compression wrap with adjustable straps, not otherwise specified” is used when submitting claims for this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II “Not Otherwise Specified” codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Summary of Public Feedback

See Appendix A for a summary of public feedback for the HCPCS Level II lymphedema management applications.

CMS Final HCPCS Coding Decision

This application is being deferred for additional consideration in a subsequent biannual coding cycle. CMS will continue to monitor the lymphedema compression treatment item benefit category, claims processing data, and health outcomes to assess the need to develop additional HCPCS Level II codes.

Claims for these items should be billed using existing HCPCS Level II code A6584, "Gradient compression wrap with adjustable straps, not otherwise specified".

Final Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Final Medicare Payment Determination

The payment determination for HCPCS Level II "Not Otherwise Specified" codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 40

Gradient Compression Garment with Adjustable Straps, Torso, Vest - HCP240625GXD90

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression garment vest with adjustable straps for the torso.

Applicant's suggested language: XXXXX, “Gradient compression wrap with adjustable straps, torso, vest, each”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression garment vest with adjustable straps for the torso. The proposed code is necessary to recognize the specific textile/technology, and precise anatomical location of lymphedema. Adjustable wrap items are uniquely constructed from multiple layers of textiles that are sewn, laminated or bonded together to create a fabric that has minimal stretch (inelastic) and high rigidity. The textiles may include but are not limited to nylon, foam, and textured fabric delivering the highest stiffness/containment compared to other compression garments. These garments use clasps or hook and loop closures to enable adjustability providing greater patient independence, adherence, and efficacy. There are mechanical and clinical differentiations discussed in this application to support a unique code for this medical device. The Lymphedema Treatment Act amended title XVIII of the Social Security Act to provide coverage of certain lymphedema compression treatment items under the Medicare Program. The term “lymphedema compression treatment items” means standard and custom fitted gradient compression garments determined to serve a medical purpose and for the treatment of lymphedema. The newly published HCPCS Level II codes are limited in its description of adjustable wrap items as there are no custom HCPCS Level II codes and no codes for several anatomical locations.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. Existing HCPCS Level II code A6584, “Gradient compression wrap with adjustable straps, not otherwise specified” is used when submitting claims for this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II “Not Otherwise Specified” codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Summary of Public Feedback

See Appendix A for a summary of public feedback for the HCPCS Level II lymphedema management applications.

CMS Final HCPCS Coding Decision

This application is being deferred for additional consideration in a subsequent biannual coding cycle. CMS will continue to monitor the lymphedema compression treatment item benefit category, claims processing data, and health outcomes to assess the need to develop additional HCPCS Level II codes.

Claims for these items should be billed using existing HCPCS Level II code A6584, "Gradient compression wrap with adjustable straps, not otherwise specified".

Final Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Final Medicare Payment Determination

The payment determination for HCPCS Level II "Not Otherwise Specified" codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 40

Gradient Compression Custom Garment with Adjustable Straps, Torso, Vest - HCP240701TWK49

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression custom garment vest with adjustable straps for the torso.

Applicant's suggested language: XXXXX, “Gradient compression wrap with adjustable straps, torso, vest, each, custom”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code a gradient compression custom garment vest with adjustable straps for the torso. The proposed code is necessary to recognize the specific textile/technology, precise anatomical location of lymphedema, and specification of customization. Adjustable wrap items are uniquely constructed from multiple layers of textiles that are sewn, laminated or bonded together to create a fabric that has minimal stretch (inelastic) and high rigidity. The textiles may include but are not limited to nylon, foam, and textured fabric delivering the highest stiffness/containment compared to other compression garments. These garments use clasps and hook and loop closures to enable adjustability providing greater individual independence, adherence, and efficacy. The Lymphedema Treatment Act amended title XVIII of the Social Security Act to provide coverage of certain lymphedema compression treatment items under the Medicare Program. The term “lymphedema compression treatment items” means standard and custom fitted gradient compression garments determined to serve a medical purpose and for the treatment of lymphedema. The newly published HCPCS Level II codes are limited in its description of adjustable wrap items as there are no custom HCPCS Level II codes and no codes for several anatomical locations.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. Existing HCPCS Level II code A6584, “Gradient compression wrap with adjustable straps, not otherwise specified” is used when submitting claims for this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II “Not Otherwise Specified” codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Summary of Public Feedback

See Appendix A for a summary of public feedback for the HCPCS Level II lymphedema management applications.

CMS Final HCPCS Coding Decision

This application is being deferred for additional consideration in a subsequent biannual coding cycle. CMS will continue to monitor the lymphedema compression treatment item benefit category, claims processing data, and health outcomes to assess the need to develop additional HCPCS Level II codes.

Claims for these items should be billed using existing HCPCS Level II code A6584, "Gradient compression wrap with adjustable straps, not otherwise specified".

Final Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Final Medicare Payment Determination

The payment determination for HCPCS Level II "Not Otherwise Specified" codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 40

HCPCS Level II Codes for Various FDA Approvals under the 505(b)(2) or Biologics License Application (BLA) Pathways and Products "Not Otherwise Classified" - HCP220517FAENJ

Topic/Issue

We are requesting public comment on the language in the code descriptors for the new HCPCS Level II codes that we established in CMS' Fourth Quarter of 2023 and First, Second and Third Quarters of 2024 Drug and Biological HCPCS code application review cycles, per our postings at https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Prior-YearsCMSHCPCSLevelII-Coding-Decisions-Narrative-Summary.

Summary of Applicant's Submission

CMS has been reviewing its approach for establishing HCPCS Level II codes to identify products approved under the 505(b)(2) New Drug Application (NDA) or the Biologics License Application (BLA) pathways after October 2003. These products are not rated as therapeutically equivalent to their reference listed drug in the Food and Drug Administration's (FDA) Orange Book, and are therefore considered single source products. Also, this effort will help reduce use of the not otherwise classified (NOC) codes.

In order to conform with the general approach used for the assignment of products paid under section 1847A of the Social Security Act (the Act) to HCPCS Level II codes as described at the following CMS link: https://www.cms.gov/files/document/frequently-asked-questionssingle-source-drugs-and-biologicals.pdf. CMS is making several code changes, including manufacturer specific codes to identify products approved under separate 505(b)(2) NDA or BLA pathways. Since the products are approved under separate 505(b)(2) NDAs and are not rated as therapeutically equivalent by the FDA in the Orange Book[8], they are single source drugs based on the statutory definition of "single source drug" in section 1847A(c)(6) of the Act. Because these are single source drugs, there is a programmatic need for each product to have a unique billing and payment code.

In cases where certain products meet the statutory definition of "multiple source drug" in section 1847A(c)(6) of the Act, CMS will remove the brand name of the drug from any existing HCPCS Level II code as needed as it will accommodate any associated generic product(s), if approved and marketed, that are rated as therapeutically equivalent.

Due to the complexity and nuanced nature of the differences between each product, we encourage providers to rely on the Average Sales Price (ASP) HCPCS-National Drug Code (NDC) crosswalk[9] to identify the correct billing and payment code for each applicable product.

[8] The FDA's Orange Book, officially entitled, Approved Drug Products With Therapeutic Equivalence Evaluations, identifies drug products approved on the basis of safety and effectiveness by the FDA, and is published at the following FDA link: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm.

[9] The ASP crosswalks are maintained by CMS on a quarterly basis to support ASP-based Medicare Part B payments only. The quarterly ASP crosswalks are published at the following CMS link: https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/2022-asp-drug-pricing-files.

CMS Final HCPCS Coding Decision

We established or revised twelve HCPCS Level II codes within the fourth quarter (Q4) of 2023, effective April 1, 2024, ten HCPCS Level II codes within the first quarter (Q1) of 2024, effective July 1, 2024, nine HCPCS Level II codes within the second quarter (Q2) of 2024, effective October 1, 2024, and twelve HCPCS Level II codes within the third quarter (Q3) of 2024, effective January 1, 2025, to separately identify products approved by the FDA after October 2003, and not rated as therapeutically equivalent to a reference listed product in an existing code.

We seek comment on these code descriptors.

See Appendix B for a complete list of new HCPCS Level II codes that we are establishing.

CMS intends to continue our review in subsequent HCPCS code application quarterly cycles to separately identify products approved under the 505(b)(2) NDA or the BLA pathways after October 2003, and not rated as therapeutically equivalent to a reference listed product in an existing code, as well as products that have been "not otherwise classified".

Summary of Public Feedback

A commenter conveyed concern that including manufacturer specific language in the code descriptors for single source 505(b)(2) drugs is not specific enough to allow providers to identify the correct HCPCS Level II code to bill. In addition, the commenter stated that the proposed solution of utilizing the ASP HCPCS-NDC crosswalk is insufficient because the file is not comprehensive. The commenter suggested a new naming convention for 505(b)(2) HCPCS code descriptors where CMS would stop using manufacturer names and instead include the FDA application number of the single source drug or biological identified by that HCPCS code. The commenter also proposed that CMS utilize the NDC's FDA approval number and therapeutic equivalence rating from the FDA Orange Book to begin publishing a comprehensive HCPCS-NDC crosswalk file.

CMS Final HCPCS Coding Decision

Thus far CMS has not included NDC's in the HCPCS Level II code descriptor language. However, we have noticed that manufacturer specific language may not be the long-term solution, as companies and individual drugs are often bought out. We will take this proposal into consideration as we continue to improve the HCPCS Level II code set.

Appendix A: Summary of Public Feedback for the HCPCS Level II Lymphedema Management Applications

The U.S. Medical Compression Alliance (USMCA) had mixed opinions on CMS' published preliminary recommendations. Below, Table 1 provides a detailed list of their responses per application. However, the speaker wanted to specifically address bandage liners, adjustable wraps, and nighttime products. The speaker disagreed that the existing codes adequately describe bandage liners (HCP2407019YVJC, HCP240701KEDHA, HCP240701FWP0N) used in clinical practice today. They also disagreed that the national payment amounts accurately reflect the spectrum of pricing for these items. The speaker requested CMS to disclose the list of analyzed products and collaborate with subject matter experts (e.g., certified lymphedema therapist training schools, clinical organizations, patient advocacy groups) to validate whether they are an accurate representation of the standard of care within lymphedema treatment. Once there is consensus on the appropriate products for review, they asked for reconsideration of the anatomical segmentation of the codes and to adjust the pricing. The speaker agreed with the CMS' preliminary recommendations that establishes new codes for gradient compression wraps with adjustable straps. However, they disagreed that there is not a need to establish additional codes, as these products already exist within the market and have an established history of utilization. Also, the use of a not otherwise specified (NOS) code presents challenges as there is limited space on the claim form to describe the items. Inconsistent descriptions entered by suppliers makes data very difficult, if not impossible, to decipher. Similarly, the speaker disagreed with CMS that there is not a need to establish additional codes for nighttime products, as these products also already exist within the market and have a history of utilization. The missing nighttime codes also demonstrate the inconsistency in HCPCS Level II code descriptions between product types. For example, there is only lower leg and foot or full leg and foot for nighttime, as opposed to the adjustable wraps, which isolate foot, below knee, above knee, and full leg. For both the adjustable wraps and nighttime products that will in the interim be coded within the NOS codes, the speaker requested that CMS identifies the necessary data points and parameters to prove the need. In addition, USMCA is willing to collect and submit their own data. Depending on the defined parameters, they asked to defer the final decisions for additional codes to a follow-up meeting, potentially for B1 cycle 2026.

Another speaker stated that through their work, they routinely engage with clinicians, individuals, and manufacturers across the lymphedema industry. When using the bandaging for an individual with lymphedema, it is essential to tailor the products to specifically treat individual's unique needs and affected anatomy. They shared their concerns about the gaps within the currently published HCPCS Level II codes for bandage liners. The speaker said that they are broadly described as "upper" or "lower extremity" which do not adequately describe the range of products applied during the multilayer bandaging process. More precise HCPCS Level II codes that reflect the way products are used in the treatment of lymphedema are necessary. For example, one would not bandage an entire upper extremity if only an individual's hand was affected. Additionally, a one-size-fits-all code to generalize the bandage liners for extremities is problematic as the current reimbursement rates are published at less than $34 per product. The speaker stated that this low payment amount does not reflect the actual cost of most bandage liners prescribed today. Lymphedema treatment is nuanced, and they recommended that CMS disclose the list of products reviewed, so the experts in the field could confirm that appropriate products were considered. By considering input from experts in lymphedema management, CMS can support meaningful, sustainable improvements in individuals' access and quality of care. They asked to create additional,

more specific bandage liner codes to accurately reflect clinical practice. This would enable clinicians to choose products based on medical necessity rather than code restrictions. They also urged CMS to increase the reimbursement amount to make these essential products more accessible to individuals, ensuring they receive the highest standard of care.

Another speaker stated that the creation of the requested codes will significantly improve the claims processing for Medicare, Medicaid and other payers which will improve access to care. Even if CMS defers to the Durable Medical Equipment Medicare Administrative Contractor (MAC) to either create pricing or process them as individual consideration, it will significantly improve the claims processing experience. All payers would be able to automatically identify the items via the assigned HCPCS Level II code which will significantly improve the claim processing efficiency by reducing the manual intervention required. This will also help the MACs as they consider creating a policy.

Another speaker stated that they received feedback from beneficiaries and caregivers reporting denials and coverage problems. They said that some significant issues exist when it comes to supplies that do not have a unique code. They have heard many instances of suppliers refusing to order an item using a "not otherwise specified" code. Sometimes this is because suppliers honestly believe that no billable code exists for that item, and sometimes it is due to lack of certainty about the amount of reimbursement. Suppliers cannot sell items at a loss. Coverage is therefore only meaningful when beneficiaries have a source for obtaining the supplies prescribed for them. The Lymphedema Treatment Act was enacted for the purpose of improving access to care for Medicare beneficiaries with lymphedema by enabling coverage for the medical supplies that they need to manage this chronic condition. Sufficient codes with adequate reimbursement are essential to ensure that this new law fulfills its intent.

Table 1: USMCA's Response and Rationale per HCPCS Level II Application.

MEARIS™ ID	**CMS' Preliminary Determinations**	**USMCA Response/ Rationale**
HCP2406275UFBP	Establish new HCPCS Level II code AXXXX, "Gradient compression garment, not otherwise specified, for nighttime use, each"	Agree
	Revise HCPCS Level II code A6549 to instead read "Gradient compression garment, not otherwise specified, for daytime use, each"	Agree
	Payment Determination = Claim by claim basis	Agree
HCP240625X0PEW	Revise existing HCPCS Level II code A6583 to instead read "Gradient compression wrap with adjustable straps, below knee, each"	Agree
HCP240626P6WKG	Establish a new HCPCS Level II code AXXXX, "Gradient compression wrap with adjustable straps, above knee, each, custom"	Agree

	Revise existing HCPCS Level II code A6585 to instead read "Gradient compression wrap with adjustable straps, above knee, each"	Agree
	Payment Determination = Claim by claim basis	Agree
HCP240626R5DGX	Establish a new HCPCS Level II code AXXXX, "Gradient compression wrap with adjustable straps, arm, each, custom"	Agree
	Revise existing HCPCS Level II code A6588 to instead read "Gradient compression wrap with adjustable straps, arm, each"	Agree
	Payment Determination = Claim by claim basis	Agree
HCP240626KQ3P4	Establish a new HCPCS Level II code AXXXX, "Gradient compression wrap with adjustable straps, below knee, each, custom"	Agree
	Payment Determination = Claim by claim basis	Agree
HCP240626K1QT5	Establish a new HCPCS Level II code AXXXX, "Gradient compression wrap with adjustable straps, foot, each, custom"	Agree
	Revise existing HCPCS Level II code A6587 to instead read "Gradient compression wrap with adjustable straps, foot, each"	Agree
	Payment Determination = Claim by claim basis	Agree
HCP2406263JJDM	Establish a new HCPCS Level II code AXXXX, "Gradient compression wrap with adjustable straps, full leg, each, custom"	Agree
	Revise existing HCPCS Level II code A6586 to instead read "Gradient compression wrap with adjustable straps, full leg, each"	Agree
	Payment Determination = Claim by claim basis	Agree
HCP2407019YVJC	Existing HCPCS Level II code A6594, "Gradient compression bandaging supply, bandage liner, lower extremity, any size or length, each" describes gradient compression bandage liners and supplies for the lower extremities.	Disagree. Reliable product information is not readily available, recommend additional input from qualified organizations to validate USMCA position.

	After finding several internet retail prices for lower extremity bandage liners, the average price was $33.14. The applicant has sent us internet retail pricing for items they believe should have been included in this average calculation. We can confirm that we already included one of these products and its price in the average calculation. Although there may be products with a higher price than $33.14, the average still reflects the spectrum of pricing on the internet.	
HCP240701KEDHA	Bra Bandage Liner. CMS has not identified a need to establish a new HCPCS Level II code. Existing HCPCS Level II code A6609, "Gradient compression bandaging supply, not otherwise specified" is used when submitting claims for this lymphedema compression treatment item (LCTI).	Disagree. Reliable product information is not readily available, recommend additional input from qualified organizations to validate USMCA position.
HCP240701FWP0N	Upper Extremity Bandage Liner Segments. Existing HCPCS Level II code A6595, "Gradient compression bandaging supply, bandage liner, upper extremity, any size or length, each" describes gradient compression bandage liners and supplies for the upper extremities. After finding several internet retail prices for lower extremity bandage liners, the average price was $32.59. The applicant has sent us internet retail pricing for items they believe should have been included in this average calculation. We can confirm that we already included one of these products and its price in the average calculation. Although there may be products with a higher price than $32.59, the average still reflects the spectrum of pricing on the internet.	Disagree. Reliable product information is not readily available, recommend additional input from qualified organizations to validate USMCA position.
HCP240627LVYYT	Nighttime, torso/abdomen. CMS has not identified a need to establish a new HCPCS Level II	Defer. There is limited space on claim forms to describe items and inconsistent

	code. Note that in our CMS Preliminary HCPCS Coding Recommendation we are proposing establishment of new HCPCS Level II code AXXXX, "Gradient compression garment, not otherwise specified, for nighttime use, each" to describe nighttime gradient compression garments (see application HCP2406275UFBP). If this code is established, suppliers would begin using this new code when submitting claims for this nighttime garment. We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.	language submitted under the NOS codes. Request CMS to define reasonable parameters and allow USMCA to collect and submit data prior to final determination being made.
HCP2406264KDYN	Nighttime, custom, arm sleeve & glove combo. CMS has not identified a need to establish a new HCPCS Level II code. Note that in our CMS Preliminary HCPCS Coding Recommendation we are proposing establishment of new HCPCS Level II code AXXXX, "Gradient compression garment, not otherwise specified, for nighttime use, each" to describe nighttime gradient compression garments (see application HCP2406275UFBP). If this code is established, suppliers would begin using this new code when submitting claims for this nighttime garment. We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.	Defer. There is limited space on claim forms to describe items and inconsistent language submitted under the NOS codes. Request CMS to define reasonable parameters and allow USMCA to collect and submit data prior to final determination being made.
HCP240626N5LFM	Nighttime, arm sleeve & glove combo. CMS has not identified a need to establish a new HCPCS Level II code. Note that in our CMS Preliminary HCPCS Coding Recommendation we are proposing establishment of new HCPCS Level II code AXXXX, "Gradient compression garment, not	Defer. There is limited space on claim forms to describe items and inconsistent language submitted under the NOS codes. Request CMS to define reasonable parameters and allow USMCA to collect and submit data prior to final determination being made.

	otherwise specified, for nighttime use, each" to describe nighttime gradient compression garments (see application HCP2406275UFBP). If this code is established, suppliers would begin using this new code when submitting claims for this nighttime garment. We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.	
HCP240627PCD0U	Nighttime, custom, body suit. CMS has not identified a need to establish a new HCPCS Level II code. Note that in our CMS Preliminary HCPCS Coding Recommendation we are proposing establishment of new HCPCS Level II code AXXXX, "Gradient compression garment, not otherwise specified, for nighttime use, each" to describe nighttime gradient compression garments (see application HCP2406275UFBP). If this code is established, suppliers would begin using this new code when submitting claims for this nighttime garment. We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.	Defer. There is limited space on claim forms to describe items and inconsistent language submitted under the NOS codes. Request CMS to define reasonable parameters and allow USMCA to collect and submit data prior to final determination being made.
HCP2406276225W	Nighttime, genital/capri. CMS has not identified a need to establish a new HCPCS Level II code. Note that in our CMS Preliminary HCPCS Coding Recommendation we are proposing establishment of new HCPCS Level II code AXXXX, "Gradient compression garment, not otherwise specified, for nighttime use, each" to describe nighttime gradient compression garments (see application HCP2406275UFBP). If this code is established, suppliers would begin using this new code when	Defer. There is limited space on claim forms to describe items and inconsistent language submitted under the NOS codes. Request CMS to define reasonable parameters and allow USMCA to collect and submit data prior to final determination being made.

	submitting claims for this nighttime garment. We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.	
HCP240626FGCQC	Nighttime, custom, foot. CMS has not identified a need to establish a new HCPCS Level II code. Note that in our CMS Preliminary HCPCS Coding Recommendation we are proposing establishment of new HCPCS Level II code AXXXX, "Gradient compression garment, not otherwise specified, for nighttime use, each" to describe nighttime gradient compression garments (see application HCP2406275UFBP). If this code is established, suppliers would begin using this new code when submitting claims for this nighttime garment. We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.	Defer. There is limited space on claim forms to describe items and inconsistent language submitted under the NOS codes. Request CMS to define reasonable parameters and allow USMCA to collect and submit data prior to final determination being made.
HCP2406275H7WW	Nighttime, foot. CMS has not identified a need to establish a new HCPCS Level II code. Note that in our CMS Preliminary HCPCS Coding Recommendation we are proposing establishment of new HCPCS Level II code AXXXX, "Gradient compression garment, not otherwise specified, for nighttime use, each" to describe nighttime gradient compression garments (see application HCP2406275UFBP). If this code is established, suppliers would begin using this new code when submitting claims for this nighttime garment. We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.	Defer. There is limited space on claim forms to describe items and inconsistent language submitted under the NOS codes. Request CMS to define reasonable parameters and allow USMCA to collect and submit data prior to final determination being made.
HCP240626GHYEP	Nighttime, custom, gauntlet. CMS has not identified a need to	Defer. There is limited space on claim forms to describe

	establish a new HCPCS Level II code. Note that in our CMS Preliminary HCPCS Coding Recommendation we are proposing establishment of new HCPCS Level II code AXXXX, "Gradient compression garment, not otherwise specified, for nighttime use, each" to describe nighttime gradient compression garments (see application HCP2406275UFBP). If this code is established, suppliers would begin using this new code when submitting claims for this nighttime garment. We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.	items and inconsistent language submitted under the NOS codes. Request CMS to define reasonable parameters and allow USMCA to collect and submit data prior to final determination being made.
HCP240627PWHRD	Nighttime, gauntlet. CMS has not identified a need to establish a new HCPCS Level II code. Note that in our CMS Preliminary HCPCS Coding Recommendation we are proposing establishment of new HCPCS Level II code AXXXX, "Gradient compression garment, not otherwise specified, for nighttime use, each" to describe nighttime gradient compression garments (see application HCP2406275UFBP). If this code is established, suppliers would begin using this new code when submitting claims for this nighttime garment. We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.	Defer. There is limited space on claim forms to describe items and inconsistent language submitted under the NOS codes. Request CMS to define reasonable parameters and allow USMCA to collect and submit data prior to final determination being made.
HCP240626Y4RCN	Nighttime, head and neck. CMS has not identified a need to establish a new HCPCS Level II code. Note that in our CMS Preliminary HCPCS Coding Recommendation we are proposing establishment of new HCPCS Level II code AXXXX, "Gradient compression garment, not	Defer. There is limited space on claim forms to describe items and inconsistent language submitted under the NOS codes. Request CMS to define reasonable parameters and allow USMCA to collect and submit data prior to final determination being made.

	otherwise specified, for nighttime use, each" to describe nighttime gradient compression garments (see application HCP2406275UFBP). If this code is established, suppliers would begin using this new code when submitting claims for this nighttime garment. We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.	
HCP240627X41TJ	Nighttime, custom, head and neck. CMS has not identified a need to establish a new HCPCS Level II code. Note that in our CMS Preliminary HCPCS Coding Recommendation we are proposing establishment of new HCPCS Level II code AXXXX, "Gradient compression garment, not otherwise specified, for nighttime use, each" to describe nighttime gradient compression garments (see application HCP2406275UFBP). If this code is established, suppliers would begin using this new code when submitting claims for this nighttime garment. We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.	Defer. There is limited space on claim forms to describe items and inconsistent language submitted under the NOS codes. Request CMS to define reasonable parameters and allow USMCA to collect and submit data prior to final determination being made.
HCP240627W1DEW	Nighttime, custom, long sleeve shirt. CMS has not identified a need to establish a new HCPCS Level II code. Note that in our CMS Preliminary HCPCS Coding Recommendation we are proposing establishment of new HCPCS Level II code AXXXX, "Gradient compression garment, not otherwise specified, for nighttime use, each" to describe nighttime gradient compression garments (see application HCP2406275UFBP). If this code is established, suppliers would begin	Defer. There is limited space on claim forms to describe items and inconsistent language submitted under the NOS codes. Request CMS to define reasonable parameters and allow USMCA to collect and submit data prior to final determination being made.

	using this new code when submitting claims for this nighttime garment. We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.	
HCP240627RKU6Y	Nighttime, custom, shorts. CMS has not identified a need to establish a new HCPCS Level II code. Note that in our CMS Preliminary HCPCS Coding Recommendation we are proposing establishment of new HCPCS Level II code AXXXX, "Gradient compression garment, not otherwise specified, for nighttime use, each" to describe nighttime gradient compression garments (see application HCP2406275UFBP). If this code is established, suppliers would begin using this new code when submitting claims for this nighttime garment. We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.	Defer. There is limited space on claim forms to describe items and inconsistent language submitted under the NOS codes. Request CMS to define reasonable parameters and allow USMCA to collect and submit data prior to final determination being made.
HCP240627U11R3	Nighttime, custom, short sleeve shirt. CMS has not identified a need to establish a new HCPCS Level II code. Note that in our CMS Preliminary HCPCS Coding Recommendation we are proposing establishment of new HCPCS Level II code AXXXX, "Gradient compression garment, not otherwise specified, for nighttime use, each" to describe nighttime gradient compression garments (see application HCP2406275UFBP). If this code is established, suppliers would begin using this new code when submitting claims for this nighttime garment. We will continue to monitor LCTI coding trends regularly and will propose	Defer. There is limited space on claim forms to describe items and inconsistent language submitted under the NOS codes. Request CMS to define reasonable parameters and allow USMCA to collect and submit data prior to final determination being made.

	new HCPCS Level II codes when appropriate.	
HCP240626MJV5R	Nighttime, upper leg. CMS has not identified a need to establish a new HCPCS Level II code. Note that in our CMS Preliminary HCPCS Coding Recommendation we are proposing establishment of new HCPCS Level II code AXXXX, "Gradient compression garment, not otherwise specified, for nighttime use, each" to describe nighttime gradient compression garments (see application HCP2406275UFBP). If this code is established, suppliers would begin using this new code when submitting claims for this nighttime garment. We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.	Defer. There is limited space on claim forms to describe items and inconsistent language submitted under the NOS codes. Request CMS to define reasonable parameters and allow USMCA to collect and submit data prior to final determination being made.
HCP240626VPRN2	Nighttime, custom, upper leg. CMS has not identified a need to establish a new HCPCS Level II code. Note that in our CMS Preliminary HCPCS Coding Recommendation we are proposing establishment of new HCPCS Level II code AXXXX, "Gradient compression garment, not otherwise specified, for nighttime use, each" to describe nighttime gradient compression garments (see application HCP2406275UFBP). If this code is established, suppliers would begin using this new code when submitting claims for this nighttime garment. We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.	Defer. There is limited space on claim forms to describe items and inconsistent language submitted under the NOS codes. Request CMS to define reasonable parameters and allow USMCA to collect and submit data prior to final determination being made.
HCP2406277F2M1	Nighttime, custom, vest. CMS has not identified a need to establish a new HCPCS Level II code. Note that in our CMS Preliminary HCPCS Coding Recommendation	Defer. There is limited space on claim forms to describe items and inconsistent language submitted under the NOS codes. Request CMS to

	we are proposing establishment of new HCPCS Level II code AXXXX, "Gradient compression garment, not otherwise specified, for nighttime use, each" to describe nighttime gradient compression garments (see application HCP2406275UFBP). If this code is established, suppliers would begin using this new code when submitting claims for this nighttime garment. We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.	define reasonable parameters and allow USMCA to collect and submit data prior to final determination being made.
HCP240625LVHRC	Wrap, Gauntlet. CMS has not identified a need to establish a new HCPCS Level II code. Existing HCPCS Level II code A6584, "Gradient compression wrap with adjustable straps, not otherwise specified" is used when submitting claims for this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.	Defer. There is limited space on claim forms to describe items and inconsistent language submitted under the NOS codes. Request CMS to define reasonable parameters and allow USMCA to collect and submit data prior to final determination being made.
HCP2406267T4RF	Wrap, Custom, Gauntlet. CMS has not identified a need to establish a new HCPCS Level II code. Existing HCPCS Level II code A6584, "Gradient compression wrap with adjustable straps, not otherwise specified" is used when submitting claims for this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.	Defer. There is limited space on claim forms to describe items and inconsistent language submitted under the NOS codes. Request CMS to define reasonable parameters and allow USMCA to collect and submit data prior to final determination being made.
HCP240625HTAQK	Wrap, Glove. CMS has not identified a need to establish a new HCPCS Level II code. Existing HCPCS Level II code A6584, "Gradient compression wrap with adjustable straps, not otherwise	Defer. There is limited space on claim forms to describe items and inconsistent language submitted under the NOS codes. Request CMS to define reasonable parameters

	specified" is used when submitting claims for this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.	and allow USMCA to collect and submit data prior to final determination being made.
HCP240626CP3CR	Wrap, Custom, Glove. CMS has not identified a need to establish a new HCPCS Level II code. Existing HCPCS Level II code A6584, "Gradient compression wrap with adjustable straps, not otherwise specified" is used when submitting claims for this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.	Defer. There is limited space on claim forms to describe items and inconsistent language submitted under the NOS codes. Request CMS to define reasonable parameters and allow USMCA to collect and submit data prior to final determination being made.
HCP240625YVAET	Wrap, Knee. CMS has not identified a need to establish a new HCPCS Level II code. Existing HCPCS Level II code A6584, "Gradient compression wrap with adjustable straps, not otherwise specified" is used when submitting claims for this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.	Defer. There is limited space on claim forms to describe items and inconsistent language submitted under the NOS codes. Request CMS to define reasonable parameters and allow USMCA to collect and submit data prior to final determination being made.
HCP240626ACU0W	Wrap, Custom, Knee. CMS has not identified a need to establish a new HCPCS Level II code. Existing HCPCS Level II code A6584, "Gradient compression wrap with adjustable straps, not otherwise specified" is used when submitting claims for this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.	Defer. There is limited space on claim forms to describe items and inconsistent language submitted under the NOS codes. Request CMS to define reasonable parameters and allow USMCA to collect and submit data prior to final determination being made.

HCP240625AGT7L	Wrap, Lobe. CMS has not identified a need to establish a new HCPCS Level II code. Existing HCPCS Level II code A6584, "Gradient compression wrap with adjustable straps, not otherwise specified" is used when submitting claims for this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.	Defer. There is limited space on claim forms to describe items and inconsistent language submitted under the NOS codes. Request CMS to define reasonable parameters and allow USMCA to collect and submit data prior to final determination being made.
HCP240626J6KD6	Wrap, Custom, Lobe. CMS has not identified a need to establish a new HCPCS Level II code. Existing HCPCS Level II code A6584, "Gradient compression wrap with adjustable straps, not otherwise specified" is used when submitting claims for this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.	Defer. There is limited space on claim forms to describe items and inconsistent language submitted under the NOS codes. Request CMS to define reasonable parameters and allow USMCA to collect and submit data prior to final determination being made.
HCP240625462HD	Wrap, Toe. CMS has not identified a need to establish a new HCPCS Level II code. Existing HCPCS Level II code A6584, "Gradient compression wrap with adjustable straps, not otherwise specified" is used when submitting claims for this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.	Defer. There is limited space on claim forms to describe items and inconsistent language submitted under the NOS codes. Request CMS to define reasonable parameters and allow USMCA to collect and submit data prior to final determination being made.
HCP240626HQRC0	Wrap, Custom, Toe. CMS has not identified a need to establish a new HCPCS Level II code. Existing HCPCS Level II code A6584, "Gradient compression wrap with adjustable straps, not otherwise specified" is used when submitting claims for this lymphedema compression treatment item	Defer. There is limited space on claim forms to describe items and inconsistent language submitted under the NOS codes. Request CMS to define reasonable parameters and allow USMCA to collect and submit data prior to final determination being made.

	(LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.	
HCP240625GXD90	Wrap, Vest. CMS has not identified a need to establish a new HCPCS Level II code. Existing HCPCS Level II code A6584, "Gradient compression wrap with adjustable straps, not otherwise specified" is used when submitting claims for this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.	Defer. There is limited space on claim forms to describe items and inconsistent language submitted under the NOS codes. Request CMS to define reasonable parameters and allow USMCA to collect and submit data prior to final determination being made.
HCP240701TWK49	Wrap, Custom, Vest. CMS has not identified a need to establish a new HCPCS Level II code. Existing HCPCS Level II code A6584, "Gradient compression wrap with adjustable straps, not otherwise specified" is used when submitting claims for this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.	Defer. There is limited space on claim forms to describe items and inconsistent language submitted under the NOS codes. Request CMS to define reasonable parameters and allow USMCA to collect and submit data prior to final determination being made.

Appendix B: HCPCS Level II Codes for Products Approved by the FDA Under the 505(b)(2) NDA or BLA Pathways and Products "Not Otherwise Classified"

HCPCS Code	Action	Long Descriptor
J0139	Add	Injection, adalimumab, 1 mg
J0208	Revise	Injection, sodium thiosulfate (pedmark), 100 mg
J0209	Add	Injection, sodium thiosulfate (hope), 100 mg
J0211	Add	Injection, sodium nitrite 3 mg and sodium thiosulfate 125 mg (nithiodote)
J0612	Revise	Injection, calcium gluconate, not otherwise specified, 10 mg
J0613	Revise	Injection, calcium gluconate (wg critical care) not therapeutically equivalent to J0612, 10 mg
J0650	Add	Injection, levothyroxine sodium, not otherwise specified, 10 mcg
J0651	Add	Injection, levothyroxine sodium (fresenius kabi) not therapeutically equivalent to J0650, 10 mcg
J0652	Add	Injection, levothyroxine sodium (hikma) not therapeutically equivalent to J0650, 10 mcg
J0687	Add	Injection, cefazolin sodium (wg critical care), not therapeutically equivalent to j0690, 500 mg
J1010	Add	Injection, methylprednisolone acetate, 1 mg
J1171	Add	Injection, hydromorphone, 0.1 mg
J1552	Add	Injection, immune globulin (alyglo), 100 mg
J1597	Add	Injection, glycopyrrolate (glyrx-pf), 0.1 mg
J1598	Add	Injection, glycopyrrolate (fresenius kabi), not therapeutically equivalent to J1596, 0.1 mg
J2002	Add	Injection, lidocaine hcl in 5% dextrose, 1 mg
J2003	Add	Injection, lidocaine hydrochloride, 1 mg
J2004	Add	injection, lidocaine hcl with epinephrine, 1 mg
J2183	Add	Injection, meropenem (wg critical care), not therapeutically equivalent to j2185, 100 mg
J2251	Revise	Injection, midazolam in 0.9% sodium chloride, intravenous, not therapeutically equivalent to J2250, 1 mg
J2252	Add	Injection, midazolam in 0.8% sodium chloride, intravenous, not therapeutically equivalent to J2250, 1 mg
J2253	Add	Injection, midazolam (seizalam), 1 mg
J2290	Add	Injection, nafcillin sodium, 20 mg
J2373	Add	Injection, phenylephrine hydrochloride (immphentiv), 20 micrograms
J2470	Add	Injection, pantoprazole sodium, 40 mg
J2471	Add	Injection, pantoprazole (hikma), not therapeutically equivalent to J2470, 40 mg
J2802	Add	Injection, romiplostim, 1 microgram
J2919	Add	Injection, methylprednisolone sodium succinate, 5 mg

J3424	Add	Injection, hydroxocobalamin, intravenous, 25 mg
J8522	Add	Capecitabine, oral, 50 mg
J8541	Add	Dexamethasone (hemady), oral, 0.25 mg
J8611	Add	Methotrexate (jylamvo), oral, 2.5 mg
J8612	Add	Methotrexate (xatmep), oral, 2.5 mg
J9033	Revise	Injection, bendamustine hydrochloride, 1 mg
J9073	Add	Injection, cyclophosphamide (ingenus), 5 mg
J9075	Add	Injection, cyclophosphamide, not otherwise specified, 5mg
Q0155	Add	Dronabinol (syndros), 0.1 mg, oral, fda approved prescription anti-emetic, for use as a complete therapeutic substitute for an iv anti-emetic at the time of chemotherapy treatment, not to exceed a 48 hour dosage regimen
Q5140	Add	Injection, adalimumab-fkjp, biosimilar, 1 mg
Q5141	Add	Injection, adalimumab-aaty, biosimilar, 1 mg
Q5142	Add	Injection, adalimumab-ryvk biosimilar, 1 mg
Q5143	Add	Injection, adalimumab-adbm, biosimilar, 1 mg
Q5144	Add	Injection, adalimumab-aacf (idacio), biosimilar, 1 mg
Q5145	Add	Injection, adalimumab-afzb (abrilada), biosimilar, 1 mg

Appendix C: 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.