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

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

First Biannual (B1), 2025 HCPCS Coding Cycle

This document presents a summary of each HCPCS Level II code application and CMS' coding decision for each application processed in CMS' First Biannual 2025 Non-Drug and Non-Biological Items and Services HCPCS Level II code application review cycle. Each summary includes the Medicare Electronic Application Request Information System™ (MEARIS™) identification number; topic; a summary of the applicant's request as written by the applicant with occasional non-substantive editorial changes made by CMS; CMS' preliminary HCPCS Level II coding recommendation; a summary of public feedback from or following the HCPCS Level II public meeting; CMS' final HCPCS Level II coding decision, as well as CMS' preliminary and final benefit category and payment determination, if applicable.

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

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

All new coding actions will be effective October 1, 2025, unless otherwise indicated.

The HCPCS Level II coding decisions below will also be included in the October 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 Public Meeting on June 2, 2025 to June 3, 2025.

Marigen™ Pacto - HCP24123106LQY

Topic/Issue

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

Applicant's suggested language: AXXXX, “Marigen™ Pacto, per sq cm”

Summary of Applicant's Submission

Kerecis® submitted a request to establish a new HCPCS Level II code to identify Marigen™ Pacto. Marigen™ Pacto received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on August 21, 2024. Marigen™ Pacto is a single use, lyophilized, terminally sterilized, fish skin substitute graft composed of North Atlantic cod skin. As a sheet-based biological product, Marigen™ Pacto functions as a scaffold for cellular ingrowth and tissue regeneration, remaining on the recipient’s wound to support healing. Marigen™ Pacto is indicated for the management of partial- and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, trauma wounds, and certain surgical or draining wounds. This product is made from small fish skin grafts reconstituted into a larger sheet that maintains stability on the wound bed. The dosage is per square centimeter and is dependent on wound size and clinical need. Marigen™ Pacto is packaged in Tyvek® single or double peel pouches at various dimensions from 4 - 114 square centimeters and is designed for single use.

CMS Preliminary HCPCS Coding Determination

Establish a new HCPCS Level II code AXXXX, "Marigen pacto, per square centimeter" to describe Marigen™ Pacto.

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

Kerecis® agreed with CMS’ published preliminary determination.

CMS Final HCPCS Coding Determination

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

Establish new HCPCS Level II code A2038, "Marigen pacto, per square centimeter" to describe Marigen™ Pacto.

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.

O2Remote - HCP2410087BRMG

Topic/Issue

Request to establish a new HCPCS Level II code to identify O2Remote.

Applicant's suggested language: XXXXX, “Remotely controlled device that dispenses and retracts oxygen tubing connected to a stationary concentrator”

Summary of Applicant's Submission

Oxygen Management Systems, LLC submitted a request to establish a new HCPCS Level II code to identify the O2Remote. The O2Remote is a class I device, exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The O2Remote oxygen tube reel is a wireless, remote controlled oxygen tube reel that is designed to help individuals who require home oxygen therapy to walk and move safely in their homes while connected to a stationary oxygen concentrator. The O2Remote is a small, motorized oxygen tube reel that consists of two roller wheels; one of which is powered to rotate in forward and reverse directions, and the other as an idler. The oxygen tube is placed and captured between these rollers. The device is hung on the side of a small collection container which is strapped to the side of the oxygen concentrator for stability. The individual carries a small remote control that controls the direction of the powered roller, thereby allowing the user to dispense the tubing out of the container, and to collect all excess tubing into the container.

CMS Preliminary HCPCS Coding Determination

CMS has not identified a program operating need for Medicare or other insurers to establish a new HCPCS Level II code to identify O2Remote. Medicare has a bundled, monthly payment that includes all components of the service as required by durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) quality standards and national coverage determinations. For Medicare, 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, “Oxygen concentrator, single delivery port, capable of delivering 85 percent or greater oxygen concentration at the prescribed flow rate”).

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

As explained in the Medicare Benefit Policy Manual, section 110.1.B.2. (Pub. 100-2), precautionary-type equipment (such as preset portable oxygen units) and self-help devices (such as safety grab bars) are considered nonmedical in nature. The O2Remote is used to dispense and retract the oxygen tubing with increased control for safety and therefore is considered nonmedical in nature.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Note that the monthly Medicare Part B payment for oxygen and oxygen equipment includes payment for all equipment and supplies, including tubing. Separate payment for individual items that are classified as oxygen equipment, accessories, or supplies is not allowed.

Summary of Public Feedback

Oxygen Management Systems, LLC disagreed with CMS' published preliminary determinations. The speaker disagreed with no DMEPOS benefit category, no need for a separate code and therefore, no payment. They stated that the preliminary benefit category determination cited the Medicare Benefit Policy Manual section 110.1.B.2 as the basis for considering the O2Remote non-medical in nature and therefore not a benefit of Medicare. However, when compared to Local Coverage Determination (LCD) L33791 for walkers, the speaker believed that the coverage decision should be the same for the O2Remote. The introduction of medical oxygen tubing into the environment of a patient that uses a mobility aid, constitutes a mobility limitation as specified in LCD L33791. Oxygen tubing creates an additional risk of morbidity and mortality in the attempts to perform mobility related activity of daily living that the mobility aids not only fail to mitigate but increase the risk of falling without proper mitigation for safe management of the oxygen tubing. This condition would meet the same definition for a mobility limitation CMS has previously agreed is medical in nature. Safe handling and management of oxygen tubing is essential and necessary for safe ambulation. The O2Remote provides sufficient mitigation for the trip hazard, enables the patient to safely manage their oxygen tubing and therefore, should be considered a benefit of Medicare. The speaker stated that the O2Remote meets DME requirements for durability and only serves a medical purpose. Even though oxygen equipment is included in HCPCS Level II code E1390, the technology offered by the O2Remote did not exist when this code was priced and populated. As such, the speaker requested a separate HCPCS Level II code and reimbursement.

CMS Final HCPCS Coding Determination

We appreciate the comments provided in response to CMS' published preliminary determinations. Based on the information provided in the application and after consideration of the comments we received, CMS is revising its preliminary coding determination. CMS has not identified a need to establish a unique HCPCS Level II code to describe O2Remote. The O2Remote is designed to help individuals who require home oxygen therapy to move safely while connected to a stationary oxygen concentrator. The O2Remote is an optional safety feature that is non-medical in nature and is available for oxygen users at home. 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 110.1.B.2. (Pub. 100-2), precautionary-type equipment (such as preset portable oxygen units) and self-help devices (such as safety grab bars) are considered nonmedical in nature. The O2Remote is used to dispense and retract oxygen tubing with increased control for safety and therefore is considered nonmedical in nature.

Final Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Cath Dry Sterile Dressing - HCP241006Y8YGL

Topic/Issue

Request to be assigned existing HCPCS Level II codes:

1. A6258, “Transparent film, sterile, more than 16 sq. in. but less than or equal to 48 sq. in., each dressing” to describe the Cath Dry Sterile Dressings for hemodialysis regular catheter and peripherally inserted central catheter (PICC).

2. A6259, “Transparent film, sterile, more than 48 sq. in., each dressing” to describe the Cath Dry Sterile Dressings for hemodialysis long catheter and peritoneal dialysis catheter.

The applicant did not submit any suggested language.

Summary of Applicant's Submission

Cath Dry Global, Inc. submitted a request to be assigned existing HCPCS Level II codes A6258 and A6259 to describe various Cath Dry Sterile Dressings. Cath Dry Sterile Dressings are exempt from the premarket notification procedures by the Food and Drug Administration (FDA). Cath Dry Sterile Dressings are intended for individuals who are high risk for catheter related infections. Cath Dry Sterile Dressings are transparent, breathable (high moisture vapor transmission rate), water resistant, bacteriostatic, and hypoallergenic. Cath Dry Sterile Dressings are applied over a central venous catheter and the adhesive ring attaches to the skin around the catheter exit site. It covers and protects the catheter exit site and the entire catheter to prevent infections and allow for safe showering and even swimming. Cath Dry Sterile Dressings have a white moisture ring around the catheter exit site which turns red if the dressing is wet, so it can be changed immediately. The transparent film allows individuals to identify early signs of infection. Cath Dry Sterile Dressings are available in hemodialysis regular, hemodialysis long, peritoneal dialysis, PICC and midline catheter dressings. The hemodialysis catheter dressing is changed three times per week with each hemodialysis session. The peritoneal dialysis catheter and PICC dressings are changed weekly. The zip lock mechanism allow access to the catheters as needed.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II code A4221, “Supplies for maintenance of non-insulin drug infusion catheter, per week (list drugs separately)” describes the peripherally inserted central catheter version of the Cath Dry Sterile Dressing. For Medicare, when the hemodialysis regular, hemodialysis long, or peritoneal dialysis versions of the Cath Dry Sterile Dressings are used for the administration of renal dialysis services, these products would be considered included in the End Stage Renal Disease (ESRD) Prospective Payment System (PPS) bundled payment.

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment (supplies necessary for the effective use of a durable infusion pump covered as DME).

The current Medicare policy and prior established Medicare benefit category determination for HCPCS Level II code A4221 apply to this item.

Preliminary Medicare Payment Determination

The payment rule and pricing associated with existing HCPCS Level II code A4221 apply to this product, if covered. The current average 2025 rural fee schedule amount for HCPCS Level II code A4221 is $26.19. The current average 2025 non-rural fee schedule amount is $25.52.

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 = 34

Summary of Public Feedback

Cath Dry Global, Inc., disagreed with CMS' published preliminary determinations. The speaker requested to be assigned HCPCS Level II codes A6258 and A6259 to describe the Cath Dry Sterile Dressings. The speaker urged CMS to consider the Cath Dry Sterile Dressings for Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) as defined in 42 CFR § 413.236 or an equivalent payment exception. Additionally, the speaker suggested that CMS adopt the Cath Dry Sterile Dressings as the standard of care dressings for individuals with central venous catheters because it addresses the following concerns: risk of catheter-related infections in individuals with ESRD; individuals with ESRD catheters are unable to safely shower, resulting in poor hygiene and reduced quality of life; and individuals with ESRD may also be immunocompromised, consequently increasing the risk of skin infections. The speaker suggested that fewer catheter infections would translate to significant cost avoidance for CMS and improved individual experience and quality of life on dialysis.

CMS Final HCPCS Coding Determination

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

Existing HCPCS Level II code A4221, “Supplies for maintenance of non-insulin drug infusion catheter, per week (list drugs separately)” to describe the peripherally inserted central catheter version of the Cath Dry Sterile Dressings when used outside of dialysis.

According to the Medicare Benefit Policy Manual, Chapter 11, Section 20.4, “all medically necessary equipment and supplies used to furnish dialysis (in-facility or in a patient’s home) are included in the ESRD PPS and are not separately paid as of January 1, 2011.” It further states that “all medically necessary dressings or protective access coverings used during or after dialysis to protect a dialysis patient’s access site including for example, coverings used for day-to-day activities such as bathing, are considered to be renal dialysis items.”

ESRD facilities should provide medically necessary dressings or protective access coverings for individuals dialysis access sites, as these items are considered renal dialysis items under the ESRD PPS for all dialysis individuals regardless of the method of dialysis. In addition, "all home dialysis equipment, supplies, and other medically necessary items for home dialysis ordered by a physician were included in the composite rate and are therefore included under the ESRD PPS." As such, for Medicare, when the Cath Dry Sterile Dressings are used for the administration of renal dialysis services, the product would be considered included in the ESRD PPS bundled payment.

To be eligible for TPNIES, ESRD equipment and supplies must meet six key criteria: CMS designation as renal dialysis service, newness (application within 3 years of FDA authorization), commercial availability, proper HCPCS coding, innovation standards, and must not be capital-related assets except for home dialysis machines. The Cath Cry Sterile Dressings are exempt from the premarket notification procedures by the FDA. As such, they do not qualify for TPNIES consideration.

Additionally, for Medicare, the Cath Dry Sterile Dressings do not fall under the Medicare Part B benefit category for surgical dressings and therefore cannot be classified under HCPCS Level II codes for surgical dressings for Medicare billing and claims processing purposes. In accordance with Medicare program instructions in section 100 of chapter 15 of the Medicare Benefit Policy Manual (Publication # 100-02), surgical dressings are limited to primary and secondary dressings required for the treatment of a wound caused by, or treated by, a surgical procedure that has been performed by a physician or other health care professional to the extent permissible under State law. Primary dressings are therapeutic or protective coverings applied directly to wounds or lesions either on the skin or caused by an opening to the skin. Secondary dressing materials that serve a therapeutic or protective function and that are needed to secure a primary dressing are also covered. The Cath Dry Sterile Dressings are not applied directly to wounds or lesions and are not needed to secure a primary dressing.

Final Medicare Benefit Category Determination

Durable Medical Equipment (supplies necessary for the effective use of a durable infusion pump covered as DME).

The current Medicare policy and prior established Medicare benefit category determination for HCPCS Level II code A4221 apply to this item.

Final Medicare Payment Determination

The payment rule and pricing associated with existing HCPCS Level II code A4221 apply to this product, if covered. The current average 2025 rural fee schedule amount for HCPCS Level II code A4221 is $26.19 and covers one week of all supplies, including dressings, necessary for use of an external drug infusion pump covered under the DME benefit. The current average 2025 non-rural fee schedule amount is $25.52.

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 = 34

Flexitouch® Plus System - HCP241220F16G7

Topic/Issue

Request to revise the existing HCPCS Level II code E0670, “Segmental pneumatic appliance for use with pneumatic compressor, integrated, 2 full legs and trunk” to include other anatomical locations.

Applicant's suggested language: E0670, “Segmental pneumatic appliance system for use with pneumatic compressor, integrated, covering two or more adjacent body areas such as head/neck, chest, trunk, upper extremities, and/or lower extremities”

Summary of Applicant's Submission

Tactile Systems Technology, Inc. submitted a request to revise the existing HCPCS Level II code E0670 to include other anatomical locations (such as head, neck and chest, trunk and two full arms). Flexitouch® Plus System received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on May 26, 2017. Integrated appliances for the head, neck and chest, and for the trunk and two full arms also exist, such as Tactile Medicals’ Flexitouch® Plus System with ComfortEase™ Garments, and should be included in HCPCS Level II code E0670 as they all share the “integrated” feature of covering separate but adjacent sections of the body. There are roughly 21 integrated garment systems that cover different connecting/adjacent parts of the body and should be included in HCPCS Level II code E0670. Revision of HCPCS Level II code E0670 to include those integrated pneumatic appliances that are used on parts of the body other than the trunk and both legs would ensure that individuals with lymphedema have access to updated technology.

CMS Preliminary HCPCS Coding Determination

1. Establish a new HCPCS Level II code EXXX1, “Segmental pneumatic appliance for use with pneumatic compressor, integrated, 2 full arms and trunk” to describe segmental pneumatic appliances for two full arms and trunk.

2. Establish a new HCPCS Level II code EXXX2, “Segmental pneumatic appliance for use with pneumatic compressor, integrated, head, neck and trunk” to describe segmental pneumatic appliances for head, neck and trunk.

CMS agrees that existing HCPCS Level II code E0670 does not fully capture other anatomical locations of integrated garment systems currently available. We believe that the creation of these more specific and relevant codes is more appropriate than revising existing HCPCS Level II code E0670.

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

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 items 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 the Flexitouch Plus® System with the integrated appliance for the trunk and two full arms and the Flexitouch Plus® System with the integrated appliance for the head, neck, and trunk are comparable to HCPCS Level II code E0670 with respect to the physical components, mechanical components, electrical components, function and intended use. While devices classified under HCPCS Level II code E0670 are intended for use with different parts of the body (i.e., two full legs and trunk), this distinction is not sufficient to warrant a unique payment determination for HCPCS Level II codes EXXX1 and EXXX2. Therefore, the preliminary payment determination for HCPCS Level II codes EXXX1 and EXXX2, is to establish the fee schedule amounts using existing fee schedule amounts for comparable items described by HCPCS Level II code E0670.

Payment for existing HCPCS Level II code E0670 is made on a capped rental basis. Therefore, the monthly capped rental fee schedule amount for new HCPCS Level II codes EXXX1 and EXXX2 would be approximately $182.82 on average for months 1 through 3, and approximately $137.12 on average for months 4 through 13, resulting in a total capped payment of $1,919.66 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

Summary of Public Feedback

Tactile Systems Technology, Inc. mostly agreed with CMS' published preliminary determinations and asked for two changes. First, the speaker requested to modify both proposed HCPCS Level II code descriptors to revise the term "trunk" with "chest." This change would describe the appliance technology, ensure individuals receive the correct treatment, and provide appropriate reimbursement for products. Second, the speaker agreed with the determination to establish equal payment rates because the new codes are comparable to HCPCS Level II code E0670, but they disagreed with placing the new codes in a different payment category. HCPCS Level II code E0670 was established in 2013 in the fee schedule category of inexpensive or routinely purchased. The speaker stated that there are 16 pneumatic compression E codes and 14 of them, including all the pneumatic compression pumps and E0670, are assigned to the inexpensive/routinely purchased category. Aligning the new codes with the same payment category as the controlling device would ensure individuals have access to necessary treatments without financial barriers or disruptions in their care. The speaker emphasized that the definition of "routinely purchased equipment" is critical in this context, as it underscores the ongoing need individuals have for lymphedema devices. The speaker added that lymphedema is a chronic condition requiring lifelong treatment, and establishing these devices as routinely purchased is essential for individual access and affordability. This classification will ensure individuals can obtain the necessary equipment and treatment throughout their lives. Proposed HCPCS Level II code EXXX1 would replace two existing codes categorized as routinely purchased. The speaker continued

with stating that CMS confirmed these integrated appliances are comparable to HCPCS Level II code E0670 within the preliminary determination, thus, should establish the same payment methodology as for E0670. This would ensure that individuals continue to receive the necessary treatments without interruption.

Another speaker strongly supported the preliminary determination to create two new HCPCS Level II codes, so that individuals with lymphedema in the head, neck, chest and torso have access to pneumatic compression therapy to help them to better manage this chronic condition. They, however, strongly recommended for these individuals to be able to purchase these items, as opposed to renting them. The speaker stated that by establishing a "rental only" payment method unfairly penalizes these individuals with higher out-of-pocket costs. Medicare already allows the purchase of other pneumatic items used in the treatment of lymphedema. Therefore, rental for these new codes would be inconsistent with existing policy and does not make sense given that lymphedema is a life-long condition.

CMS Final HCPCS Coding Determination

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

1. Establish a new HCPCS Level II code E0658, "Segmental pneumatic appliance for use with pneumatic compressor, integrated, 2 full arms and chest" to describe segmental pneumatic appliances for two full arms and chest.

2. Establish a new HCPCS Level II code E0659, "Segmental pneumatic appliance for use with pneumatic compressor, integrated, head, neck and chest" to describe segmental pneumatic appliances for head, neck and chest.

CMS agrees that existing HCPCS Level II code E0670 does not fully capture other anatomical locations of integrated garment systems currently available. CMS also agrees with the need to replace the term "trunk" with "chest" to fully capture the clinical application of integrated garment systems, and their anatomical and physiological functionality based upon lymphatic system principles. The creation of these more specific and relevant codes is more appropriate than revising existing HCPCS Level II code E0670.

Final Medicare Benefit Category Determination

Durable Medical Equipment.

Final Medicare Payment Determination

For the reasons stated in the Preliminary Medicare Payment Determination, the final payment determination for HCPCS Level II codes E0658 and E0659, is to establish the fee schedule amounts using existing fee schedule amounts for comparable items described by HCPCS Level II code E0670.

While we understand that HCPCS Level II code E0670 is currently paid as a routinely purchased item, HCPCS Level II codes E0658 and E0659 must be classified and paid as

capped rental items. CMS issued regulations (78 FR 72156) which clarified the definition of "routinely purchased" items as those items that were purchased 75 percent of the time during the period July 1986 through June 1987. The issue of applying the payment rules mandated by section 1834(a) of the Social Security Act to items falling under HCPCS Level II code E0760 is a separate matter that CMS would address through notice and comment rulemaking, if necessary.

The average capped rental fee schedule amount stated in the preliminary payment determination was incorrectly based on the rental fee schedule amounts rather than the purchase fee schedule amounts. The monthly capped rental fee schedule amount for new HCPCS Level II codes E0658 and E0659 will be approximately $171.51 on average for months 1 through 3, and approximately $128.63 on average for months 4 through 13, resulting in a total capped payment of $1,800.83 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

mign ICON Adult Scoliosis - HCP250101R7PF2

Topic/Issue

Request to establish a new HCPCS Level II code to identify mign ICON Adult Scoliosis.

Applicant's suggested language: LXXXX, “ADULT SCOLIOSIS ORTHOSIS AND ACCESSORY PADS, CUSTOM FABRICATED, INCLUDES DESIGN, FITTING, AND ADJUSTMENTS”

Summary of Applicant's Submission

mign Inc. submitted a request to establish a new HCPCS Level II code to identify mign ICON Adult Scoliosis. mign ICON Adult Scoliosis is a class I device, exempt from premarket notification procedures by the Food and Drug Administration (FDA). The mign ICON Adult Scoliosis orthosis is digitally designed and custom fabricated to provide functional, postural support and pain relief for the adult scoliotic spine. It is specifically engineered to apply anatomically accurate mechanical counterforces to the trunk, combined with intracavitary pressure to relieve pain. The orthosis features a rigid lateral frame that bridges the affected vertebral curve, and contralateral rigid stays help enhance a more neutral, balanced posture. This design allows for cantilevered tension and intracavitary pressure, both crucial for individuals with degenerative spine scoliosis. The mign ICON Adult Scoliosis is indicated for individuals with progressive or symptomatic scoliosis, including degenerative scoliosis, post-surgical deformity, or idiopathic scoliosis requiring non-operative management. The device is digitally designed and custom-fabricated. It includes fitting, adjustments, and instructions for clinical use.

CMS Preliminary HCPCS Coding Determination

We have not identified a program operating need for Medicare or other insurers to establish a new HCPCS Level II code to describe mign ICON Adult Scoliosis. Existing HCPCS Level II code L1499, “Spinal orthosis, not otherwise specified” describes mign ICON Adult Scoliosis. mign ICON Adult Scoliosis is custom fabricated to provide corrective, postural support and pain relief for adult scoliotic spine deformity and is similar to other orthotics in existing HCPCS Level II code L1499.

Preliminary Medicare Benefit Category Determination

Back Brace.

The current Medicare policy and prior established benefit category determination for HCPCS Level II code L1499 apply to mign ICON Adult Scoliosis.

Preliminary Medicare Payment Determination

Local fee schedule amounts are established by the DME MACs for use in paying claims submitted using HCPCS Level II code L1499.

Pricing Indicator = 46

Summary of Public Feedback

mign Inc. and other commenters disagreed with CMS' published preliminary determinations. The speaker described mign ICON Adult Scoliosis brace as a custom-designed, adult scoliosis brace that can be customized to fit an individual's specific anatomy, unlike prefabricated designs. The speaker also shared that the brace provides an additional treatment option for individuals who cannot tolerate prefabricated braces. However, the speaker did confirm that research studies have not shown evidence that the custom-designed scoliosis braces are more effective than prefabricated off-the-shelf braces in the management of scoliosis in adult populations. Commenters detailed that mign ICON Adult Scoliosis brace should not be assigned to a miscellaneous code that does not accurately describe the brace's clinical function and limits access to beneficiaries, and that a dedicated HCPCS Level II code is needed to capture the brace as a biomechanically distinct tool in the non-operative management of complex deformity.

CMS Final HCPCS Coding Determination

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

Establish a new HCPCS Level II code L1007, "Scoliosis orthosis, sagittal-coronal control provided by a rigid lateral frame, extends from axilla to trochanter, includes all accessory pads, straps, and interface, custom fabricated" to describe mign ICON Adult Scoliosis brace.

After further review of the clinical data provided in the application and presented during the public meeting, we have concluded that the custom-fabricated design of the mign ICON Adult Scoliosis brace could be beneficial to individuals with adult scoliosis based on the personalized fit, targeted postural alignment, possibility of pain reduction, and as a non-invasive alternative to surgery. As such, CMS has determined a need to differentiate between custom fabricated and prefabricated scoliosis braces by establishing a new HCPCS Level II code L1007 to identify custom fabricated scoliosis braces like mign ICON Adult Scoliosis brace.

Final Medicare Benefit Category Determination

Back Brace.

Final Medicare Payment Determination

No determination.

CMS cannot make a final Medicare payment determination without first proposing a preliminary payment determination and publishing this decision prior to a public meeting in accordance with 42 CFR 414.240(b). The payment determination for this item will be addressed at a subsequent HCPCS Level II public meeting.

In the meantime, 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 and program instructions at section 60.3 of chapter 23 of the Medicare Claims Processing Manual (CMS Pub. 100-04).

Pricing Indicator = 46

Flyte® System Wand - HCP250102G2MHH

Topic/Issue

Request to revise an existing HCPCS Level II code E0716, “Supplies and accessories for intravaginal device intended to strengthen pelvic floor muscles during kegel exercises” to further define the Flyte® System Wand.

Applicant's suggested language: E0716, “Intravaginal mechanotherapy system intended to strengthen pelvic floor muscles for treatment of urinary incontinence, wand”

Summary of Applicant's Submission

Pelvital USA, Inc. submitted a request to revise an existing HCPCS Level II code E0716 to further define the Flyte® System Wand. The Flyte® System received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on December 29, 2023. This request is to align CMS’s determination that the Flyte® System Wand is the medically necessary component of the system. The Flyte® System is a non-sterile, vaginal device intended to condition and strengthen the pelvic floor muscle system to treat women with urinary incontinence. The Flyte® System is designed for in-home use. The product consists of a Wand and a hand-held Controller. The Flyte® Wand is placed in the vagina and delivers a series of mechanical vibrations while the pelvic floor muscles are voluntarily contracting, with the Flyte® System Controller dictating the motor speed and the timing and frequency of the mechanical vibrations. The Flyte® System has a mechanism of action referred to as mechanotherapy. Specifically, the Flyte® System takes advantage of the natural mechanotransduction properties of muscle to condition and strengthen the pelvic floor muscle. The standard treatment is 5 minutes per day for 6-12 weeks followed by maintenance as directed by a clinician (for example, then once weekly for 12 months). The Flyte® System Controller is packaged together with a charger cord, charging block, and the removable cord that connects the Controller to the Flyte® System Wand.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II code E0716, “Supplies and accessories for intravaginal device intended to strengthen pelvic floor muscles during kegel exercises” identifies the Flyte® System Wand.

The request for a revision to HCPCS Level II code E0716 to further define the Flyte® System Wand does not improve the code descriptor. We have not identified a claims processing need for Medicare or other insurers to revise HCPCS Level II code E0716.

Preliminary Medicare Benefit Category Determination

CMS determined that the Flyte® System Wand does not fall within a Medicare DMEPOS benefit category in the First Biannual 2024 HCPCS Coding Cycle and re-confirmed that determination in writing to the applicant on September 30, 2024.

The current application states that the Flyte® System Wand has an expected lifetime of at least three years and can be rented and used by successive patients. We have the following questions/requests for information regarding these statements:

- While the application states that the Flyte® System Wand can be rented and used by successive patients, the previous application (HCP240102C74P1) indicated it could not. Is the Flyte® System Wand now being rented and used by successive patients? Could you provide the cleaning disinfection, and functionality check process mentioned in the application?

- While the application states that the Flyte® System Wand has a three-year useful life, the previous application (HCP240102C74P1) indicated it did not. What has changed with the Flyte® System Wand that results in it now lasting at least three years? Do you have independent laboratory test results that you could provide that demonstrate the three-year durability for the Flyte® System Wand? Why does the warranty described in the Instructions for Use (IFU) attached to the application differ from the warranty described on the product registration website page and from the warranty described in the IFU on the product website?

Preliminary Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Summary of Public Feedback

Pelvital USA, Inc. and other commenters disagreed with CMS' published preliminary determinations. The commenters addressed the current HCPCS Level II codes E0715 and E0716 as inaccurate and overly broad. The current code descriptors do not properly identify the Flyte® System's key characteristic - its mechanism of action through mechanotherapy. The commenters suggested that the Flyte® System Controller is an accessory to the Flyte® System Wand and indicated that the current coding descriptor could describe different device categories like biofeedback devices. This imprecision forces healthcare providers to submit supplementary billing language and require unnecessary prior authorization requests, creating delays for individuals and additional costs for both providers and payers. The commenters recommended updating the code descriptors to include "mechanotherapy" terminology, making them more specific and accurate while reducing administrative burdens and improving billing efficiency. The commenters emphasized the significant clinical need for this technology, particularly highlighting how the Flyte® System addresses a critical gap in conservative treatment options for female urinary incontinence. The commenters suggested that traditional treatments face substantial barriers: pelvic floor physical therapy is often costly, time-consuming, and geographically inaccessible (especially in rural areas where individuals may need to travel significant distances); medications frequently have problematic side effects and drug interactions; and surgical options are invasive, risky, expensive, and require lengthy recovery times that many individuals living paycheck-to-paycheck cannot afford. The commenters report life-changing results for individuals using the Flyte® System, describing it as an effective first-line treatment that can be administered at home without requiring specialty referrals, thereby eliminating delays, costs, and frustration associated with traditional care pathways.

In addition, the commenters expressed that both the Flyte® System Wand and Controller should be identified as Durable Medical Equipment (DME) under Medicare. However, Pelvital USA, Inc. indicated in their initial HCPCS Level II application that the Flyte® Wand is a supply item and cannot be rented or used by successive individuals. The applicant has since made claims that the Wand is a durable device based on CMS' feedback from the

previous HCPCS Level II biannual coding cycle. They requested that the Flyte® System Wand be paid as a capped rental service and the Flyte® System Controller on a lump sum purchase basis. Commenters argued that the Flyte® System Wand meets all established DME criteria: it's used in individuals' homes, has a three-year useful life, and can be used by successive individuals and the Flyte® System Controller serves as an essential accessory for the Flyte® System Wand's effective operation.

CMS Final HCPCS Coding Determination[1]

We appreciate the comments provided in response to CMS' published preliminary determinations. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary coding determination. The request for a revision to HCPCS Level II code E0716 to further define the Flyte® System Wand does not improve the code descriptor. We have not identified a claims processing need for Medicare or other insurers to revise HCPCS Level II code E0716. As such,

Existing HCPCS Level II code E0716, "Supplies and accessories for intravaginal device intended to strengthen pelvic floor muscles during kegel exercises" describes the Flyte® System Wand.

Per FDA's 510(k) regulatory pathway device description for the Flyte® System, it "is designed for in-home use to deliver treatment to the pelvic floor muscles during normal Kegel exercises." It further explains that the Flyte® Wand "delivers a series of mechanical vibrations while the pelvic floor muscles are contracting." The applicant has referred to this use of mechanical forces as mechanotherapy to describe the Flyte® System. We disagree with the request to add the term "mechanotherapy" to the code description as it is a broad term that can be achieved through various methods (e.g., specialized devices, exercise, massage, etc.). In addition, CMS typically does not include the mechanism of action of a device in a HCPCS Level II code descriptor. We note that the current descriptor for HCPCS Level II code E0715 is already very specific in that it limits the code to devices that strengthen pelvic floor muscles during Kegel exercises. By comparison, the existing HCPCS Level II code E0740 for electrical pelvic floor stimulators used to treat urinary incontinence is much more generic than the descriptor for HCPCS Level II code E0715.

Final Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

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

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

[1] Updated on September 2, 2025 to keep HCPCS Level II code E0716 as valid code and not have the code be discontinued.

All five of these conditions must be met for equipment to be classified as DME. We have reviewed the cycle testing results provided by Pelvital, Inc. and agree that the Wand has an expected life of at least 3 years. However, the Flyte® System Wand currently does not meet the following condition:

Can withstand repeated use – The First Biannual 2024 HCPCS coding cycle Flyte® System Wand application (HCP240102C74P1) states that the Wand "cannot be rented or used by successive patients." In this current cycle the application (HCP250102G2MHH) states that the Wand "is capable of being rented and used by successive patients (following a cleaning, disinfection and functionality check process)" while also noting that the Food and Drug Administration (FDA) 510(k) approval is as a "reusable, single patient" product. Given this evolution, CMS consulted with the FDA about the ability of the Wand to be used by successive patients and confirmed that, as the applicant states, the Flyte® System 510(k) approval K240805 is for single patient use, but reusable for a given patient. It was not cleared to be used on multiple patients. The Flyte® System Wand will need FDA 510(k) clearance for use by multiple patients before it can meet the "can withstand repeated use" condition for an item and be classified as DME.

Should the FDA clear the Wand for use by multiple patients, CMS will assess whether further comment at a public meeting is necessary or whether we have sufficient information to reach a benefit category determination.

Final Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Flyte® System Controller - HCP250102AMMNX

Topic/Issue

Request to revise an existing HCPCS Level II code E0715, “Intravaginal device intended to strengthen pelvic floor muscles during kegel exercises” to further define the Flyte® System Controller.

Applicant's suggested language: E0715, “Intravaginal mechanotherapy system intended to strengthen pelvic floor muscles for treatment of urinary incontinence, controller”

Summary of Applicant's Submission

Pelvital USA, Inc. submitted a request to revise an existing HCPCS Level II code E0715 to further define the Flyte® System Controller. The Flyte® System received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on December 29, 2023. The Flyte® System is a non-sterile, vaginal device intended to condition and strengthen the pelvic floor muscle system to treat women with urinary incontinence. The Flyte® System is designed for in-home use. The product consists of a hand-held Controller and a Wand. The Flyte® Wand is placed in the vagina and delivers a series of mechanical vibrations while the pelvic floor muscles are voluntarily contracting, with the Flyte® System Controller dictating the motor speed and the timing and frequency of the mechanical vibrations. The Flyte® System has a mechanism of action referred to as mechanotherapy. Specifically, the Flyte® System takes advantage of the natural mechanotransduction properties of muscle to condition and strengthen the pelvic floor muscle. The existing HCPCS Level II code E0715 descriptor does not reflect the key element (unique mechanism of action) differentiating the Flyte® System from other codes. The standard treatment is 5 minutes per day for 6-12 weeks followed by maintenance as directed by a clinician (for example, then once weekly for 12 months). The Flyte® System Controller, together with a charger cord, charging block, and the removable cord that connects the Controller to the Wand.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II code E0715, “Intravaginal device intended to strengthen pelvic floor muscles during kegel exercises” describes the Flyte® System Controller.

The request for a revision to HCPCS Level II code E0715 to further define the Flyte® System Controller does not improve the code descriptor. We have not identified a claims processing need for Medicare or other insurers to revise HCPCS Level II code E0715.

Preliminary Medicare Benefit Category Determination

CMS determined that the Flyte® System Controller does not fall within a Medicare DMEPOS benefit category in the First Biannual 2024 HCPCS Coding Cycle and re-confirmed that determination in writing to the applicant on September 30, 2024.

As the benefit category determination for the Flyte® System Controller is closely related to the benefit category determination for the Flyte® System Wand, please also refer to the preliminary benefit category determination for the Flyte® System Wand.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Summary of Public Feedback

Pelvital USA, Inc. and other commenters disagreed with CMS' published preliminary determinations. The commenters addressed the current HCPCS Level II codes E0715 and E0716, as inaccurate and overly broad. The current code descriptors do not properly identify the Flyte® System's key characteristic - its mechanism of action through mechanotherapy. The commenters suggested that the Flyte® System Controller is an accessory to the Flyte® System Wand and indicated that the current coding descriptor could describe different device categories like biofeedback devices. This imprecision forces healthcare providers to submit supplementary billing language and require unnecessary prior authorization requests, creating delays for individuals and additional costs for both providers and payers. The commenters recommended updating the code descriptors to include "mechanotherapy" terminology, making them more specific and accurate while reducing administrative burdens and improving billing efficiency. The commenters emphasized the significant clinical need for this technology, particularly highlighting how the Flyte® System addresses a critical gap in conservative treatment options for female urinary incontinence. The commenters suggested that traditional treatments face substantial barriers: pelvic floor physical therapy is often costly, time-consuming, and geographically inaccessible (especially in rural areas where individuals may need to travel significant distances); medications frequently have problematic side effects and drug interactions; and surgical options are invasive, risky, expensive, and require lengthy recovery times that many individuals living paycheck-to-paycheck cannot afford. The commenters report life-changing results for individuals using the Flyte® System, describing it as an effective first-line treatment that can be administered at home without requiring specialty referrals, thereby eliminating delays, costs, and frustration associated with traditional care pathways.

In addition, the commenters expressed that both the Flyte® System Wand and Controller should be identified as Durable Medical Equipment (DME) under Medicare. However, Pelvital USA, Inc. indicated in their initial HCPCS Level II application that the Flyte® Wand is a supply item and cannot be rented or used by successive individuals. The applicant has since made claims that the Wand is a durable device based on CMS feedback from the previous HCPCS Level II biannual coding cycle. They requested that the Flyte® System Wand be paid as a capped rental service and the Flyte® System Controller on a lump sum purchase basis. Commenters argued that the Flyte® System Wand meets all established DME criteria: it is used in individuals' homes, has a three-year useful life, and can be used by successive individuals and the Flyte® System Controller serves as an essential accessory for the Flyte® System Wand's effective operation.

CMS Final HCPCS Coding Determination

We appreciate the comments provided in response to CMS' published preliminary determinations. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary coding determination. CMS' coding determination from the First Biannual 2024 HCPCS Level II Coding Cycle (prior application HCP24010236LW3) is still appropriate.

Existing HCPCS Level II code E0715, “Intravaginal device intended to strengthen pelvic floor muscles during kegel exercises” describes the Flyte® System Controller.

Per FDA’s 510(k) regulatory pathway device description for the Flyte® System, it “is designed for in-home use to deliver treatment to the pelvic floor muscles during normal Kegel exercises.” It further explains that the Flyte® Wand “delivers a series of mechanical vibrations while the pelvic floor muscles are contracting.” The applicant has referred to this use of mechanical forces as mechanotherapy to describe the Flyte® System. We disagree with the request to add the term “mechanotherapy” to the code description as it is a broad term that can be achieved through various methods (e.g., specialized devices, exercise, massage, etc.). In addition, CMS typically does not include the mechanism of action of a device in a HCPCS Level II code descriptor. We note that the current descriptor for HCPCS Level II code E0715 is already very specific in that it limits the code to devices that strengthen pelvic floor muscles during Kegel exercises. By comparison, the existing HCPCS Level II code E0740 for electrical pelvic floor stimulators used to treat urinary incontinence is much more generic than the descriptor for HCPCS Level II code E0715.

Final Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

As stated in the First Biannual 2024 HCPCS Coding Cycle and re-confirmed in writing to the applicant on September 30, 2024, the Flyte® System Wand is the component of the Flyte® System that performs the medically necessary function of rendering direct treatment via mechanical vibrations. As the Flyte® System Wand is not classified as durable medical equipment at this time, the Flyte® System Controller component would not be eligible for coverage under the benefit category for durable medical equipment.

Should the FDA clear the Wand for use by multiple patients, CMS will assess whether further comment at a public meeting is necessary or whether we have sufficient information to reach a benefit category determination.

Final Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

FSYX™ Ocular Pressure Adjusting Pump - HCP2501014576E

Topic/Issue

Request to establish a new HCPCS Level II code to identify FSYX™ Ocular Pressure Adjusting Pump.

Applicant's suggested language: EXXXX, “External ocular negative pressure system, electrical, programmable pressure-adjusting pump”

Summary of Applicant's Submission

Balance Ophthalmics, Inc. submitted a request to establish a new HCPCS Level II code to identify FSYX™ Ocular Pressure Adjusting Pump. FSYX™ Ocular Pressure Adjusting Pump (FSYX™) received De Novo classification by the Food and Drug Administration (FDA) on June 27, 2024. The FSYX™ is a prescription-only device system for the treatment of glaucoma in individuals with measured intraocular pressure (IOP) ≤ 21 mmHg, often referred to as normal tension glaucoma (NTG). This system consists of single-use individually fitted eye goggles connected to a durable, programmable pressure-modulating pump, and specialized vacuum tubing that applies targeted negative pressure to the ocular tissue microenvironment inside the goggles, thereby lowering an individual’s IOP during sleep. Open-angle glaucoma (OAG) is characterized by elevation of IOP, which results in progressive vision loss due to atrophy of the optic nerve and loss of retinal ganglion cells. NTG is a form of OAG characterized by the presence of glaucomatous optic nerve damage despite a measured IOP of ≤ 21 mmHg, which is considered the upper limit of statistically normal IOP. Treatment of NTG represents a particular challenge for providers because achieving IOP reduction targets is more difficult in individuals whose pre-treatment IOP levels are measured at ≤ 21 mmHg during the day. A leading cause of continued glaucoma progression in NTG individuals is uncontrolled nocturnal elevations in IOP, in which pressures increase to levels that can cause damage to the optic nerve (Dubey et al., 2020). The FSYX™ specifically addresses the critical and often overlooked nocturnal pressure spikes that can significantly impact glaucoma progression, despite adequately controlled IOP during the day. By providing consistent nocturnal IOP reduction, the FSYX™ slows vision loss in individuals with daytime IOP under 21 mmHg. A recent pivotal study demonstrates that the FSYX™ provides statistically and clinically significant IOP lowering during use, with lower pressures beginning with device activation and remaining consistent throughout device wear. Again, the FSYX™ is indicated for the reduction of IOP during sleep in adults with OAG and IOP ≤ 21 mmHg who are currently using or have undergone another IOP-lowering treatment. The FSYX™ system is intended to be used by the individual in their home while sleeping as prescribed by a physician. The FSYX™ packaging includes the durable FSYX™ pump, which connects to the FSYX™ goggles through tubing supplied with the goggles to create a vacuum system inside the goggles, and an initial supply of the FSYX™ goggles, which are fitted around an individual’s eyes to create a seal.

CMS Preliminary HCPCS Coding Determination

The FSYX™ Ocular Pressure Adjusting Pump is a programmable pressure-modulating pump with vacuum tubing that applies targeted negative pressure to the ocular tissue microenvironment inside the goggles. The treating physician continues to monitor the treatment and use of the equipment all while making adjustments to the pressure settings.

We have several follow-up questions that seek to clarify the usage of the FSYX™ Ocular Pressure Adjusting Pump, and we welcome responses to these questions in the upcoming public meeting to assist us:

1. We have received conflicting information regarding who can program the treatment settings for the device prior to delivery and during treatment. Please clarify when the physician would program the treatment settings. Also, please clarify if and when someone other than the prescribing physician would program the treatment settings. We are asking these questions to better understand what role the physician and supplier play in furnishing the FSYX™ Ocular Pressure Adjusting Pump.

2. Building off the above question, we seek to better understand the laptop component of the device. We have received information from the applicant indicating that the laptop is an optional tool for the physician to use after the device is initially programmed, for use in follow-up visits if adjustments are needed. Can you confirm if this laptop is optional or instead is an integral component to the pump? If a physician has multiple individuals using the device, are multiple laptops sent to that physician or just one? Does one laptop program multiple devices? Does the physician return the laptop after use? Is the laptop locked with only the application to adjust FSYX™ Ocular Pressure Adjusting Pump? Does the physician need a laptop or are there other ways in which the device is adjusted?

3. To better understand how integral treatment is to the physician service, we would like to know more about treatment duration. How many days per week and for how many hours is the device recommended for individual use? Also, what is the typical or recommended total duration of treatment and how often does the typical individual meet with a physician regarding the treatment? In other words, how integrally involved is the device with the physician?

Preliminary Medicare Benefit Category Determination

No determination – Please see the CMS Preliminary HCPCS Coding Determination regarding additional information we are seeking prior to our making a benefit category determination.

Preliminary Medicare Payment Determination

No determination.

Summary of Public Feedback

Balance Ophthalmics, Inc. responded to CMS' published preliminary determination by providing answers to the questions that CMS presented. The primary speaker stated that there is an unmet need that this product addresses, namely managing nocturnal intraocular pressure, also known as IOP, to prevent glaucoma progression., and requests that CMS create two new HCPCS Level II codes to describe the FSYX™ Ocular Pressure Adjusting Pump (FSYX™) and its related supplies and integrated goggles under the DME benefit category. Balance Ophthalmics, Inc. developed a safe, effective, non-invasive, non-drug system/device to lower IOP in the most challenging individuals with glaucoma, and to help serve these individuals that are at considerable risk of going blind. The U.S. Food and Drug

Administration (FDA) granted De Novo pathway authorization for the FSYX in June of 2024. The FSYX™ is indicated for adults with open angle glaucoma whose IOP is less than 21 millimeters of mercury (mm Hg), and who are currently using or have undergone other IOP-lowering treatments. It is the first and only FDA-authorized device indicated to lower nocturnal IOP, which is again recognized as a significant unmet need in glaucoma. The FSYX™ device uses a dual microprocessor-controlled programmable vacuum pump and pressure sensors to provide independent treatment to each eye that reliably lowers IOP while worn at home at night, to a personalized level prescribed by the physician. By applying negative pressure over the eye, the FSYX™ predictably lowers the pressure in the eye, by delivering these precise real-time desired adjustments and preventing excessive vacuum in the periocular region, which is one of the most sensitive areas of the body. The pumps are controlled autonomously and continuously during treatment by a pair of pressure sensors connected to the goggles dual looping integrated tubing, as well as special software. This closed-loop system enables the pumps to maintain consistent pressure compensating for motion during sleep or other factors that could impact the negative pressure level. The pressure sensors also feed into redundant safety mechanisms to prevent excessive vacuum. The speaker added that the goggles are for single-individual at-home use and are replaced on a regular basis to ensure that they can reliably maintain an airtight seal.

If an individual requires additional IOP lowering with the FSYX™, the prescribing eye doctor writes a prescription for the negative pressure level that they want for each eye. That order is then sent to the DME supplier. The DME supplier then initially programs the pump with the software, based on the physician's prescription, and it is shipped to the individual. Once programmed, the pressure settings in the pump are locked so that the individual cannot change them, and once the FSYX™ arrives, DME supplier personnel train the individual on device use and assist with proper sizing and fit of the goggles. The speaker then commented that the roles of the physician and the DME supplier are consistent with the traditional DME devices. There is no physician involvement in any of the steps to furnish the FSYX™ to the individual. At this point, neither the individual nor the prescribing physician can program the initial FSYX™ pressure settings. The DME supplier manages any ongoing device maintenance and individual use. The DME supplier also answers any device-related questions and makes adjustments, as needed, and if necessary. The physician only performs the ongoing glaucoma management like they would for any other individual with glaucoma, and so if the eye doctor needs to make a change to the device settings, the typical approach would be to notify the DME supplier that a change is needed. The DME supplier then reprograms the pump settings and provides that updated pump back to the individual. The treating physician then again continues glaucoma management based on the severity of the glaucoma. Under a different set of circumstances, the manufacturer can also provide, if requested by the physician, the software that will allow the physician or office staff to program the pump directly themselves, too. The speaker indicated that this is not the typical approach, but it is an option. In this situation, if the physician has more than one individual, only one laptop would be needed. This is more for convenience, and not necessary for device use, but with the required software loaded on a dedicated laptop (this is currently required because of cybersecurity controls that the FDA is concerned about), the physician can adjust pump settings and obtain usage data, if desired. Again, in a rare and atypical situation where the FSYX™ indeed needs physician-directed adjustments and/or modifications, the DME supplier will then go out and pick it up from the individual and deliver it to the clinician to adjust the settings and reprogram it.

The FSYX™ is intended for nightly wear up to eight hours per night. Clinical studies generally required a minimum individual wear time of three to four hours per night. With individuals averaging about five and a half hours per night, the individuals may continue to use the device as long as the treatments are adequately managing their glaucoma, and the pace of vision loss doesn't support progressing to more intensive treatments, such as risky glaucoma surgeries. Consistent with the current preferred ophthalmic practice guidelines, these individuals will probably be seen for follow-up by the physician closer to a 3-to-6-month timeframe, since most of these individuals will have more severe glaucoma disease and thus require closer monitoring. The expected mechanical lifetime of the FSYX™ device is greater than 3 years. The speaker likened the FSYX™ to other DME devices used for the treatment of diabetes, chronic obstructive pulmonary disease, and other serious health conditions.

CMS Final HCPCS Coding Determination[2]

We appreciate the comments provided in response to CMS' published preliminary determinations. Based on the information provided in the application, consideration of the comments we received, and clarifying conversations with the FDA, existing HCPCS Level II code E1399, "Durable medical equipment, miscellaneous" will be used to describe the FSYX™ Ocular Pressure Adjusting Pump. Consideration of a new code for the FSYX™ Ocular Pressure Adjusting Pump will be addressed at a future HCPCS Level II public meeting.

Final Medicare Benefit Category Determination

Durable Medical Equipment.

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

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

All five of these conditions must be met for the equipment to be classified as DME. After further evaluation, consideration of input received during the public meeting, and clarification from the FDA, we have determined that the FSYX™ Ocular Pressure Adjusting Pump is DME.

Final Medicare Payment Determination

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

[2] Updated all of CMS' final determinations on November 14, 2025 to reflect clarifying information from the FDA post-publication.

In the meantime, 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.

In accordance with section 60.3 of chapter 23 of the Medicare Claims Processing Manual (Pub. 100-04), the DME MACs or A/B MACs must establish fee schedule amounts for DMEPOS items and services billed using HCPCS codes for miscellaneous items not otherwise classified under the HCPCS (e.g., E1399, L2999, and L8699). Once the fee schedule amounts are established for DMEPOS items and services billed using HCPCS codes for miscellaneous items, these fee schedule amounts would only change when update factors are applied, to correct an error in the calculation of the fee schedule amounts, for based on program instructions. For DME items, the DME MACs must apply the DME payment method depending on the DME class the item falls under (e.g., the item would be paid on a capped rental basis if it is expensive, not customized, not oxygen and oxygen equipment, and does not require frequent and substantial servicing in order to avoid risk to the patient).

Pricing Indicator = 46

FSYX™ Ocular Pressure Adjusting Pump Goggles - HCP250101BJQNN

Topic/Issue

Request to establish a new HCPCS Level II code to identify FSYX™ Ocular Pressure Adjusting Pump goggles.

Applicant's suggested language: AXXXX, “Supplies and accessories for external ocular negative pressure system, 1 month supply”

Summary of Applicant's Submission

Balance Ophthalmics, Inc. submitted a request to establish a new HCPCS Level II code to identify FSYX™ Ocular Pressure Adjusting Pump goggles. FSYX™ Ocular Pressure Adjusting Pump (FSYX™) received De Novo classification by the Food and Drug Administration (FDA) on June 27, 2024. The FSYX™ is a prescription-only device system for the treatment of glaucoma in individuals with measured intraocular pressure (IOP) ≤ 21 mmHg, often referred to as normal tension glaucoma (NTG). This system consists of single-use, individually fitted eye goggles connected to a durable, programmable pressure-modulating pump, and specialized vacuum tubing that applies targeted negative pressure to the ocular tissue microenvironment inside the goggles, thereby lowering an individual’s IOP during sleep. Open-angle glaucoma (OAG) is characterized by elevation of IOP, which results in progressive vision loss due to atrophy of the optic nerve and loss of retinal ganglion cells. NTG is a form of OAG characterized by the presence of glaucomatous optic nerve damage despite a measured IOP of ≤ 21 mmHg, which is considered the upper limit of statistically normal IOP. Treatment of NTG represents a particular challenge for providers because achieving IOP reduction targets is more difficult in individuals whose pre-treatment IOP levels are measured at ≤ 21 mmHg during the day. A leading cause of continued glaucoma progression in NTG individuals is uncontrolled nocturnal elevations in IOP, in which pressures increase to levels that can cause damage to the optic nerve (Dubey et al., 2020). The FSYX™ specifically addresses the critical and often overlooked nocturnal pressure spikes that can significantly impact glaucoma progression, despite adequately controlled IOP during the day. By providing consistent nocturnal IOP reduction, the FSYX™ slows vision loss in individuals with daytime IOP under 21 mmHg. A recent pivotal study demonstrates that the FSYX™ provides statistically and clinically significant IOP lowering during use, with lower pressures beginning with device activation and remaining consistent throughout device wear. Again, the FSYX™ is indicated for the reduction of IOP during sleep in adult individuals with OAG and IOP ≤ 21 mmHg who are currently using or have undergone another IOP-lowering treatment. The FSYX™ device system is intended to be used by the individual in their home while sleeping as prescribed by a physician. The FSYX™ packaging includes the durable FSYX™ pump, which connects to the FSYX™ goggles through tubing supplied with the goggles to create a vacuum system inside the goggles, and an initial supply of the FSYX™ goggles, which are fitted around an individual’s eyes to create a seal.

CMS Preliminary HCPCS Coding Determination

The FSYX™ Ocular Pressure Adjusting Pump is a programmable pressure-modulating pump with vacuum tubing that applies targeted negative pressure to the ocular tissue microenvironment inside the goggles. The treating physician continues to monitor the

treatment and use of the equipment all while making adjustments to the pressure settings. Since the FSYX™ Ocular Pressure Adjusting Pump goggles is an accessory to the FSYX™ Ocular Pressure Adjusting Pump, the final determination for the FSYX™ Ocular Pressure Adjusting Pump will inform the coding determination for these goggles.

Preliminary Medicare Benefit Category Determination

No determination.

Preliminary Medicare Payment Determination

No determination.

Summary of Public Feedback

Balance Ophthalmics, Inc. responded to CMS' published preliminary determination by providing answers to the questions that CMS presented. The primary speaker stated that there is an unmet need that this product addresses, namely managing nocturnal intraocular pressure, also known as IOP, to prevent glaucoma progression., and requests that CMS creates two new HCPCS Level II codes to describe the FSYX™ Ocular Pressure Adjusting Pump (FSYX™) and its related supplies and integrated goggles under the DME benefit category. Balance Ophthalmics, Inc. developed a safe, effective, non-invasive, non-drug system/device to lower IOP in the most challenging individuals with glaucoma, and to help serve these individuals that are at considerable risk of going blind. The U.S. Food and Drug Administration (FDA) granted De Novo pathway authorization for the FSYX in June of 2024. The FSYX™ is indicated for adults with open angle glaucoma whose IOP is less than 21 millimeters of mercury (mm Hg), and who are currently using or have undergone other IOP-lowering treatments. It is the first and only FDA-authorized device indicated to lower nocturnal IOP, which is again recognized as a significant unmet need in glaucoma. The FSYX™ device uses a dual microprocessor-controlled programmable vacuum pump and pressure sensors to provide independent treatment to each eye that reliably lowers IOP while worn at home at night, to a personalized level prescribed by the physician. By applying negative pressure over the eye, the FSYX™ predictably lowers the pressure in the eye, by delivering these precise real-time desired adjustments and preventing excessive vacuum in the periocular region, which is one of the most sensitive areas of the body. The pumps are controlled autonomously and continuously during treatment by a pair of pressure sensors connected to the goggles dual looping integrated tubing, as well as special software. This closed-loop system enables the pumps to maintain consistent pressure compensating for motion during sleep or other factors that could impact the negative pressure level. The pressure sensors also feed into redundant safety mechanisms to prevent excessive vacuum. The speaker added that the goggles are for single-individual at-home use and are replaced on a regular basis to ensure that they can reliably maintain an airtight seal.

If an individual requires additional IOP lowering with the FSYX™, the prescribing eye doctor writes a prescription for the negative pressure level that they want for each eye. That order is then sent to the DME supplier. The DME supplier then initially programs the pump with the software, based on the physician's prescription, and it is shipped to the individual. Once programmed, the pressure settings in the pump are locked so that the individual cannot change them, and once the FSYX™ arrives, DME supplier personnel train the individual on device use and assist with proper sizing and fit of the goggles. The speaker then commented

that the roles of the physician and the DME supplier are consistent with the traditional DME devices. There is no physician involvement in any of the steps to furnish the FSYX™ to the individual. At this point, neither the individual nor the prescribing physician can program the initial FSYX™ pressure settings. The DME supplier manages any ongoing device maintenance and individual use. The DME supplier also answers any device-related questions and makes adjustments, as needed, and if necessary. The physician only performs the ongoing glaucoma management like they would for any other individual with glaucoma, and so if the eye doctor needs to make a change to the device settings, the typical approach would be to notify the DME supplier that a change is needed. The DME supplier then reprograms the pump settings and provides that updated pump back to the individual. The treating physician then again continues glaucoma management based on the severity of the glaucoma. Under a different set of circumstances, the manufacturer can also provide, if requested by the physician, the software that will allow the physician or office staff to program the pump directly themselves, too. The speaker indicated that this is not the typical approach, but it is an option. In this situation, if the physician has more than one individual, only one laptop would be needed. This is more for convenience, and not necessary for device use, but with the required software loaded on a dedicated laptop (this is currently required because of cybersecurity controls that the FDA is concerned about), the physician can adjust pump settings and obtain usage data, if desired. Again, in a rare and atypical situation where the FSYX™ indeed needs physician-directed adjustments and/or modifications, the DME supplier will then go out and pick it up from the individual and deliver it to the clinician to adjust the settings and reprogram it.

The FSYX™ is intended for nightly wear up to eight hours per night. Clinical studies generally required a minimum individual wear time of three to four hours per night. With individuals averaging about five and a half hours per night, the individuals may continue to use the device as long as the treatments are adequately managing their glaucoma, and the pace of vision loss doesn't support progressing to more intensive treatments, such as risky glaucoma surgeries. Consistent with the current preferred ophthalmic practice guidelines, these individuals will probably be seen for follow-up by the physician closer to a 3-to-6-month timeframe, since most of these individuals will have more severe glaucoma disease and thus require closer monitoring. The expected mechanical lifetime of the FSYX™ device is greater than 3 years. The speaker likened the FSYX™ to other DME devices used for the treatment of diabetes, chronic obstructive pulmonary disease, and other serious health conditions.

CMS Final HCPCS Coding Determination[3]

We appreciate the comments provided in response to CMS' published preliminary determinations. Based on the information provided in the application, consideration of the comments we received, and clarifying conversations with the FDA, existing HCPCS Level II code E1399, "Durable medical equipment, miscellaneous" will be used to describe the FSYX™ Ocular Pressure Adjusting Pump Goggles. Consideration of a new code for the FSYX™ Ocular Pressure Adjusting Pump Goggles will be addressed at a future HCPCS Level II public meeting.

[3] Updated all of CMS' final determinations on October XX, 2025 to reflect clarifying information from the FDA post-publication.

Final Medicare Benefit Category Determination

Durable Medical Equipment.

The FSYX™ Ocular Pressure Adjusting Pump Goggles are an accessory necessary for the effective use of the FSYX™ Ocular Pressure Adjusting Pump.

Final Medicare Payment Determination

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

In the meantime, 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.

In accordance with section 60.3 of chapter 23 of the Medicare Claims Processing Manual (Pub. 100-04), the DME MACs or A/B MACs must establish fee schedule amounts for DMEPOS items and services billed using HCPCS codes for miscellaneous items not otherwise classified under the HCPCS (e.g., E1399, L2999, and L8699). Once the fee schedule amounts are established for DMEPOS items and services billed using HCPCS codes for miscellaneous items, these fee schedule amounts would only change when update factors are applied, to correct an error in the calculation of the fee schedule amounts, for based on program instructions. For DME items, the DME MACs must apply the DME payment method depending on the DME class the item falls under (e.g., the item would be paid on a capped rental basis if it is expensive, not customized, not oxygen and oxygen equipment, and does not require frequent and substantial servicing in order to avoid risk to the patient).

Pricing Indicator = 46

SAM 2.0 Long Duration Ultrasound Device - HCP241226VKJNR

Topic/Issue

Request to establish a new HCPCS Level II code to identify SAM 2.0 Long Duration Ultrasound Device.

Applicant's suggested language: EXXXX, “SAM 2.0 Device sustained acoustic medicine long duration continuous-wave high-frequency ultrasound device, FDA-cleared, prescription only, for home use”

Summary of Applicant's Submission

ZetrOZ Systems, LLC submitted a request to establish a new HCPCS Level II code to identify SAM 2.0 Long Duration Ultrasound Device. SAM 2.0 Long Duration Ultrasound Device received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on June 23, 2023. SAM 2.0 Long Duration Ultrasound Device is sustained acoustic medicine and indicated for prescription home use to apply high-frequency, high-dosimetry, multi-hour ultrasonic stimulation to generate, regulate, and sustain deep non-thermal (mechanotransduction) and thermal (vigorous diathermy at 44˚C) treatment of knee osteoarthritis. The technology is clinically proven to reduce pain, improve function, reduce the use of opioid medication in the home setting. Physicians prescribe sustained acoustic medicine treatment for the treatment of knee osteoarthritis and soft-tissue injuries. The SAM 2.0 device delivers 18,720 joules of high-frequency (3 MHz) ultrasound stimulation into deep tissue (5 - 10 cm) which provides thermal and mechanical stimulation that increases local circulation, stimulates cellular proliferation and replication, improves joint lubricity, reduces pain and inflammation, which enhances arthritic joint function. Sustained acoustic medicine treatment is non-opioid, non-invasive, and a clinically proven intervention with multiple level I studies.

CMS Preliminary HCPCS Coding Determination

Revise existing HCPCS Level II code K1004, “Low frequency ultrasonic diathermy treatment device for home use” to instead read “Ultrasonic diathermy treatment device for home use” to describe SAM 2.0 Long Duration Ultrasound Device.

CMS believes revising the description of existing HCPCS Level II code K1004 will accurately capture various types of ultrasonic diathermy devices, such as SAM 2.0 Long Duration Ultrasound Device.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

When clarifying the meaning of "durable" in regulations (76 FR 70291), we noted that a multi-component system may consist of durable and nondurable components that function together to serve a medical purpose. As explained in that regulation, a multi-component system consisting of durable and nondurable components is considered nondurable if the component that serves the medical purpose is nondurable, even if other components that are part of the system are durable. As explained in the preliminary benefit category determination

for the SAM Applicator Replacement Device (HCP24122627H63), the SAM Applicator Replacement Device is the component of the multi-component device which performs the medical purpose for the SAM Device. CMS has determined that the SAM Applicator Replacement Device does not meet the definition of DME.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Summary of Public Feedback

ZetrOZ Systems, LLC and other commenters disagreed with CMS' published preliminary determinations. The commenters expressed disagreement with including the SAM 2.0 Device with other ultrasound diathermy devices because some of the other devices are not indicated for the treatment of osteoarthritis, like SAM 2.0. The speakers discussed that the device delivers a continuous wave frequency, a long-duration dose that provides acoustic streaming, delivering a therapeutic dose directly into the affected joint. Additionally, the speakers expressed that the device provides four hours of sustained acoustic stimulus, which differs from other devices currently assigned to the proposed HCPCS Level II code. A speaker mentioned that the SAM coupling device is not an accessory rather it is an articulating spacer. The speaker stated that the coupling device is an integral component of the technology, when combined with the applicator and applied to either side of the joint space, acoustic streaming and long-duration ultrasonic diathermy are delivered to the osteoarthritic site, which makes the SAM 2.0 Device unique from any other diathermy device.

CMS Final HCPCS Coding Determination

We appreciate the comments provided in response to CMS' published preliminary determinations. CMS recognizes that the SAM 2.0 Device does not fall under the traditional definition of diathermy. Rather, it is a form of ultrasound diathermy that uses low-intensity, long-duration ultrasound waves to deliver continuous micro-massage and gentle heat to tissues. The key difference is that the SAM 2.0 Device uses low-intensity, long-duration ultrasound waves, whereas traditional diathermy devices use electromagnetic waves. Despite this difference in energy type, both therapies function by delivering energy beneath the skin to target muscles and soft tissues, promoting tissue healing and pain relief. Additionally, both can produce therapeutic heat in the deeper layers of muscles and soft tissues. The SAM 2.0 Applicator Replacement Device is the component of the multi-component device which performs the medical purpose for the SAM 2.0 Device. Based on the information provided in the application and after consideration of the comments we received, CMS is revising its preliminary coding determination and is not making a final coding determination regarding this device, and will defer this application for consideration in a future cycle. For Medicare, it is unclear whether or not the SAM 2.0 Applicator Replacement Device is a supply to SAM 2.0 Long Duration Ultrasound Device. Existing HCPCS Level II code K1004, "Low frequency ultrasonic diathermy treatment device for home use" or K1036, "Supplies and accessories (e.g., transducer) for low frequency ultrasonic diathermy treatment device, per month" is available if other payers deem appropriate; the applicant may submit new clarifying information for consideration in a future cycle. In the meantime, determinations regarding coding for this item will be made by the DME Medicare Administrative Contractors (MACs).

Final Medicare Benefit Category Determination

No determination.

In the preliminary benefit category determination, CMS determined that the SAM 2.0 Applicator Replacement Device is the primary component responsible for serving a medical purpose as part of the SAM 2.0 3-component system that includes the Long Duration Ultrasound device and the Gel Capture Coupling device. At this time, CMS will need additional information from the applicant in order to determine whether the primary component falls within the DME benefit category. Once this information is received and a BCD is established for the primary component, CMS will establish BCDs for the remaining components.

Should new information be presented to CMS that would result in a preliminary determination that the primary component falls within the DME benefit category, CMS will assess whether further comment at a public meeting is necessary or whether we have sufficient information to reach a benefit category determination.

Final Medicare Payment Determination

No determination.

SAM Applicator Replacement Device - HCP24122627H63

Topic/Issue

Request to establish a new HCPCS Level II code to identify SAM Applicator replacement device.

Applicant's suggested language: EXXXX, “SAM Applicator Replacement Device (sustained acoustic medicine generator and regulator, FDA-cleared, dual replacement set)”

Summary of Applicant's Submission

ZetrOZ Systems, LLC submitted a request to establish a new HCPCS Level II code to identify SAM Applicator replacement device. SAM 2.0 Long Duration Ultrasound Device received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on June 23, 2023. This application accompanies the application for the primary device for the SAM 2.0 Device (sustained acoustic medicine long duration continuous wave high-frequency ultrasound device, FDA-cleared, prescription only, for home use).

CMS Preliminary HCPCS Coding Determination

Revise existing HCPCS Level II code K1036, “Supplies and accessories (e.g., transducer) for low frequency ultrasonic diathermy treatment device, per month” to instead read “Supplies and accessories (e.g., transducer) for ultrasonic diathermy treatment device, per month” to describe SAM Applicator replacement device.

CMS believes revising the description of existing HCPCS Level II code K1036 will accurately capture all supplies and accessories associated with the SAM 2.0 Long Duration Ultrasound Device.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

When clarifying the meaning of "durable" in regulations (76 FR 70291), we noted that a multi-component system may consist of durable and nondurable components that function together to serve a medical purpose. As explained in that regulation, a multi-component system consisting of durable and nondurable components is considered nondurable if the component that serves the medical purpose is nondurable, even if other components that are part of the system are durable. While reviewing the SAM 2.0 Device as a multi-component system, CMS determined that the SAM Applicator replacement device is the component responsible for serving the medical purpose. CMS found that the SAM Ultrasound Applicators act as the ultrasound transducers for the SAM Device, playing an essential role in delivering effective therapeutic treatments. Also, CMS acknowledges that the applicators are a vital component, as it enables real-time echogenic feedback by incorporating ultrasonic and temperature control mechanisms at the transducer-circuit interface.

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:

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

All five of these conditions must be met for equipment to be classified as DME. However, the SAM Applicator Replacement device does not meet one of the conditions that must be met for equipment to be classified as DME:

> **Has an expected life of 3 years -** According to the application as well as the applicant's response to an RFI, the SAM Applicator replacement component of the overall device that provides the medical purpose has an expected lifetime of 1,500 hours for 3 years. The applicant stated that "the typical active-aging patient with knee osteoarthritis will apply regular treatment for 1-4 hours for 8 weeks (5 days x 8 weeks x 4 hours = 160 hours of use). After the initial treatment, the patient will utilize sustained acoustic medicine to manage arthritis pain and joint stiffness with annual usage not exceeding 480 hours per year. Over a 3-year period this equates to 1440 hours of treatment for high-use patients. Continuous life cycle and real-world performance testing of the SAM Applicator Replacement Device shows 6 years of functional performance for patients."
>
> However, our calculations are as follows:
>
> - 5 days of use x 4 hours of maximum usage = 20 hours of use per week.
> - 20 hours of use a week x 8 weeks = 160 hours (The applicant explained that 8 weeks is the usual span of time that the device is used by one patient.)
> - 20 hours of use per week x 52 weeks = 1,040 hours per year. (This estimate applies if the device is used for at least 8 weeks at a time by successive patients.)
> - 1,040 hours of use per year x 3 years = 3,120 hours.

Since the SAM Applicator replacement device does not have an expected lifetime of 3 years (with 3,120 hours of use), it does not meet the definition of DME.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Summary of Public Feedback

ZetrOZ Systems, LLC and other commenters disagreed with CMS' published preliminary determinations. The commenters expressed disagreement with including the SAM 2.0 Device with other ultrasound diathermy devices because some of the other devices are not indicated for the treatment of osteoarthritis, like SAM 2.0. The speakers discussed that the device delivers a continuous wave frequency, a long-duration dose that provides acoustic streaming,

delivering a therapeutic dose directly into the affected joint. Additionally, the speakers expressed that the device provides four hours of sustained acoustic stimulus, which differs from other devices currently assigned to the proposed HCPCS Level II code. A speaker mentioned that the SAM coupling device is not an accessory rather it is an articulating spacer. The speaker stated that the coupling device is an integral component of the technology, when combined with the applicator and applied to either side of the joint space, acoustic streaming and long-duration ultrasonic diathermy are delivered to the osteoarthritic site, which makes the SAM 2.0 Device unique from any other diathermy device.

CMS Final HCPCS Coding Determination

We appreciate the comments provided in response to CMS' published preliminary determinations. CMS recognizes that the SAM 2.0 Device does not fall under the traditional definition of diathermy. Rather, it is a form of ultrasound diathermy that uses low-intensity, long-duration ultrasound waves to deliver continuous micro-massage and gentle heat to tissues. The key difference is that the SAM 2.0 Device uses low-intensity, long-duration ultrasound waves, whereas traditional diathermy devices use electromagnetic waves. Despite this difference in energy type, both therapies function by delivering energy beneath the skin to target muscles and soft tissues, promoting tissue healing and pain relief. Additionally, both can produce therapeutic heat in the deeper layers of muscles and soft tissues. The SAM 2.0 Applicator Replacement Device is the component of the multi-component device which performs the medical purpose for the SAM 2.0 Device. Based on the information provided in the application and after consideration of the comments we received, CMS is revising its preliminary coding determination and is not making a final coding determination regarding this device, and will defer this application for consideration in a future cycle. For Medicare, it is unclear whether or not the SAM 2.0 Applicator Replacement Device is a supply to SAM 2.0 Long Duration Ultrasound Device; the applicant may submit new clarifying information for consideration in a future cycle. Existing HCPCS Level II code K1004, "Low frequency ultrasonic diathermy treatment device for home use" or K1036, "Supplies and accessories (e.g., transducer) for low frequency ultrasonic diathermy treatment device, per month" is available if other payers deem appropriate. In the meantime, determinations regarding coding for this item will be made by the DME Medicare Administrative Contractors (MACs).

Final Medicare Benefit Category Determination

No determination.

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

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

All five of these conditions must be met for equipment to be classified as DME. However, it is unclear if the SAM 2.0 Applicator Replacement Device meets one of the conditions that must be met for equipment to be classified as DME:

> **Has an expected life of 3 years –** While the manufacturer provided some data to support the SAM Device's durability, there are notable gaps in the testing that raise questions about the reliability of the 3-year lifespan claim. Specifically, there is no indication that any form of accelerated life or environmental stress testing was conducted to simulate long-term or real-world use. The report provided to CMS also lacks clarity on how results were interpreted—key metrics such as failure rates or lifespan thresholds are not addressed. Additionally, it does not appear that typical daily usage patterns were replicated in the testing process. Without this level of validation, it is difficult to conclude that the device meets the definition of "durability" under CMS regulations. As such, CMS will need the following information to determine whether this item falls within the DME benefit category:
>
> - Evidence of testing designed to simulate long-term use within a condensed timeframe.
> - Evaluation under conditions that replicate real-world environmental and operational stressors.
> - A summary explaining how the results were analyzed to assess reliability and durability.
> - Data that reflects typical daily usage patterns to help validate the expected lifespan.

Should new information be presented to CMS that would result in a preliminary determination that the primary component falls within the DME benefit category, CMS will assess whether further comment at a public meeting is necessary or whether we have sufficient information to reach a benefit category determination.

Final Medicare Payment Determination

No determination.

SAM Gel Capture Coupling Device - HCP2412264YJEY

Topic/Issue

Request to establish a new HCPCS Level II code to identify SAM Gel Capture Coupling Device.

Applicant's suggested language: XXXXX, “Sustained Acoustic Medicine multi-hour coupling device, FDA-cleared, single use”

Summary of Applicant's Submission

ZetrOZ Systems, LLC submitted a request to establish a new HCPCS Level II code to identify SAM Gel Capture Coupling Device. SAM 2.0 Long Duration Ultrasound Device received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on June 23, 2023. This application accompanies the application for the primary device for the SAM 2.0 Device (sustained acoustic medicine long duration continuous wave high-frequency ultrasound device, FDA-cleared, prescription only, for home use).

CMS Preliminary HCPCS Coding Determination

Revise existing HCPCS Level II code K1036, “Supplies and accessories (e.g., transducer) for low frequency ultrasonic diathermy treatment device, per month” to instead read “Supplies and accessories (e.g., transducer) for ultrasonic diathermy treatment device, per month” to describe SAM Gel Capture Coupling Device.

CMS believes revising the description of existing HCPCS Level II code K1036 will accurately capture all supplies and accessories associated with the SAM 2.0 Long Duration Ultrasound Device.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

When clarifying the meaning of "durable" in regulations (76 FR 70291), we noted that a multi-component system may consist of durable and nondurable components that function together to serve a medical purpose. As explained in that regulation, a multi-component system consisting of durable and nondurable components is considered nondurable if the component that serves the medical purpose is nondurable, even if other components that are part of the system are durable. As explained in the preliminary benefit category determination for the SAM Applicator Replacement Device (HCP24122627H63), the SAM Applicator Replacement Device is the component of the multi-component device which performs the medical purpose for the SAM Device. CMS has determined that the SAM Applicator Replacement Device does not meet the definition of DME.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Summary of Public Feedback

ZetrOZ Systems, LLC and other commenters disagreed with CMS' published preliminary determinations. The commenters expressed disagreement with including the SAM 2.0 device with other ultrasound diathermy devices because some of the other devices are not indicated for the treatment of osteoarthritis, like SAM 2.0. The speakers discussed that the device delivers a continuous wave frequency, a long-duration dose that provides acoustic streaming, delivering a therapeutic dose directly into the affected joint. Additionally, the speakers expressed that the device provides four hours of sustained acoustic stimulus, which differs from other devices currently assigned to the proposed HCPCS Level II code. A speaker mentioned that the SAM coupling device is not an accessory rather it is an articulating spacer. The speaker stated that the coupling device is an integral component of the technology, when combined with the applicator and applied to either side of the joint space, acoustic streaming and long-duration ultrasonic diathermy are delivered to the osteoarthritic site, which makes the SAM 2.0 device unique from any other diathermy device.

CMS Final HCPCS Coding Determination

We appreciate the comments provided in response to CMS' published preliminary determinations. CMS recognizes that the SAM 2.0 Device does not fall under the traditional definition of diathermy. Rather, it is a form of ultrasound diathermy that uses low-intensity, long-duration ultrasound waves to deliver continuous micro-massage and gentle heat to tissues. The key difference is that the SAM 2.0 Device uses low-intensity, long-duration ultrasound waves, whereas traditional diathermy devices use electromagnetic waves. Despite this difference in energy type, both therapies function by delivering energy beneath the skin to target muscles and soft tissues, promoting tissue healing and pain relief. Additionally, both can produce therapeutic heat in the deeper layers of muscles and soft tissues. The SAM 2.0 Applicator Replacement Device is the component of the multi-component device which performs the medical purpose for the SAM 2.0 Device. Based on the information provided in the application and after consideration of the comments we received, CMS is revising its preliminary coding determination and is not making a final coding determination regarding this device, and will defer this application for consideration in a future cycle. For Medicare, it is unclear whether or not the SAM 2.0 Applicator Replacement Device is a supply to SAM 2.0 Long Duration Ultrasound Device; the applicant may submit new clarifying information for consideration in a future cycle. Existing HCPCS Level II code K1036, "Supplies and accessories (e.g., transducer) for low frequency ultrasonic diathermy treatment device, per month" is available if other payers deem appropriate. In the meantime, determinations regarding coding for this item will be made by the DME Medicare Administrative Contractors (MACs).

Final Medicare Benefit Category Determination

No determination.

In the preliminary benefit category determination, CMS determined that the SAM 2.0 Applicator Replacement Device is the primary component responsible for serving a medical purpose as part of the SAM 2.0 3-component system that includes the Long Duration Ultrasound device and the Gel Capture Coupling device. At this time, CMS will need additional information from the applicant in order to determine whether the primary component falls within the DME benefit category. Once this information is received and a

BCD is established for the primary component, CMS will establish BCDs for the remaining components.

Should new information be presented to CMS that would result in a preliminary determination that the primary component falls within the DME benefit category, CMS will assess whether further comment at a public meeting is necessary or whether we have sufficient information to reach a benefit category determination.

Final Medicare Payment Determination

No determination.

Point Digit and Point Digit Mini - HCP241231JNNFX

Topic/Issue

Request to establish two new HCPCS Level II codes to identify Point Digit and Point Digit Mini prosthetic terminal devices and their associated mounting brackets.

Applicant's suggested language:

1. LXXX1, “Terminal device, digit, heavy-duty, mechanical, locking, articulating MCP, PIP, and DIP joints, remote anatomical MCP center of motion, automatic extension, per each, initial issue or replacement”

2. LXXX2, “Addition to terminal device, digit, mounting bracket”

Summary of Applicant's Submission

Point Designs submitted a request to establish two new HCPCS Level II codes to identify the Point Digit and Point Digit Mini prosthetic terminal devices and their associated mounting brackets. The Point Digit and Point Digit Mini are class I devices, exempt from the premarket notification procedures by the Food and Drug Administration (FDA). These mechanical finger prosthetic terminal devices are designed for individuals with partial hand amputations. These devices feature a ratcheting mechanism with up to 11 distinct locking positions and include integrated touchscreen-compatible fingertip pads. Made of titanium for strength, they allow for one-handed operation, provide high durability, and maintain anatomical joint alignment for functional and anatomical accuracy. The mounting bracket is used to appropriately align and attach the Point Digit(s) to the partial hand socket in a functional manner. These prosthetic devices restore hand function by replicating the anatomical motions of the metacarpophalangeal (MCP), proximal interphalangeal (PIP), and distal interphalangeal (DIP) joints. Their ratchet mechanism provides fixed locking positions, enabling stable grasps and high-load functionality. Unlike existing prosthetic devices, they integrate a curved knuckle track, ensuring alignment with anatomical joint centers for enhanced performance alongside intact digits. The Point Digit and Point Digit Mini represent significant advancements in material strength, functional range, and anatomical replication, making the existing HCPCS Level II codes insufficient to address the technological distinction and clinical benefits these devices provide.

CMS Preliminary HCPCS Coding Determination

CMS recognizes the applicant’s effort to establish updated code language for partial finger prostheses. The design and materials used for prosthetic digits have evolved considerably, necessitating the creation of more specific and relevant codes to meet the needs of individuals and reflect the developments in prosthetic technology.

CMS tends to categorize partial prosthetic digits into three major types: body-powered, mechanical, and electrical prostheses. Based on the nature of the devices outlined in the applications submitted by Point Designs, these prostheses fall under the mechanical partial digits category. This application requested two specific codes to describe the Point Digit or Point Digit Mini mounting bracket. To address various features of the devices submitted by Point Designs, such as locking mechanisms and specific joint configurations, CMS proposes

to establish a generalized code that could effectively capture these design elements without over-complicating the HCPCS Level II code set. The attachment bracket and any other mounting mechanisms do not need separate or individual codes; they can all be encompassed within a single code to describe the necessary attachment and support features for these partial digit prostheses. This generalized code would be capable of accommodating all the different articulation and attachment mechanisms of the mechanical partial digits. As such, CMS is proposing to:

1. Establish a new HCPCS Level II code LXXX1, "Single digit, per articulation, mechanical, metacarpophalangeal (mcp), proximal interphalangeal (pip), and/or distal interphalangeal (dip) joint(s), with or without locking mechanism, any material, attachment, initial issue or replacement" to describe Point Digit and Point Digit Mini.

CMS believes that the proposed HCPCS Level II code LXXX1 would accurately represent the devices described under the applicant's two requested codes. The proposed HCPCS Level II code LXXX1 is designed to encompass the various anatomical joints and articulations, providing flexibility in its application across different digit prosthetic types. Specifically, the proposed HCPCS Level II code LXXX1 would apply to single-digit prosthetics with mechanical articulation at the MCP, PIP, and/or DIP joints, irrespective of the material used or the type of attachment (such as single axis vs. multiple axial systems). The code descriptor also accommodates devices with different task-performing mechanisms, including both locking and non-locking options.

The applicant's suggested code language implies that all devices described as "heavy-duty" are universally required, but CMS does not agree with this assumption. Given the rapid development of prosthetic technology, CMS believes that devices previously considered "heavy-duty" as described in the applicant's suggested code language are no longer as relevant or necessary as they once were. While these devices may have been designed for durability in the past, advancements in materials and mechanics have allowed for lighter, more advanced prostheses that effectively meet an individual's needs.

Instead of establishing separate codes specifically for attachments, CMS believes it would be more efficient to incorporate the additional attachments or brackets directly into the language of a single base code. This approach streamlines the coding process by consolidating the relevant components under a single, more comprehensive code, ensuring that all necessary elements are captured without the need for multiple distinct codes. As an example, the coding structure for lower limb prostheses using the existing HCPCS Level II code L5701, "Replacement, socket, above knee/knee disarticulation, including attachment plate, molded to patient model" could serve as a guide to create a similar coding structure for partial digit prostheses, including the necessary attachment mechanisms to connect partial digits to the overall hand prosthesis.

By implementing a more generalized coding system, CMS aims to create a more efficient and practical approach to classifying partial digit and thumb prostheses, considering the evolving technology in the field and ensuring that codes remain relevant as new devices are introduced to the market.

Preliminary Medicare Benefit Category Determination

Prosthesis (Artificial Arm).

Preliminary Medicare Payment Determination

No determination.

CMS is collectively reviewing the HCPCS Level II codes established in the Second Biannual 2024 HCPCS Level II coding cycle along with the HCPCS Level II codes proposed under this HCPCS Level II coding cycle and plans to make a payment determination once all of the codes have been finalized. As such, the payment determination for this item will be addressed at a subsequent HCPCS Level II public meeting.

As an alternative, we are seeking input on whether to: 1) finalize the coding determination for this item under this coding cycle (the First Biannual 2025 HCPCS public meeting cycle) but defer the effective date of the code until April 1, 2026, to align with a potential payment determination, or 2) defer a final coding determination on this item and finalize along with the payment determinations in a subsequent HCPCS Level II public meeting cycle.

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 and program instructions at section 60.3 of chapter 23 of the Medicare Claims Processing Manual (CMS Pub. 100-04).

Pricing Indicator = 38

Summary of Public Feedback

Point Designs and other commenters generally agree with CMS' published preliminary determinations with some requested revisions for more specificity and clarification. A commenter stated that the preliminary codes adequately describe the applicable prosthetics while creating a competitive environment that benefits a broad spectrum of patients. However, others commented that CMS' preliminary coding descriptors were too generic, lacked sufficient granularity to distinguish between the different prosthetic partial hand and finger prostheses, and therefore did not reflect contemporary clinical practice. Those commenters requested CMS revise its preliminary coding determination to include more descriptive and specific language that would also remain broad enough to represent the mechanical finger systems currently commercially available to restore a similar level of function to an individual. The commenters further suggested that any products, besides the predicate products, undergo the Medicare Pricing, Data Analysis and Coding (PDAC) code verification process to ensure that all devices meet the code definitions.

Point Designs, the applicant, agreed with CMS' opinion that prosthetic digits fall into three major types: body-powered, mechanical, and electrical prostheses, and that the devices outlined in this application are correctly categorized as mechanical. Because other manufacturers produce mechanical prosthetic fingers, the applicant fully supported CMS' approach to establish a set of codes that could include current and future mechanical prosthetic finger options that are heavy duty, locking, and have a motion-assist feature. The applicant noted that while their requested codes did not represent any single product or company, they also did not accommodate all available prosthetic digits. They also acknowledged they were unable to comment on or speculate about the engineering, functions, features, or pricing of other stakeholders' products beyond what is publicly available.

To describe Point Digit and Point Digit Mini, the applicant suggested the following revised HCPCS Level II code language:

1. LXXX1, "Single digit terminal device, heavy-duty, mechanical, 3 articulating joints, locking mechanism, flexion or extension assist, any material, initial issue or replacement"

The commenters suggested to add the phrase "terminal device" as the industry standard terminology to describe a prosthetic device attached externally to a prosthetic socket at the end of an arm or leg.

Next, the commenters suggested to remove the phrase "per articulation" to prevent confusion as to whether the code should be applied multiple times for a device with multiple joints, and to instead simply indicate the number of joints.

The commenters also suggested to remove the phrase "metacarpophalangeal (mcp), proximal interphalangeal (pip), and/or distal interphalangeal (dip)" to reduce the anatomical specificity and create a broader code that still recognizes the engineering complexity of devices with more joints and the different therapeutic benefits offered by devices with a certain number of joints by adding the phrase "3 articulating joints". The commenter explained that a prosthetic finger with fewer components requires significantly less engineering effort and has a much lower cost of goods; Thus, separate codes are needed for three jointed fingers and two jointed fingers to ensure more accurate billing and reimbursement calculations.

Commenters suggested to remove the phrase "with or without locking mechanism" and instead only specify "locking mechanism" to ensure that devices described by the codes would include a locking mechanism that is critical for individuals to perform most daily activities. Devices with locking mechanisms require more engineering time to develop and involve more components, which is important when evaluating equivalent devices to determine code reimbursement.

The commenters suggested to add the phrase "flexion or extension assist" to describe a specific feature that helps the device meet the user needs without requiring the intact hand to manipulate the prosthetic finger into position. Devices with this feature include more components that increase the device complexity and cost.

Additionally, the commenters suggested to add the phrase "heavy-duty" to ensure that devices represented by this code meet the requirements for DME and can be used by patients every day, all day. The commenters emphasized that "heavy-duty" is a result of material choice, engineering design, robust testing, and high-quality manufacturing and assembly; and they agree with CMS that including the phrase "any material" is appropriate language in the code as devices can be considered heavy-duty with other materials besides titanium or stainless steel. The commenters also noted that there is currently no recognized standards for evaluating prosthetic hands or fingers to determine if something is heavy-duty and therefore recommend mandatory PDAC code verification for these new codes to ensure that only high-quality devices will be represented by these codes. The commenter also suggested that other insurers use criteria loosely based on the International Standards for External limb prostheses

and external orthoses - Requirements and test methods[4] including certain weight bearing thresholds.

Finally, the commenters suggested to remove the phrase "attachment" to allow for the creation of a separate HCPCS Level II code specifically to describe mounting hardware associated with mechanical digits as follows:

2. LXXX6, "Upper extremity addition, attachment hardware for mechanical digit or thumb, per digit"

The commenters stated the purpose of devices described by this separate code, LXXX6, would be to align and mount the prosthetic digit, thumb, or additions to the prosthesis and one mounting component is needed for each digit. The commenters explained that for most mechanical fingers, the mounting hardware is a separate consumable item that is permanently fabricated into the prosthetic socket, so if a new socket is needed for a patient, the prosthetist can reuse the terminal devices but must order new mounting hardware. The commenters emphasized that a separate code is needed to identify this expense, and that they do not recommend including the mounting hardware into the other codes.

In its published preliminary Medicare payment determination, CMS sought input on whether to finalize the HCPCS coding determinations under this HCPCS Level II public meeting cycle but defer the effective date of the codes until April 1, 2026, to align with a potential payment determination, or finalize the coding determinations along with the payment determinations in a subsequent HCPCS Level II public meeting cycle. Most commenters suggested that the coding determinations be finalized as normal under this current coding cycle with an effective date of October 1, 2025, instead of delaying the codes to align with a delayed payment determination. The commenters further suggested that the Medicare payment determinations should be finalized in the next coding cycle with an effective date of April 1, 2026, and established independently of the timeline for any other partial hand prosthetic code changes.

Point Designs requested that CMS establish pricing of the codes through the gap-filling process, supported by explanations of benefits (EOBs) submitted. The sample EOBs represented the entire prosthesis including estimated payment for the digit based on the manufacturer's suggested retail price (MSRP), estimated payment for the mounting hardware based on MSRP, and the residual amount that would be estimated for the socket design/fabrication and clinical care. The applicant used a gap filling calculator created with CMS guidelines to ultimately recommend gap filled fees for each requested code.

A commenter discussed personal experience using the Point Digit device and emphasized how its heavy-duty and lightweight design makes it comfortable to wear for more than eight hours a day in wet and dirty environments. The commenter also stated that the auto spring back offers the individual the ability to be as quick and productive in daily activities, and the movement in all three joints of the Point Digit mimics intact fingers and helps the individual to handle both large and small items for various projects as needed.

[4] International Organization for Standardization (2006) "International Standards for External limb prostheses and external orthoses - Requirements and test methods" (ISO 22523:2006). Retrieved from https://www.iso.org/standard/37546.html

CMS Final HCPCS Coding Determination

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

Establish a new HCPCS Level II code L6035, "Single prosthetic digit, mechanical, can include metacarpophalangeal (mcp), proximal interphalangeal (pip), and/or distal interphalangeal (dip) joint(s), with or without locking mechanism, can include flexion or extension assist, any material, attachment, initial issue or replacement" to describe Point Digit and Point Digit Mini.

This code language is more specific in order to help differentiate amputated and sound digits. We did not include the term "terminal device" as suggested by the commenters, as that term has historically been used to describe hooks, body-powered hands, externally powered (myoelectric) hands, and cosmetic/restorative hands. To maintain consistency with previous coding terminology, CMS used the term "prosthetic digit" and "prosthetic thumb" to describe components attached to the partial hand and finger interface.

CMS agrees with the speaker that titanium constructions will make partial hand and digit prostheses durable enough to meet the requirements for heavy-duty activities. However, CMS disagrees that a new code is necessary to describe this. The existing code L6032, "Addition to upper extremity prosthesis, partial hand including fingers, ultralight material (titanium, carbon fiber or equal)," established in the second biannual 2024 HCPCS Level II coding cycle, adequately describes the heavy-duty features and materials needed for such activities. Therefore, creating a new code would be redundant.

Historical examples of the use of "heavy duty" in the HCPCS Level II code set for lower limb prostheses, such as L5994, "Addition to lower extremity prosthesis, heavy duty feature, knee only, for patient weight greater than 300 lbs" and L5995, "Addition to lower extremity prosthesis, heavy duty feature, other than foot or knee, for patient weight greater than 300 lbs" were intended to withstand loads for beneficiaries weighing over 300 lbs. Also, upper limb prosthesis codes, such as L6639, "Upper extremity addition, heavy duty feature, any elbow," describe prosthetic elbows constructed of high-strength materials (e.g., stainless steel) to withstand lifting of large objects. The statements above show that the heavy-duty designation should be reserved for codes where durability and strength are clinically relevant, rather than applied broadly to all partial hand or digit prostheses. The general partial hand and finger prosthetic codes do not need to include heavy-duty language, as most do not require these enhanced specifications.

CMS agrees with the commenters that locking features increase usability. However, CMS disagrees to exclude the "non-locking" term in the language. The applicant, Point Design Company, primarily produces non-body-powered partial hand and digit prostheses that might only require locking mechanisms. However, body-powered partial hand and prostheses, which are also mechanical but not passive, do not necessarily have locking mechanisms. The current verbiage of HCPCS Level II code L6035 should encompass all current products in the industry that share the same structure and mechanism, not only for a specific manufacturer but aim to describe those that share the same primary features.

CMS agrees with the commenters to add extension and flexion assist in the proposed language, as it would assist beneficiaries in rapidly prepositioning prostheses that secure objects while still performing tasks with their intact hands.

CMS has determined that specifying articulating joints in the code description will be more appropriate than the number of articulating joints. Specifying joints helps align the description with clinical documentation and prosthetic features, which is important for approval, audits, and reimbursement. Additionally, many prosthetic digits and thumbs vary significantly in design. For example, some articulate at MCP only, others at MCP + PIP, or even with locking DIP joints.

Final Medicare Benefit Category Determination

Prosthesis (Artificial Arm).

Final Medicare Payment Determination

No determination.

While we understand the concerns expressed during the public meeting regarding the creation of HCPCS Level II codes without national fee schedule amounts, CMS cannot make a final Medicare payment determination without first proposing a preliminary payment determination and publishing this decision prior to a public meeting in accordance with 42 CFR 414.240(b). It is our intention that the payment determination for these items will be addressed during the Second Biannual 2025 HCPCS Level II coding cycle.

In the meantime, 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 and program instructions at section 60.3 of chapter 23 of the Medicare Claims Processing Manual (CMS Pub. 100-04).

Pricing Indicator = 38

Point Partial - HCP241231VULPL

Topic/Issue

Request to establish two new HCPCS Level II codes to identify Point Partial prosthetic terminal devices and their associated mounting brackets.

Applicant's suggested language:

1. LXXX3, “Terminal device, partial digit, heavy-duty, mechanical, locking, articulating PIP and DIP joints, remote anatomical PIP center of motion, automatic extension, per each, initial issue or replacement”

2. LXXX4, “Addition to terminal device, partial digit, mounting bracket”

Summary of Applicant's Submission

Point Designs submitted a request to establish two new HCPCS Level II codes to identify Point Partial prosthetic terminal devices and their associated mounting brackets. The Point Partial is a class I device, exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The Point Partial is a mechanical finger prosthetic terminal device designed for individuals with partial finger amputations. These devices feature a ratcheting mechanism with up to seven distinct locking positions and include integrated touchscreen-compatible fingertip pads. Made of titanium for strength, they allow for one-handed operation, provide high durability, and maintain anatomical joint alignment for functional and anatomical accuracy. The mounting bracket is used to appropriately align and attach the Point Partial to the partial hand socket in a functional manner. These prosthetic devices restore hand function by replicating the anatomical motions of the proximal interphalangeal and distal interphalangeal joints. Their ratchet mechanism provides fixed locking positions, enabling stable grasps and high loading abilities. Unlike existing prosthetic devices, they integrate a curved knuckle track, ensuring alignment with anatomical joint centers for enhanced performance alongside intact digits. The Point Partial represents significant advancements in material strength, functional range, and anatomical replication, making the existing HCPCS Level II codes insufficient to address the technological distinction and clinical benefits these devices provide.

CMS Preliminary HCPCS Coding Determination

CMS recognizes the applicant’s effort to establish updated code language for partial finger prostheses, as the current coding system no longer accurately reflects the new technological advancements in the prosthetics market. The design and materials used for prosthetic digits have evolved considerably, necessitating the creation of more specific and relevant codes to meet the needs of individuals and reflect the developments in prosthetic technology.

CMS tends to categorize partial prosthetic digits into three major types: body-powered, mechanical, and electrical prostheses. Based on the nature of the devices outlined in the applications submitted by Point Designs, these prostheses fall under the mechanical partial digits category.

This application requested two specific codes to describe the Point Partial device with its corresponding mounting brackets. To address various features of the devices submitted by Point Designs, such as locking mechanisms and specific joint configurations, CMS proposes to establish a generalized code that could effectively capture these design elements without over-complicating the HCPCS Level II code set. The attachment bracket and any other mounting mechanisms do not need separate or individual codes; they can all be encompassed within a single code to describe the necessary attachment and support features for these partial digit prostheses. This generalized code would be capable of accommodating all the different articulation and attachment mechanisms of the mechanical partial digits. As such, CMS proposes to:

1. Establish a new HCPCS Level II code LXXX1, "Single digit, per articulation, mechanical, metacarpophalangeal (mcp), proximal interphalangeal (pip), and/or distal interphalangeal (dip) joint(s), with or without locking mechanism, any material, attachment, initial issue or replacement" to describe Point Partial.

CMS believes that the proposed HCPCS Level II code LXXX1 will accurately represent the devices described under the applicant's two requested codes. The proposed HCPCS Level II code LXXX1 is designed to encompass the various joints and articulations, providing flexibility in its application across different digit prosthetic types. Specifically, the proposed HCPCS Level II code LXXX1 will apply to single-digit prosthetics with mechanical articulation at the metacarpophalangeal (MCP), proximal interphalangeal (PIP), and distal interphalangeal (DIP) joints, irrespective of the material used or the type of attachment (such as single-axial vs. multi-axial systems). It will also accommodate different task-performing mechanisms, including both locking and non-locking options.

The applicant's suggested code language implies that all devices described as "heavy-duty" are universally required, but CMS does not agree with this blanket assumption. Given the rapid development of prosthetic technology, CMS believes that devices previously considered "heavy-duty" as described in the applicant's suggested code language are no longer as relevant or necessary as they once were. While these devices may have been designed for durability in the past, advancements in materials and mechanics have allowed for lighter, more advanced prostheses that still effectively meet an individual's needs.

Instead of establishing separate codes specifically for attachments, CMS believes it would be more efficient to incorporate the additional attachments or brackets directly into the language of a single base code. This approach streamlines the coding process by consolidating the relevant components under a single, more comprehensive code, ensuring that all necessary elements are captured without the need for multiple distinct codes. As an example, the coding structure for lower limb prostheses using the existing HCPCS Level II code L5701, "Replacement, socket, above knee/knee disarticulation, including attachment plate, molded to patient model" could serve as a guide to create a similar coding structure for partial digit prostheses, including the necessary attachment mechanisms to connect partial digits to the overall hand prosthesis.

By implementing a more generalized coding system, CMS aims to create a more efficient and practical approach to classifying partial digit and thumb prostheses, considering the evolving technology in the field and ensuring that codes remain relevant as new devices are introduced to the market.

Preliminary Medicare Benefit Category Determination

Prosthesis (Artificial Arm).

Preliminary Medicare Payment Determination

No determination.

CMS is collectively reviewing the HCPCS Level II codes established in the Second Biannual 2024 HCPCS Level II coding cycle along with the HCPCS Level II codes proposed under this HCPCS Level II coding cycle and plans to make a payment determination once all of the codes have been finalized. As such, the payment determination for this item will be addressed at a subsequent HCPCS Level II public meeting.

As an alternative, we are seeking input on whether to: 1) finalize the coding determination for this item under this coding cycle (the First Biannual 2025 HCPCS public meeting cycle) but defer the effective date of the code until April 1, 2026, to align with a potential payment determination, or 2) defer a final coding determination on this item and finalize along with the payment determinations in a subsequent HCPCS Level II public meeting cycle.

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 and program instructions at section 60.3 of chapter 23 of the Medicare Claims Processing Manual (CMS Pub. 100-04).

Pricing Indicator = 38

Summary of Public Feedback

Point Designs and other commenters generally agreed with CMS' published preliminary determinations with some requested revisions for more specificity and clarification. A commenter stated that the preliminary codes adequately describe the applicable prosthetics while creating a competitive environment that benefits a broad spectrum of patients. However, others commented that CMS' preliminary coding descriptors were too generic, lacked sufficient granularity to distinguish between the different prosthetic partial hand and finger prostheses, and therefore did not reflect contemporary clinical practice. Those commenters requested CMS to revise its preliminary coding determination to include more descriptive and specific language that would also remain broad enough to represent the mechanical finger systems currently commercially available to restore a similar level of function to an individual. The commenters further suggested that any products, besides the predicate products, undergo the Medicare Pricing, Data Analysis and Coding (PDAC) code verification process to ensure that all devices meet the code definitions.

Point Designs, the applicant, agreed with CMS' opinion that prosthetic digits fall into three major types: body-powered, mechanical, and electrical prostheses, and that the devices outlined in this application are correctly categorized as mechanical. Because other manufacturers produce mechanical prosthetic fingers, the applicant fully supported CMS' approach to establish a set of codes that could include current and future mechanical prosthetic finger options that are heavy duty, locking, and have a motion-assist feature. The applicant noted that while their requested codes did not represent any single product or

company, they also did not accommodate all available prosthetic digits. They also acknowledged they were unable to comment on or speculate about the engineering, functions, features, or pricing of other stakeholders' products beyond what is publicly available.

To describe Point Partial, the applicant suggested the following revised HCPCS Level II code language:

1. LXXX2, "Single digit terminal device, heavy-duty, mechanical, 2 articulating joints, locking mechanism, flexion or extension assist, any material, initial issue or replacement"

The commenters suggested to add the phrase "terminal device" as the industry standard terminology to describe a prosthetic device attached externally to a prosthetic socket at the end of an arm or leg.

Next, the commenters suggested to remove the phrase "per articulation" to prevent confusion as to whether the code should be applied multiple times for a device with multiple joints, and to instead simply indicate the number of joints.

The commenters also suggested to remove the phrase "metacarpophalangeal (mcp), proximal interphalangeal (pip), and/or distal interphalangeal (dip)" to reduce the anatomical specificity and create a broader code that still recognizes the engineering complexity of devices with more joints and the different therapeutic benefits offered by devices with a certain number of joints by adding the phrase "3 articulating joints". The commenter explained that a prosthetic finger with fewer components requires significantly less engineering effort and has a much lower cost of goods; Thus, separate codes are needed for three jointed fingers and two jointed fingers to ensure more accurate billing and reimbursement calculations.

Commenters suggested to remove the phrase "with or without locking mechanism" and instead only specify "locking mechanism" to ensure that devices described by the codes would include a locking mechanism that is critical for individuals to perform most daily activities. Devices with locking mechanisms require more engineering time to develop and involve more components, which is important when evaluating equivalent devices to determine code reimbursement.

The commenters suggested to add the phrase "flexion or extension assist" to describe a specific feature that helps the device meet the user needs without requiring the intact hand to manipulate the prosthetic finger into position. Devices with this feature include more components that increase the device complexity and cost.

Additionally, the commenters suggested to add the phrase "heavy-duty" to ensure that devices represented by this code meet the requirements for DME and can be used by patients every day, all day. The commenters emphasized that "heavy-duty" is a result of material choice, engineering design, robust testing, and high-quality manufacturing and assembly; and they agree with CMS that including the phrase "any material" is appropriate language in the code as devices can be considered heavy-duty with other materials besides titanium or stainless steel. The commenters also noted that there is currently no recognized standards for evaluating prosthetic hands or fingers to determine if something is heavy-duty and therefore recommend mandatory PDAC code verification for these new codes to ensure that only high-quality devices will be represented by these codes. The commenter also suggested that other

insurers use criteria loosely based on the International Standards for External limb prostheses and external orthoses - Requirements and test methods[5] including certain weight bearing thresholds.

Finally, the commenters suggested to remove the phrase "attachment" to allow for the creation of a separate code specifically to describe mounting hardware associated with mechanical digits as follows:

2. LXXX6, "Upper extremity addition, attachment hardware for mechanical digit or thumb, per digit"

The commenters stated the purpose of devices described by this separate code, LXXX6, is for aligning and mounting the prosthetic digit, thumb, or additions to the prosthesis and one mounting component is needed for each digit. The commenters explained that for most mechanical fingers, the mounting hardware is a separate consumable item that is permanently fabricated into the prosthetic socket, so if a new socket is needed for a patient, the prosthetist can reuse the terminal devices but must order new mounting hardware. The commenters emphasized that a separate code is needed to identify this expense, and that they do not recommend including the mounting hardware into the other codes.

In its published preliminary Medicare payment determination, CMS sought input on whether to finalize the HCPCS coding determinations under this HCPCS Level II public meeting cycle but defer the effective date of the codes until April 1, 2026, to align with a potential payment determination, or finalize the coding determinations along with the payment determinations in a subsequent HCPCS Level II public meeting cycle. Most commenters suggested that the coding determinations be finalized as normal under this current coding cycle with an effective date of October 1, 2025, instead of delaying the codes to align with a delayed payment determination. The commenters further suggested that the Medicare payment determinations should be finalized in the next coding cycle with an effective date of April 1, 2026, and established independently of the timeline for any other partial hand prosthetic code changes.

Point Designs requested that CMS establish pricing of the codes through the gap-filling process, supported by explanations of benefits (EOBs) submitted. The sample EOBs represented the entire prosthesis including estimated payment for the digit based on the manufacturer's suggested retail price (MSRP), estimated payment for the mounting hardware based on MSRP, and the residual amount that would be estimated for the socket design/fabrication and clinical care. The applicant used a gap filling calculator created with CMS guidelines to ultimately recommend gap filled fees for each requested code.

CMS Final HCPCS Coding Determination

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

[5] International Organization for Standardization (2006) "International Standards for External limb prostheses and external orthoses - Requirements and test methods" (ISO 22523:2006). Retrieved from https://www.iso.org/standard/37546.html

1. Establish a new HCPCS Level II code L6035, “Single prosthetic digit, mechanical, can include metacarpophalangeal (mcp), proximal interphalangeal (pip), and/or distal interphalangeal (dip) joint(s), with or without locking mechanism, can include flexion or extension assist, any material, attachment, initial issue or replacement” to describe Point Partial.

This code language is more specific in order to help differentiate amputated and sound digits. We did not include the term “terminal device” as suggested by the commenters, as that term has historically been used to describe hooks, body-powered hands, externally powered (myoelectric) hands, and cosmetic/restorative hands. To maintain consistency with previous coding terminology, CMS used the term “prosthetic digit” and “prosthetic thumb” to describe components attached to the partial hand and finger interface.

CMS agrees with the speaker that titanium constructions will make partial hand and digit prostheses durable enough to meet the requirements for heavy-duty activities. However, CMS disagrees that a new code is necessary to describe this. The existing code L6032, “Addition to upper extremity prosthesis, partial hand including fingers, ultralight material (titanium, carbon fiber or equal),” established in the second biannual 2024 HCPCS Level II coding cycle, adequately describes the heavy-duty features and materials needed for such activities. Therefore, creating a new code would be redundant.

Historical examples of the use of “heavy duty” in the HCPCS Level II code set for lower limb prostheses, such as L5994, “Addition to lower extremity prosthesis, heavy duty feature, knee only, for patient weight greater than 300 lbs” and L5995, “Addition to lower extremity prosthesis, heavy duty feature, other than foot or knee, for patient weight greater than 300 lbs” were intended to withstand loads for beneficiaries weighing over 300 lbs. Also, upper limb prosthesis codes, such as L6639, “Upper extremity addition, heavy duty feature, any elbow,” describe prosthetic elbows constructed of high-strength materials (e.g., stainless steel) to withstand lifting of large objects. The statements above show that the heavy-duty designation should be reserved for codes where durability and strength are clinically relevant, rather than applied broadly to all partial hand or digit prostheses. The general partial hand and finger prosthetic codes do not need to include heavy-duty language, as most do not require these enhanced specifications.

CMS agrees with the commenters that locking features increase usability. However, CMS disagrees to exclude the “non-locking” term in the language. The applicant, Point Design Company, primarily produces non-body-powered partial hand and digit prostheses that might only require locking mechanisms. However, body-powered partial hand and prostheses, which are also mechanical but not passive, do not necessarily have locking mechanisms. The current verbiage of HCPCS Level II code L6035 should encompass all current products in the industry that share the same structure and mechanism, not only for a specific manufacturer but aim to describe those that share the same primary features.

CMS agrees with the commenters to add extension and flexion assist in the proposed language, as it would assist beneficiaries in rapidly prepositioning prostheses that secure objects while still performing tasks with their intact hands.

CMS has determined that specifying articulating joints in the code description will be more appropriate than the number of articulating joints. Specifying joints helps align the description with clinical documentation and prosthetic features, which is important for

approval, audits, and reimbursement. Additionally, many prosthetic digits and thumbs vary significantly in design. For example, some articulate at MCP only, others at MCP + PIP, or even with locking DIP joints.

Final Medicare Benefit Category Determination

Prosthesis (Artificial Arm).

Final Medicare Payment Determination

No determination.

While we understand the concerns expressed during the public meeting regarding the creation of HCPCS Level II codes without national fee schedule amounts, CMS cannot make a final Medicare payment determination without first proposing a preliminary payment determination and publishing this decision prior to a public meeting in accordance with 42 CFR 414.240(b). It is our intention that the payment determination for these items will be addressed during the Second Biannual 2025 HCPCS Level II coding cycle.

In the meantime, 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 and program instructions at section 60.3 of chapter 23 of the Medicare Claims Processing Manual (CMS Pub. 100-04).

Pricing Indicator = 38

Point Thumb - HCP241231UNXL1

Topic/Issue

Request to establish two new HCPCS Level II codes to identify Point Thumb prosthetic terminal devices and their associated mounting brackets.

Applicant's suggested language:

1. LXXX5, “Terminal device, thumb, heavy-duty, mechanical, locking, articulating MCP and IP joints, remote anatomical MCP center of motion, automatic extension, per each, initial issue or replacement”

2. LXXX6, “Addition to terminal device, thumb, mounting bracket”

Summary of Applicant's Submission

Point Designs submitted a request to establish two new HCPCS Level II codes to identify the Point Thumb prosthetic terminal devices and their associated mounting brackets. The Point Thumb is a class I device, exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The Point Thumb is a mechanical prosthetic terminal device designed for individuals with thumb amputations. It features a ratcheting mechanism with up to 11 distinct locking positions and includes integrated gripping surfaces and touchscreen-compatible thumb tip pads. Made of titanium for strength and durability, they allow for one-handed operation and maintain anatomical joint alignment for functional accuracy. The mounting bracket is used to appropriately align and attach the Point Thumb to the partial hand socket in a functional manner. These prosthetic devices restore hand function by replicating the anatomical motions of the metacarpophalangeal and interphalangeal joints. Unlike existing prosthetic devices, they integrate a curved knuckle track, ensuring alignment with anatomical joint centers for enhanced performance alongside intact digits. Their ratchet mechanism provides fixed locking positions, enabling stable grasps and high loading abilities. The Point Thumb represents significant advancements in material strength, functional range, and anatomical replication, making the existing HCPCS Level II codes insufficient to address the technological distinction and clinical benefits these devices provide.

CMS Preliminary HCPCS Coding Determination

CMS recognizes the applicant’s effort to establish updated code language for partial finger prostheses, as the current coding system no longer accurately reflects the new technological advancements in the prosthetics market. The design and materials used for prosthetic digits have evolved considerably, necessitating the creation of more specific and relevant codes to meet the needs of individuals and reflect the developments in prosthetic technology.

CMS tends to categorize partial prosthetic digits into three major types: body-powered, mechanical, and electrical prostheses. Based on the nature of the devices outlined in the applications submitted by Point Designs, these prostheses fall under the mechanical partial digits category.

This application requested two specific codes to describe the Point Thumb with its corresponding mounting brackets. To address the various features of the devices submitted by Point Designs, such as locking mechanisms and specific joint configurations, CMS proposes to establish a generalized code that could effectively capture these design elements without over-complicating the HCPCS Level II code set. The attachment bracket and any other mounting mechanisms do not need separate or individual codes; they can all be encompassed within a single code to describe the necessary attachment and support features for these partial digit prostheses. This generalized code would be capable of accommodating all the different articulation and attachment mechanisms of the mechanical partial digits. As such, CMS is proposing to:

1. Establish a new HCPCS Level II code LXXX2, "Thumb, per articulation, mechanical, metacarpophalangeal (mcp) and interphalangeal (ip) joint, with or without locking mechanism, any material, attachment, initial issue or replacement" to describe Point Thumb.

CMS believes that the proposed HCPCS Level II code LXXX2 will accurately represent the devices described under the applicant's two requested codes. This proposed HCPCS Level II code LXXX2 is designed to encompass the various joints and articulations of a prosthetic thumb. Specifically, the proposed HCPCS Level II code LXXX2 will apply to a prosthetic thumb with mechanical articulation at the metacarpophalangeal (MCP) and/or interphalangeal (IP) joints, irrespective of the material used or the type of attachment (such as single axis vs. multiple axial systems). It will also accommodate different task-performing mechanisms, including both locking and non-locking options.

The applicant's suggested code language implies that all devices described as "heavy-duty" are universally required, but CMS does not agree with this blanket assumption. Given the rapid development of prosthetic technology, CMS believes that devices previously considered "heavy-duty" as described in the applicant's suggested code language are no longer as relevant or necessary as they once were. While these devices may have been designed for durability in the past, advancements in materials and mechanics have allowed for lighter, more advanced prostheses that still effectively meet an individual's needs.

Instead of establishing separate codes specifically for attachments, CMS believes it would be more efficient to incorporate the additional attachments or brackets directly into the language of a single base code. This approach streamlines the coding process by consolidating the relevant components under a single, more comprehensive code, ensuring that all necessary elements are captured without the need for multiple distinct codes. As an example, the coding structure for lower limb prostheses using the existing HCPCS Level II code L5701, "Replacement, socket, above knee/knee disarticulation, including attachment plate, molded to patient model" could serve as a guide to create a similar coding structure for partial digit prostheses, including the necessary attachment mechanisms to connect partial digits to the overall hand prosthesis.

By implementing a more generalized coding system, CMS aims to create a more efficient and practical approach to classifying partial digit and thumb prostheses, considering the evolving technology in the field and ensuring that codes remain relevant as new devices are introduced to the market.

Preliminary Medicare Benefit Category Determination

Prosthesis (Artificial Arm).

Preliminary Medicare Payment Determination

No determination.

CMS is collectively reviewing the HCPCS Level II codes established in the Second Biannual 2024 HCPCS Level II coding cycle along with the HCPCS Level II codes proposed under this HCPCS Level II coding cycle and plans to make a payment determination once all of the codes have been finalized. As such, the payment determination for this item will be addressed at a subsequent HCPCS Level II public meeting.

As an alternative, we are seeking input on whether to: 1) finalize the coding determination for this item under this coding cycle (the First Biannual 2025 HCPCS public meeting cycle) but defer the effective date of the code until April 1, 2026, to align with a potential payment determination, or 2) defer a final coding determination on this item and finalize along with the payment determinations in a subsequent HCPCS Level II public meeting cycle.

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 and program instructions at section 60.3 of chapter 23 of the Medicare Claims Processing Manual (CMS Pub. 100-04).

Pricing Indicator = 38

Summary of Public Feedback

Point Designs and other commenters generally agree with CMS' published preliminary determinations with some requested revisions for more specificity and clarification. A commenter stated that the preliminary codes adequately describe the applicable prosthetics while creating a competitive environment that benefits a broad spectrum of patients. However, others commented that CMS' preliminary coding descriptors were too generic, lacked sufficient granularity to distinguish between the different prosthetic partial hand and finger prostheses, and therefore did not reflect contemporary clinical practice. Those commenters requested CMS to revise its preliminary coding determination to include more descriptive and specific language that would also remain broad enough to represent the mechanical finger systems currently commercially available to restore a similar level of function to an individual. The commenters further suggested that any products, besides the predicate products, undergo the Medicare Pricing, Data Analysis and Coding (PDAC) code verification process to ensure that all devices meet the code definitions.

Point Designs, the applicant, agreed with CMS' opinion that prosthetic digits fall into three major types: body-powered, mechanical, and electrical prostheses, and that the devices outlined in this application are correctly categorized as mechanical. Because other manufacturers produce mechanical prosthetic fingers, the applicant fully supported CMS' approach to establish a set of codes that could include current and future mechanical prosthetic finger options that are heavy duty, locking, and have a motion-assist feature. The applicant noted that while their requested codes did not represent any single product or

company, they also did not accommodate all available prosthetic digits. They also acknowledged they were unable to comment on or speculate about the engineering, functions, features, or pricing of other stakeholders' products beyond what is publicly available.

To specifically describe Point Thumb, the applicant suggested the following revised HCPCS Level II code language:

1. LXXX3, "Thumb terminal device, heavy-duty, mechanical, 2 articulating joints, locking mechanism, flexion or extension assist, any material, initial issue or replacement"

The commenters suggested to add the phrase "terminal device" as the industry standard terminology to describe a prosthetic device attached externally to a prosthetic socket at the end of an arm or leg.

Next, the commenters suggested to remove the phrase "per articulation" to prevent confusion as to whether the code should be applied multiple times for a device with multiple joints, and to instead simply indicate the number of joints.

The commenters also suggested to remove the phrase "metacarpophalangeal (mcp), proximal interphalangeal (pip), and/or distal interphalangeal (dip)" to reduce the anatomical specificity and create a broader code that still recognizes the engineering complexity of devices with more joints and the different therapeutic benefits offered by devices with a certain number of joints by adding the phrase "3 articulating joints". The commenter explained that a prosthetic finger with fewer components requires significantly less engineering effort and has a much lower cost of goods; Thus, separate codes are needed for three jointed fingers and two jointed fingers to ensure more accurate billing and reimbursement calculations.

Commenters suggested to remove the phrase "with or without locking mechanism" and instead only specify "locking mechanism" to ensure that devices described by the codes would include a locking mechanism that is critical for individuals to perform most daily activities. Devices with locking mechanisms require more engineering time to develop and involve more components, which is important when evaluating equivalent devices to determine code reimbursement.

The commenters suggested to add the phrase "flexion or extension assist" to describe a specific feature that helps the device meet the user needs without requiring the intact hand to manipulate the prosthetic finger into position. Devices with this feature include more components that increase the device complexity and cost.

Additionally, the commenters suggested to add the phrase "heavy-duty" to ensure that devices represented by this code meet the requirements for DME and can be used by patients every day, all day. The commenters emphasized that "heavy-duty" is a result of material choice, engineering design, robust testing, and high-quality manufacturing and assembly; and they agree with CMS that including the phrase "any material" is appropriate language in the code as devices can be considered heavy-duty with other materials besides titanium or stainless steel. The commenters also noted that there is currently no recognized standards for evaluating prosthetic hands or fingers to determine if something is heavy-duty and therefore recommend mandatory PDAC code verification for these new codes to ensure that only high-quality devices will be represented by these codes. The commenter also suggested that other

insurers use criteria loosely based on the International Standards for External limb prostheses and external orthoses - Requirements and test methods[6] including certain weight bearing thresholds.

Finally, the commenters suggested to remove the phrase "attachment" to allow for the creation of a separate code specifically to describe mounting hardware associated with mechanical digits as follows:

2. LXXX6, "Upper extremity addition, attachment hardware for mechanical digit or thumb, per digit"

The commenters stated the purpose of devices described by this separate code, LXXX6, is for aligning and mounting the prosthetic digit, thumb, or additions to the prosthesis and one mounting component is needed for each digit. The commenters explained that for most mechanical fingers, the mounting hardware is a separate consumable item that is permanently fabricated into the prosthetic socket, so if a new socket is needed for a patient, the prosthetist can reuse the terminal devices but must order new mounting hardware. The commenters emphasized that a separate code is needed to identify this expense, and that they do not recommend including the mounting hardware into the other codes.

In its published preliminary Medicare payment determination, CMS sought input on whether to finalize the HCPCS coding determinations under this HCPCS Level II public meeting cycle but defer the effective date of the codes until April 1, 2026, to align with a potential payment determination, or finalize the coding determinations along with the payment determinations in a subsequent HCPCS Level II public meeting cycle. Most commenters suggested that the coding determinations be finalized as normal under this current coding cycle with an effective date of October 1, 2025, instead of delaying the codes to align with a delayed payment determination. The commenters further suggested that the Medicare payment determinations should be finalized in the next coding cycle with an effective date of April 1, 2026, and established independently of the timeline for any other partial hand prosthetic code changes.

Point Designs requested that CMS establish pricing of the codes through the gap-filling process, supported by explanations of benefits (EOBs) submitted. The sample EOBs represented the entire prosthesis including estimated payment for the digit based on the manufacturer's suggested retail price (MSRP), estimated payment for the mounting hardware based on MSRP, and the residual amount that would be estimated for the socket design/fabrication and clinical care. The applicant used a gap filling calculator created with CMS guidelines to ultimately recommend gap filled fees for each requested code.

CMS Final HCPCS Coding Determination

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

[6] International Organization for Standardization (2006) "International Standards for External limb prostheses and external orthoses - Requirements and test methods" (ISO 22523:2006). Retrieved from https://www.iso.org/standard/37546.html

Establish a new HCPCS Level II code L6036, "Prosthetic thumb, mechanical, can include metacarpophalangeal (mcp), interphalangeal (ip) joint(s), with or without locking mechanism, can include flexion or extension assist, any material, attachment, initial issue or replacement" to describe Point Thumb.

This code language is more specific in order to help differentiate amputated and sound digits. We did not include the term "terminal device" as suggested by the commenters, as that term has historically been used to describe hooks, body-powered hands, externally powered (myoelectric) hands, and cosmetic/restorative hands. To maintain consistency with previous coding terminology, CMS used the term "prosthetic digit" and "prosthetic thumb" to describe components attached to the partial hand and finger interface.

CMS agrees with the speaker that titanium constructions will make partial hand and digit prostheses durable enough to meet the requirements for heavy-duty activities. However, CMS disagrees that a new code is necessary to describe this. The existing code L6032, "Addition to upper extremity prosthesis, partial hand including fingers, ultralight material (titanium, carbon fiber or equal)," established in the second biannual 2024 HCPCS Level II coding cycle, adequately describes the heavy-duty features and materials needed for such activities. Therefore, creating a new code would be redundant.

Historical examples of the use of "heavy duty" in the HCPCS Level II code set for lower limb prostheses, such as L5994, "Addition to lower extremity prosthesis, heavy duty feature, knee only, for patient weight greater than 300 lbs" and L5995, "Addition to lower extremity prosthesis, heavy duty feature, other than foot or knee, for patient weight greater than 300 lbs" were intended to withstand loads for beneficiaries weighing over 300 lbs. Also, upper limb prosthesis codes, such as L6639, "Upper extremity addition, heavy duty feature, any elbow," describe prosthetic elbows constructed of high-strength materials (e.g., stainless steel) to withstand lifting of large objects. The statements above show that the heavy-duty designation should be reserved for codes where durability and strength are clinically relevant, rather than applied broadly to all partial hand or digit prostheses. The general partial hand and finger prosthetic codes do not need to include heavy-duty language, as most do not require these enhanced specifications.

CMS agrees with the commenters that locking features increase usability. However, CMS disagrees to exclude the "non-locking" term in the language. The applicant, Point Design Company, primarily produces non-body-powered partial hand and digit prostheses that might only require locking mechanisms. However, body-powered partial hand and prostheses, which are also mechanical but not passive, do not necessarily have locking mechanisms. The current verbiage of HCPCS Level II code L6036 should encompass all current products in the industry that share the same structure and mechanism, not only for a specific manufacturer but aim to describe those that share the same primary features.

CMS agrees with the commenters to add extension and flexion assist in the proposed language, as it would assist beneficiaries in rapidly prepositioning prostheses that secure objects while still performing tasks with their intact hands.

CMS has determined that specifying articulating joints in the code description will be more appropriate than the number of articulating joints. Specifying joints helps align the description with clinical documentation and prosthetic features, which is important for

approval, audits, and reimbursement. Additionally, many prosthetic digits and thumbs vary significantly in design. For example, some articulate at MCP only, others at MCP + PIP, or even with locking DIP joints.

Final Medicare Benefit Category Determination

Prosthesis (Artificial Arm).

Final Medicare Payment Determination

No determination.

While we understand the concerns expressed during the public meeting regarding the creation of HCPCS Level II codes without national fee schedule amounts, CMS cannot make a final Medicare payment determination without first proposing a preliminary payment determination and publishing this decision prior to a public meeting in accordance with 42 CFR 414.240(b). It is our intention that the payment determination for these items will be addressed during the Second Biannual 2025 HCPCS Level II coding cycle.

In the meantime, 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 and program instructions at section 60.3 of chapter 23 of the Medicare Claims Processing Manual (CMS Pub. 100-04).

Pricing Indicator = 38

Point Pivot and Point Pivot+ - HCP2412317JPKJ

Topic/Issue

Request to establish four new HCPCS Level II codes to identify Point Pivot and Point Pivot+.

Applicant's suggested language:

1. LXXX7, “Addition to terminal device, thumb or digit, heavy-duty, mechanical, locking, internal/external rotation mechanism”

2. LXXX8, “Addition to terminal device, internal/external rotation mechanism, mounting bracket”

3. LXXX9, “Addition to terminal device, thumb, heavy-duty, mechanical, locking, adduction/abduction mechanism”

4. LXX10, “Addition to terminal device, thumb, adduction/abduction mechanism, mounting bracket”

Summary of Applicant's Submission

Point Designs submitted a request to establish four new HCPCS Level II codes to identify the Point Pivot and the Point Pivot+ prosthetic terminal device additions. The Point Pivot and Point Pivot+ prosthetic devices are class I devices, exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The Point Pivot is a dynamic system that enables 18 locking positions of internal/external rotation for the thumb or digit, providing an additional degree of freedom for creating stable hand grasps. It is intended for integration with custom prosthetic sockets to restore functionality for amputations slightly proximal to the metacarpophalangeal joint. The Point Pivot+ expands basic thumb functionality by adding 19 locking positions of thumb adduction/abduction and three locking positions of thumb rotation, making it ideal for amputations at or near the carpometacarpal joint of the thumb or for individuals with minimal residual motion of the thumb. Both devices are constructed with titanium for durability and are lightweight, providing significant strength and long-term use. Both devices are designed to be used with a Point Thumb or Digit such that the flexion-extension motion of the digit is enhanced to replace all the ranges of motion lost from the amputation. Both systems are mounted using a mounting kit for modular attachment and proper functional alignment. The Point Pivot and Point Pivot+ introduce ratcheting mechanisms that restore natural joint motion and alignment, enabling tasks requiring fine motor control and grip stability. They represent significant advancements in material strength, functional range, and anatomical replication, making the existing HCPCS Level II codes insufficient to address the technological distinction and clinical benefits these devices provide.

CMS Preliminary HCPCS Coding Determination

CMS recognizes the applicant’s effort to establish updated code language for partial finger prostheses, as the current coding system no longer accurately reflects the new technological advancements in the prosthetics market. The design and materials used for prosthetic digits

have evolved considerably, necessitating the creation of more specific and relevant codes to meet the needs of individuals and reflect the developments in prosthetic technology.

CMS tends to categorize partial prosthetic digits into three major types: body-powered, mechanical, and electrical prostheses. Based on the nature of the devices outlined in the applications submitted by Point Designs, these prostheses fall under the mechanical partial digits category.

In this application the applicant requested four specific codes to describe the Point Pivot and Point Pivot+ with their corresponding mounting brackets. To address various features of the devices submitted by Point Designs, such as locking mechanisms and specific joint configurations, CMS proposes to establish a generalized code that could effectively capture these design elements without over-complicating the HCPCS Level II code set. The attachment bracket and any other mounting mechanisms do not need separate or individual codes; they can all be encompassed within a single code to describe the necessary attachment and support features for these partial digit prostheses. This generalized code would be capable of accommodating all the different articulation and attachment mechanisms of the mechanical partial digits. As such, CMS is proposing to:

1. Establish a new HCPCS Level II code LXXX3, "Addition to digit or thumb, per articulation, attachment, multiaxial and/or internal/external rotation/abduction/adduction mechanism, with or without locking feature, any material" to describe Point Pivot and Point Pivot+.

CMS believes for products like Point Pivot and Point Pivot+, which incorporate rotational units, the proposed HCPCS Level II code LXXX3 could be defined as a code for devices that enable digit or thumb rotation in multiple positions. This proposed HCPCS Level II code LXXX3 would encompass the features of internal and external rotation, as well as abduction and adduction functions, which are present across various models. Establishing one code for all rotational and articulation functions would streamline the process and eliminate the need for multiple codes to describe similar mechanisms.

The applicant's suggested code language implies that all devices described as "heavy-duty" are universally required, but CMS does not agree with this blanket assumption. Given the rapid development of prosthetic technology, CMS believes that devices previously considered "heavy-duty" as described in the applicant's suggested code language are no longer as relevant or necessary as they once were. While these devices may have been designed for durability in the past, advancements in materials and mechanics have allowed for lighter, more advanced prostheses that still effectively meet an individual's needs.

Instead of establishing separate codes specifically for attachments, CMS believes it would be more efficient to incorporate the additional attachments or brackets directly into the language of a single base code. This approach streamlines the coding process by consolidating the relevant components under a single, more comprehensive code, ensuring that all necessary elements are captured without the need for multiple distinct codes. As an example, the coding structure for lower limb prostheses using the existing HCPCS Level II code L5701, "Replacement, socket, above knee/knee disarticulation, including attachment plate, molded to patient model" could serve as a guide to create a similar coding structure for partial digit prostheses, including the necessary attachment mechanisms to connect partial digits to the overall hand prosthesis.

By implementing a more generalized coding system, CMS aims to create a more efficient and practical approach to classifying partial digit and thumb prostheses, considering the evolving technology in the field and ensuring that codes remain relevant as new devices are introduced to the market.

Preliminary Medicare Benefit Category Determination

Prosthesis (Artificial Arm).

Preliminary Medicare Payment Determination

No determination.

CMS is collectively reviewing the HCPCS Level II codes established in the Second Biannual 2024 HCPCS Level II coding cycle along with the HCPCS Level II codes proposed under this HCPCS Level II coding cycle and plans to make a payment determination once all of the codes have been finalized. As such, the payment determination for this item will be addressed at a subsequent HCPCS Level II public meeting.

As an alternative, we are seeking input on whether to: 1) finalize the coding determination for this item under this coding cycle (the First Biannual 2025 HCPCS public meeting cycle) but defer the effective date of the code until April 1, 2026, to align with a potential payment determination, or 2) defer a final coding determination on this item and finalize along with the payment determinations in a subsequent HCPCS Level II public meeting cycle.

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 and program instructions at section 60.3 of chapter 23 of the Medicare Claims Processing Manual (CMS Pub. 100-04).

Pricing Indicator = 38

Summary of Public Feedback

Point Designs and other commenters generally agree with CMS' published preliminary determinations with some requested revisions for more specificity and clarification. A commenter stated that the preliminary codes adequately describe the applicable prosthetics while creating a competitive environment that benefits a broad spectrum of patients. However, others commented that CMS' preliminary coding descriptors were too generic, lacked sufficient granularity to distinguish between the different prosthetic partial hand and finger prostheses, and therefore did not reflect contemporary clinical practice. Those commenters requested CMS to revise its preliminary coding determination to include more descriptive and specific language that would also remain broad enough to represent the mechanical finger systems currently commercially available to restore a similar level of function to an individual. The commenters further suggested that any products, besides the predicate products, undergo the Medicare Pricing, Data Analysis and Coding (PDAC) code verification process to ensure that all devices meet the code definitions.

Point Designs, the applicant, agreed with CMS' opinion that prosthetic digits fall into three major types: body-powered, mechanical, and electrical prostheses, and that the devices outlined in this application are correctly categorized as mechanical. Because other manufacturers produce mechanical prosthetic fingers, the applicant fully supported CMS' approach to establish a set of codes that could include current and future mechanical prosthetic finger options that are heavy duty, locking, and have a motion-assist feature. The applicant noted that while their requested codes did not represent any single product or company, they also did not accommodate all available prosthetic digits. They also acknowledged they were unable to comment on or speculate about the engineering, functions, features, or pricing of other stakeholders' products beyond what is publicly available.

To describe Point Pivot and Point Pivot+, the applicant suggested the following revised HCPCS Level II code language:

1. LXXX4, "Upper extremity addition, single-axis additional degree of freedom, heavy-duty, locking, any material, for mechanical digit or thumb, per digit" to describe Point Pivot.

2. LXXX5, "Upper extremity addition, multi-axial additional degrees of freedom, heavy-duty, locking, any material, for mechanical digit or thumb, per digit" to describe Point Digit+.

The commenters emphasized that these revised codes would describe an extra component that adds range of motion and grasping function and can be used in conjunction with a prosthetic finger or thumb, similar to adding a locking quick disconnect rotation unit to a prosthetic wrist. Separate codes are suggested because Point Digit+ offers additional motion in different planes and therefore has more complex engineering, function, and costs.

The commenters suggested to add the phrase "terminal device" as the industry standard terminology to describe a prosthetic device attached externally to a prosthetic socket at the end of an arm or leg.

Next, the commenters suggested to remove the phrase "per articulation" to prevent confusion as to whether the code should be applied multiple times for a device with multiple joints, and to instead simply indicate the number of joints.

Commenters suggested to remove the phrase "with or without locking feature" and instead only specify "locking" to ensure that devices described by the codes would include a locking mechanism that is critical for individuals to perform most daily activities. Devices with locking mechanisms require more engineering time to develop and involve more components, which is important when evaluating equivalent devices to determine code reimbursement.

Additionally, the commenters suggested to add the phrase "heavy-duty" to ensure that devices represented by this code meet the requirements for DME and can be used by patients every day, all day. The commenters emphasized that "heavy-duty" is a result of material choice, engineering design, robust testing, and high-quality manufacturing and assembly; and they agree with CMS that including the phrase "any material" is appropriate language in the code as devices can be considered heavy-duty with other materials besides titanium or stainless steel. The commenters also noted that there is currently no recognized standards for evaluating prosthetic hands or fingers to determine if something is heavy-duty and therefore

recommend mandatory PDAC code verification for these new codes to ensure that only high-quality devices will be represented by these codes. The commenter also suggested that other insurers use criteria loosely based on the International Standards for External limb prostheses and external orthoses - Requirements and test methods[7] including certain weight bearing thresholds.

Finally, the commenters suggested to remove the phrase "attachment" to allow for the creation of a separate code specifically to describe mounting hardware associated with mechanical digits as follows:

3. LXXX6, "Upper extremity addition, attachment hardware for mechanical digit or thumb, per digit"

The commenters stated the purpose of devices described by this separate code, LXXX6, is for aligning and mounting the prosthetic digit, thumb, or additions to the prosthesis and one mounting component is needed for each digit. The commenters explained that for most mechanical fingers, the mounting hardware is a separate consumable item that is permanently fabricated into the prosthetic socket, so if a new socket is needed for a patient, the prosthetist can reuse the terminal devices but must order new mounting hardware. The commenters emphasized that a separate code is needed to identify this expense, and that they do not recommend including the mounting hardware into the other codes.

In its published preliminary Medicare payment determination, CMS sought input on whether to finalize the HCPCS coding determinations under this HCPCS Level II public meeting cycle but defer the effective date of the codes until April 1, 2026, to align with a potential payment determination, or finalize the coding determinations along with the payment determinations in a subsequent HCPCS Level II public meeting cycle. Most commenters suggested that the coding determinations be finalized as normal under this current coding cycle with an effective date of October 1, 2025, instead of delaying the codes to align with a delayed payment determination. The commenters further suggested that the Medicare payment determinations should be finalized in the next coding cycle with an effective date of April 1, 2026, and established independently of the timeline for any other partial hand prosthetic code changes.

Point Designs requested that CMS establish pricing of the codes through the gap-filling process, supported by explanations of benefits (EOBs) submitted. The sample EOBs represented the entire prosthesis including estimated payment for the digit based on the manufacturer's suggested retail price (MSRP), estimated payment for the mounting hardware based on MSRP, and the residual amount that would be estimated for the socket design/fabrication and clinical care. The applicant used a gap filling calculator created with CMS guidelines to ultimately recommend gap filled fees for each requested code.

CMS Final HCPCS Coding Determination

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

[7] International Organization for Standardization (2006) "International Standards for External limb prostheses and external orthoses - Requirements and test methods" (ISO 22523:2006). Retrieved from https://www.iso.org/standard/37546.html

of the comments we received, CMS is revising its preliminary coding determination and finalizing the decision to:

Establish a new HCPCS Level II code L6038, "Addition to single prosthetic digit or thumb, mechanical, attachment, multiaxial and/or internal/external rotation/abduction/adduction mechanism, with or without locking feature, any material" to describe Point Pivot and Point Pivot+.

This code language is more specific in order to help differentiate amputated and sound digits. We did not include the term "terminal device" as suggested by the commenters, as that term has historically been used to describe hooks, body-powered hands, externally powered (myoelectric) hands, and cosmetic/restorative hands. To maintain consistency with previous coding terminology, CMS used the term "prosthetic digit" and "prosthetic thumb" to describe components attached to the partial hand and finger interface.

CMS agrees with the speaker that titanium constructions will make partial hand and digit prostheses durable enough to meet the requirements for heavy-duty activities. However, CMS disagrees that a new code is necessary to describe this. The existing code L6032, "Addition to upper extremity prosthesis, partial hand including fingers, ultralight material (titanium, carbon fiber or equal)," established in the second biannual 2024 HCPCS Level II coding cycle, adequately describes the heavy-duty features and materials needed for such activities. Therefore, creating a new code would be redundant.

Historical examples of the use of "heavy duty" in the HCPCS Level II code set for lower limb prostheses, such as L5994, "Addition to lower extremity prosthesis, heavy duty feature, knee only, for patient weight greater than 300 lbs" and L5995, "Addition to lower extremity prosthesis, heavy duty feature, other than foot or knee, for patient weight greater than 300 lbs" were intended to withstand loads for beneficiaries weighing over 300 lbs. Also, upper limb prosthesis codes, such as L6639, "Upper extremity addition, heavy duty feature, any elbow," describe prosthetic elbows constructed of high-strength materials (e.g., stainless steel) to withstand lifting of large objects. The statements above show that the heavy-duty designation should be reserved for codes where durability and strength are clinically relevant, rather than applied broadly to all partial hand or digit prostheses. The general partial hand and finger prosthetic codes do not need to include heavy-duty language, as most do not require these enhanced specifications.

CMS agrees with the commenters that locking features increase usability. However, CMS disagrees to exclude the "non-locking" term in the language. The applicant, Point Design Company, primarily produces non-body-powered partial hand and digit prostheses that might only require locking mechanisms. However, body-powered partial hand and prostheses, which are also mechanical but not passive, do not necessarily have locking mechanisms. The current verbiage of HCPCS Level II code L6038 should encompass all current products in the industry that share the same structure and mechanism, not only for a specific manufacturer but aim to describe those that share the same primary features.

CMS agrees with the commenters to add extension and flexion assist in the proposed language, as it would assist beneficiaries in rapidly prepositioning prostheses that secure objects while still performing tasks with their intact hands.

CMS has determined that specifying articulating joints in the code description will be more appropriate than the number of articulating joints. Specifying joints helps align the description with clinical documentation and prosthetic features, which is important for approval, audits, and reimbursement. Additionally, many prosthetic digits and thumbs vary significantly in design. For example, some articulate at MCP only, others at MCP + PIP, or even with locking DIP joints.

There will be no reason to separate the codes that show single or multi-axial additional degrees of freedom. CMS generally takes the position that coding distinctions should reflect meaningful clinical or functional differences, not just technical design variations. In the case of single axis versus multi-axial joints or differences in degrees of freedom within upper limb prosthetic digits or thumbs, CMS does not view these mechanical variations as sufficient grounds to warrant separate HCPCS Level II codes. CMS does not consider the number of axis alone to significantly alter the functional capacity of the prosthesis in a way that warrants a separate code.

Lastly, the proposed code by the speaker, LXXX6, to describe the attachment hardware is unnecessary to describe only the mounting hardware associated with mechanical digits. HCPCS Level II code L6038 includes the components that add range of motion and grasping function to the prosthetic digits or thumb while describing the components that align and mount the prosthetic digit, thumb, or additions to the prosthesis. CMS understands that if a prosthetic digit/thumb is used in conjunction with an addition, there is no need for a mounting bracket for each, and the code descriptor of L6038 with the use of "and/or" would give this option to the supplier to bill for any of the features if used. Also, the language by using "single" would address the applicant's concern as one mounting component is needed per digit.

Final Medicare Benefit Category Determination

Prosthesis (Artificial Arm).

Final Medicare Payment Determination

No determination.

While we understand the concerns expressed during the public meeting regarding the creation of HCPCS Level II codes without national fee schedule amounts, CMS cannot make a final Medicare payment determination without first proposing a preliminary payment determination and publishing this decision prior to a public meeting in accordance with 42 CFR 414.240(b). It is our intention that the payment determination for these items will be addressed during the Second Biannual 2025 HCPCS Level II coding cycle.

In the meantime, 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 and program instructions at section 60.3 of chapter 23 of the Medicare Claims Processing Manual (CMS Pub. 100-04).

Pricing Indicator = 38

Point Endo - HCP241231KBG09

Topic/Issue

Request to establish two new HCPCS Level II codes to identify Point Endo prosthetic terminal devices and their associated mounting brackets.

Applicant's suggested language:

1. LXX11, "Terminal device, digit, mechanical, endoskeletal, locking, articulating MCP and PIP joints, remote anatomical MCP center of motion, automatic extension, excluding covering/glove, per each, initial issue or replacement"

2. LXX12: "Addition to terminal device, digit, endoskeletal, mounting bracket"

Summary of Applicant's Submission

Point Designs submitted a request to establish two new HCPCS Level II codes to identify the Point Endo prosthetic terminal devices and their associated mounting brackets. The Point Endo is a class I device, exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The Point Endo is an endoskeletal, mechanical finger prosthetic terminal device designed for individuals with partial hand amputations. These devices feature a ratcheting mechanism with up to 9 distinct locking positions. Made of titanium for strength, they allow for one-handed operation and maintain anatomical metacarpophalangeal (MCP) and proximal interphalangeal (PIP) joint alignment for functional and anatomical accuracy. The mounting bracket is used to appropriately align and attach the Point Endo to the partial hand socket in a functional manner. These prosthetic devices restore hand function by replicating the anatomical motions of the MCP and PIP joints. Their unique ratcheting mechanism provides fixed locking positions, enabling stable grasps and high-load activity functionality. It also has a fused distal interphalangeal joint, as it is meant to be integrated with a silicone (or similar) cover or glove. Unlike existing prosthetic devices, they integrate a curved knuckle track, ensuring alignment with anatomical joint centers for enhanced performance alongside intact digits. The Point Endo prosthetics represent significant advancements in material strength, functional range, and anatomical replication, making the existing HCPCS Level II codes insufficient to address the technological distinction and clinical benefits these devices provide.

CMS Preliminary HCPCS Coding Determination

CMS recognizes the ongoing effort of Point Designs to establish updated code language for partial finger prostheses, as the current coding system no longer accurately reflects the new technological advancements in the prosthetics market. The design and materials used for prosthetic digits have evolved considerably, necessitating the creation of more specific and relevant codes to meet the needs of individuals and reflect the developments in prosthetic technology.

CMS tends to categorize partial prosthetic digits into three major types: body-powered, mechanical, and electrical prostheses. Based on the nature of the devices outlined in the applications submitted by Point Designs, these prostheses fall under the mechanical partial digits category.

This application requested two specific codes to describe the Point Endo device with its corresponding mounting bracket. To address various features of the devices submitted by Point Designs, such as locking mechanisms and specific joint configurations, CMS proposes to establish a generalized code that could effectively capture these design elements without over-complicating the HCPCS Level II code set. The attachment bracket and any other mounting mechanisms do not need separate or individual codes; they can all be encompassed within a single code to describe the necessary attachment and support features for these partial digit prostheses. This generalized code would be capable of accommodating all the different articulation and attachment mechanisms of the mechanical partial digits. As such, CMS is proposing to:

1. Establish a new HCPCS Level II code LXXX1, "Single digit, per articulation, mechanical, metacarpophalangeal (mcp), proximal interphalangeal (pip), and/or distal interphalangeal (dip) joint(s), with or without locking mechanism, any material, attachment, initial issue or replacement" to describe Point Endo.

CMS believes that the proposed HCPCS Level II code LXXX1 will accurately represent the devices described under the applicant's two requested codes. The proposed HCPCS Level II code LXXX1 is designed to encompass the various joints and articulations, providing flexibility in its application across different digit prosthetic types. Specifically, the proposed HCPCS Level II code LXXX1 will apply to single-digit prosthetics with mechanical articulation at the MCP, PIP, and/or distal interphalangeal (DIP) joints, irrespective of the material used or the type of attachment (such as single-axial vs. multi-axial systems). It will also accommodate different task-performing mechanisms, including both locking and non-locking options.

Instead of establishing separate codes specifically for attachments, CMS believes it would be more efficient to incorporate the additional attachments or brackets directly into the language of a single base code. This approach streamlines the coding process by consolidating the relevant components under a single, more comprehensive code, ensuring that all necessary elements are captured without the need for multiple distinct codes. As an example, the coding structure for lower limb prostheses using the existing HCPCS Level II code L5701, "Replacement, socket, above knee/knee disarticulation, including attachment plate, molded to patient model" could serve as a guide to create a similar coding structure for partial digit prostheses, including the necessary attachment mechanisms to connect partial digits to the overall hand prosthesis.

By implementing a more generalized coding system, CMS aims to create a more efficient and practical approach to classifying partial digit and thumb prostheses, considering the evolving technology in the field and ensuring that codes remain relevant as new devices are introduced to the market.

Preliminary Medicare Benefit Category Determination

Prosthesis (Artificial Arm).

Preliminary Medicare Payment Determination

No determination.

CMS is collectively reviewing the HCPCS Level II codes established in the Second Biannual 2024 HCPCS Level II coding cycle along with the HCPCS Level II codes proposed under this HCPCS Level II coding cycle and plans to make a payment determination once all of the codes have been finalized. As such, the payment determination for this item will be addressed at a subsequent HCPCS Level II public meeting.

As an alternative, we are seeking input on whether to: 1) finalize the coding determination for this item under this coding cycle (the First Biannual 2025 HCPCS public meeting cycle) but defer the effective date of the code until April 1, 2026, to align with a potential payment determination, or 2) defer a final coding determination on this item and finalize along with the payment determinations in a subsequent HCPCS Level II public meeting cycle.

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 and program instructions at section 60.3 of chapter 23 of the Medicare Claims Processing Manual (CMS Pub. 100-04).

Pricing Indicator = 38

Summary of Public Feedback

Point Designs and other commenters generally agree with CMS' published preliminary determinations with some requested revisions for more specificity and clarification. A commenter stated that the preliminary codes adequately describe the applicable prosthetics while creating a competitive environment that benefits a broad spectrum of patients. However, others commented that CMS' preliminary coding descriptors were too generic, lacked sufficient granularity to distinguish between the different prosthetic partial hand and finger prostheses, and therefore did not reflect contemporary clinical practice. Those commenters requested CMS to revise its preliminary coding determination to include more descriptive and specific language that would also remain broad enough to represent the mechanical finger systems currently commercially available to restore a similar level of function to an individual. The commenters further suggested that any products, besides the predicate products, undergo the Medicare Pricing, Data Analysis and Coding (PDAC) code verification process to ensure that all devices meet the code definitions.

Point Designs, the applicant, agreed with CMS' opinion that prosthetic digits fall into three major types: body-powered, mechanical, and electrical prostheses, and that the devices outlined in this application are correctly categorized as mechanical. Because other manufacturers produce mechanical prosthetic fingers, the applicant fully supported CMS' approach to establish a set of codes that could include current and future mechanical prosthetic finger options that are heavy duty, locking, and have a motion-assist feature. The applicant noted that while their requested codes did not represent any single product or company, they also did not accommodate all available prosthetic digits. They also acknowledged they were unable to comment on or speculate about the engineering, functions, features, or pricing of other stakeholders' products beyond what is publicly available.

To describe Point Endo, the applicant suggested the following revised HCPCS Level II code language:

1. LXXX1, “Single digit terminal device, heavy-duty, mechanical, 3 articulating joints, locking mechanism, flexion or extension assist, any material, initial issue or replacement”

The commenters suggested to add the phrase “terminal device” as the industry standard terminology to describe a prosthetic device attached externally to a prosthetic socket at the end of an arm or leg.

Next, the commenters suggested to remove the phrase “per articulation” to prevent confusion as to whether the code should be applied multiple times for a device with multiple joints, and to instead simply indicate the number of joints.

The commenters also suggested to remove the phrase “metacarpophalangeal (mcp), proximal interphalangeal (pip), and/or distal interphalangeal (dip)” to reduce the anatomical specificity and create a broader code that still recognizes the engineering complexity of devices with more joints and the different therapeutic benefits offered by devices with a certain number of joints by adding the phrase “3 articulating joints”. The commenter explained that a prosthetic finger with fewer components requires significantly less engineering effort and has a much lower cost of goods; Thus, separate codes are needed for three jointed fingers and two jointed fingers to ensure more accurate billing and reimbursement calculations.

Commenters suggested to remove the phrase “with or without locking mechanism” and instead only specify “locking mechanism” to ensure that devices described by the codes would include a locking mechanism that is critical for individuals to perform most daily activities. Devices with locking mechanisms require more engineering time to develop and involve more components, which is important when evaluating equivalent devices to determine code reimbursement.

The commenters suggested to add the phrase “flexion or extension assist” to describe a specific feature that helps the device meet the user needs without requiring the intact hand to manipulate the prosthetic finger into position. Devices with this feature include more components that increase the device complexity and cost.

Additionally, the commenters suggested to add the phrase “heavy-duty” to ensure that devices represented by this code meet the requirements for DME and can be used by patients every day, all day. The commenters emphasized that “heavy-duty” is a result of material choice, engineering design, robust testing, and high-quality manufacturing and assembly; and they agree with CMS that including the phrase “any material” is appropriate language in the code as devices can be considered heavy-duty with other materials besides titanium or stainless steel. The commenters also noted that there is currently no recognized standards for evaluating prosthetic hands or fingers to determine if something is heavy-duty and therefore recommend mandatory PDAC code verification for these new codes to ensure that only high-quality devices will be represented by these codes. The commenter also suggested that other insurers use criteria loosely based on the International Standards for External limb prostheses and external orthoses - Requirements and test methods[8] including certain weight bearing thresholds.

[8] International Organization for Standardization (2006) “International Standards for External limb prostheses and external orthoses - Requirements and test methods” (ISO 22523:2006). Retrieved from https://www.iso.org/standard/37546.html

Finally, the commenters suggested to remove the phrase “attachment” to allow for the creation of a separate code specifically to describe mounting hardware associated with mechanical digits as follows:

2. LXXX6, “Upper extremity addition, attachment hardware for mechanical digit or thumb, per digit”

The commenters stated the purpose of devices described by this separate code, LXXX6, is for aligning and mounting the prosthetic digit, thumb, or additions to the prosthesis and one mounting component is needed for each digit. The commenters explained that for most mechanical fingers, the mounting hardware is a separate consumable item that is permanently fabricated into the prosthetic socket, so if a new socket is needed for a patient, the prosthetist can reuse the terminal devices but must order new mounting hardware. The commenters emphasized that a separate code is needed to identify this expense, and that they do not recommend including the mounting hardware into the other codes.

In its published preliminary Medicare payment determination, CMS sought input on whether to finalize the HCPCS coding determinations under this HCPCS Level II public meeting cycle but defer the effective date of the codes until April 1, 2026, to align with a potential payment determination, or finalize the coding determinations along with the payment determinations in a subsequent HCPCS Level II public meeting cycle. Most commenters suggested that the coding determinations be finalized as normal under this current coding cycle with an effective date of October 1, 2025, instead of delaying the codes to align with a delayed payment determination. The commenters further suggested that the Medicare payment determinations should be finalized in the next coding cycle with an effective date of April 1, 2026, and established independently of the timeline for any other partial hand prosthetic code changes.

Point Designs requested that CMS establish pricing of the codes through the gap-filling process, supported by explanations of benefits (EOBs) submitted. The sample EOBs represented the entire prosthesis including estimated payment for the digit based on the manufacturer’s suggested retail price (MSRP), estimated payment for the mounting hardware based on MSRP, and the residual amount that would be estimated for the socket design/fabrication and clinical care. The applicant used a gap filling calculator created with CMS guidelines to ultimately recommend gap filled fees for each requested code.

CMS Final HCPCS Coding Determination

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

Establish a new HCPCS Level II code L6035, “Single prosthetic digit, mechanical, can include metacarpophalangeal (mcp), proximal interphalangeal (pip), and/or distal interphalangeal (dip) joint(s), with or without locking mechanism, can include flexion or extension assist, any material, attachment, initial issue or replacement” to describe Point Endo.

This code language is more specific in order to help differentiate amputated and sound digits. We did not include the term "terminal device" as suggested by the commenters, as that term has historically been used to describe hooks, body-powered hands, externally powered (myoelectric) hands, and cosmetic/restorative hands. To maintain consistency with previous coding terminology, CMS used the term "prosthetic digit" and "prosthetic thumb" to describe components attached to the partial hand and finger interface.

CMS agrees with the speaker that titanium constructions will make partial hand and digit prostheses durable enough to meet the requirements for heavy-duty activities. However, CMS disagrees that a new code is necessary to describe this. The existing code L6032, "Addition to upper extremity prosthesis, partial hand including fingers, ultralight material (titanium, carbon fiber or equal)," established in the second biannual 2024 HCPCS Level II coding cycle, adequately describes the heavy-duty features and materials needed for such activities. Therefore, creating a new code would be redundant.

Historical examples of the use of "heavy duty" in the HCPCS Level II code set for lower limb prostheses, such as L5994, "Addition to lower extremity prosthesis, heavy duty feature, knee only, for patient weight greater than 300 lbs" and L5995, "Addition to lower extremity prosthesis, heavy duty feature, other than foot or knee, for patient weight greater than 300 lbs" were intended to withstand loads for individuals weighing over 300 pounds. Also, upper limb prosthesis codes, such as L6639, "Upper extremity addition, heavy duty feature, any elbow," describe prosthetic elbows constructed of high-strength materials (e.g., stainless steel) to withstand lifting of large objects. The statements above show that the heavy-duty designation should be reserved for codes where durability and strength are clinically relevant, rather than applied broadly to all partial hand or digit prostheses. The general partial hand and finger prosthetic codes do not need to include heavy-duty language, as most do not require these enhanced specifications.

CMS agrees with the commenters that locking features increase usability. However, CMS disagrees to exclude the "non-locking" term in the language. The applicant, Point Design Company, primarily produces non-body-powered partial hand and digit prostheses that might only require locking mechanisms. However, body-powered partial hand and prostheses, which are also mechanical but not passive, do not necessarily have locking mechanisms. The current verbiage of HCPCS Level II code L6035 should encompass all current products in the industry that share the same structure and mechanism, not only for a specific manufacturer but aim to describe those that share the same primary features.

CMS agrees with the commenters to add extension and flexion assist in the proposed language, as it would assist beneficiaries in rapidly prepositioning prostheses that secure objects while still performing tasks with their intact hands.

CMS has determined that specifying articulating joints in the code description will be more appropriate than the number of articulating joints. Specifying joints helps align the description with clinical documentation and prosthetic features, which is important for approval, audits, and reimbursement. Additionally, many prosthetic digits and thumbs vary significantly in design. For example, some articulate at MCP only, others at MCP + PIP, or even with locking DIP joints.

Final Medicare Benefit Category Determination

Prosthesis (Artificial Arm).

Final Medicare Payment Determination

No determination.

While we understand the concerns expressed during the public meeting regarding the creation of HCPCS Level II codes without national fee schedule amounts, CMS cannot make a final Medicare payment determination without first proposing a preliminary payment determination and publishing this decision prior to a public meeting in accordance with 42 CFR 414.240(b). It is our intention that the payment determination for these items will be addressed during the Second Biannual 2025 HCPCS Level II coding cycle.

In the meantime, 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 and program instructions at section 60.3 of chapter 23 of the Medicare Claims Processing Manual (CMS Pub. 100-04).

Pricing Indicator = 38

Various Partial Hand and/or Finger Prosthetic Socket Base Codes - HCP24123181XV9

Topic/Issue

Request to discontinue the following three existing HCPCS Level II codes, and establish two new HCPCS Level II codes to identify various partial hand and/or finger prosthetic sockets:

1. L6000, “Partial hand, thumb remaining”
2. L6010, “Partial hand, little and/or ring finger remaining”
3. L6020, “Partial hand, no finger remaining”

Applicant's suggested language:

1. LXXX1, “Partial hand and finger molded socket, anatomical suspension (excludes terminal devices and prosthetic socket additions)”
2. LXXX2, “Partial finger, molded socket, with or without flexible interface (excludes terminal devices and prosthetic socket additions) independent, per digit”

Summary of Applicant's Submission

The Upper Limb Prosthetics Society of the American Academy of Orthotists and Prosthetists submitted a request to delete three existing HCPCS Level II codes L6000, L6010, and L6020, and establish two new HCPCS Level II codes to identify various partial hand and/or finger prosthetic sockets that better reflect more contemporary clinical designs and practices. The existing HCPCS Level II codes, L6000, L6010, and L6020, lack specificity and fail to describe the complexity of contemporary prosthetic sockets and are based on a predicate product that has not been commercially available for more than 20 years. These codes were originally created for simple, off-the-shelf devices such as the Robin-Aids Handi-Hook, which no longer align with the state of the art in prosthetic technology. The requested two new HCPCS Level II codes would describe two types of prosthetic sockets: (1) the full partial hand prosthetic socket, which encompasses a significant portion of the residual hand and integrates multiple prosthetic digits or terminal devices; and (2) the partial finger prosthetic socket, which is a smaller, localized device designed for individual digits. The full partial hand prosthetic socket provides suspension and stability for prosthetic components to enable functional tasks such as grasping and pinching. The partial finger prosthetic socket focuses on localized restoration, offering functional restoration for specific digits in a device that can be used independent of others. These new HCPCS Level II codes would represent distinct systems that could be used simultaneously. The existing HCPCS Level II codes do not adequately describe these items as the descriptors do not account for advancements in prosthetic technology, materials, and fabrication methods to match current clinical care. Modern partial hand prostheses integrate anatomical suspension systems with materials like silicone, carbon fiber, and plastic utilize both traditional and additive manufacturing techniques, and employ modular designs, all of which require precise customization. These features are absent from the descriptions of HCPCS Level II codes L6000, L6010, and L6020, resulting in inequities in reimbursement, underfunded care, and barriers to access.

CMS Preliminary HCPCS Coding Determination

Given the advancements in technology, CMS believes it is essential to update existing HCPCS Level II codes L6000, L6010, and L6020 to more accurately reflect current prosthetic devices. By introducing more detailed descriptors, CMS aims to ensure that the HCPCS Level II code set is able to properly identify the various available products that incorporate features like flexible or non-flexible interfaces, molded patient-specific designs, and uses with or without external power. As such, CMS is proposing to:

1. Revise existing 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" to instead read "Partial hand with or without digit(s), any amputation level, flexible or non-flexible interface, molded to patient model, for use without external power, not including inserts described by l6692"

   Effective October 1, 2025

2. Discontinue existing HCPCS Level II code L6000, "Partial hand, thumb remaining"

   Effective September 30, 2025

3. Discontinue existing HCPCS Level II code L6010, "Partial hand, little and/or ring finger remaining"

   Effective September 30, 2025

4. Discontinue existing HCPCS Level II code L6020, "Partial hand, no finger remaining"

   Effective September 30, 2025

As discussed in the HCPCS Level II Final Coding, Benefit Category and Payment Determinations for the Second Biannual, 2024 HCPCS Coding Cycle, CMS believes that HCPCS Level II code L6028 should continue to include the code for the interface used with partial hands, including digits. The current designs for partial digits involve an interface that extends over the palm section of the prosthesis. That said, the design for the partial hand can be adapted to accommodate the loss of digits, regardless of the level of amputation, whether it is at the metacarpal, proximal phalanx, or distal phalanx level. The interface created over the palm can be extended to accommodate any missing digits. Therefore, CMS proposes that the language for HCPCS Level II code L6028 be revised to specify the amputation levels, proximal or distal to the carpometacarpal joints, and to cover any custom-made interface, whether intended for articulated or passive partial digits.

Preliminary Medicare Benefit Category Determination

Prosthesis (Artificial Arm).

Preliminary Medicare Payment Determination

No determination.

CMS is collectively reviewing the HCPCS Level II codes established in the Second Biannual 2024 HCPCS Level II coding cycle along with the HCPCS Level II codes proposed under this HCPCS Level II coding cycle and plans to make a payment determination once all of the codes have been finalized. As such, the payment determination for this item will be addressed at a subsequent HCPCS Level II public meeting.

As an alternative, we are seeking input on whether to: 1) finalize the coding determination for this item under this coding cycle (the First Biannual 2025 HCPCS public meeting cycle) but defer the effective date of the code until April 1, 2026, to align with a potential payment determination, or 2) defer a final coding determination on this item and finalize along with the payment determinations in a subsequent HCPCS Level II public meeting cycle.

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 and program instructions at section 60.3 of chapter 23 of the Medicare Claims Processing Manual (CMS Pub. 100-04).

Pricing Indicator = 38

Summary of Public Feedback

The Upper Limb Prosthetics Society of the American Academy of Orthotists and Prosthetists and other commenters generally agree with CMS' published preliminary determinations with some requested reconsiderations. Commenters agreed with CMS' preliminary coding determination to discontinue HCPCS Level II codes L6000, L6010, and L6020. In addition, the commenters agreed with CMS' preliminary coding determination to finalize L6028 with the revised language using the term "digit(s)" and generalizing the insert exclusion to ensure consistency and prevent confusion across providers and payers. The commenters reiterated their request for CMS to establish a new HCPCS Level II code LXXX2, "Partial finger, molded socket, with or without flexible interface (excludes terminal devices and prosthetic socket additions) independent, per digit." Finally, the commenters emphasized the need for a Medicare payment determination to be finalized for L6028 and the other recently established HCPCS Level II codes because providers are still assuming the same financial risk when billing the new codes as when billing with miscellaneous codes.

In its published preliminary Medicare payment determination, CMS sought input on whether to finalize the HCPCS Level II coding determinations under this HCPCS Level II public meeting cycle but defer the effective date of the codes until April 1, 2026, to align with a potential payment determination, or finalize the coding determinations along with the payment determinations in a subsequent HCPCS Level II public meeting cycle. Most commenters suggested that the coding determinations be finalized as normal under this current coding cycle with an effective date of October 1, 2025, instead of delaying the codes to align with a delayed payment determination. The commenters further suggested that the Medicare payment determinations should be finalized in the next coding cycle with an effective date of April 1, 2026, and established independently of the timeline for any other partial hand prosthetic code changes.

CMS Final HCPCS Coding Determination

We appreciate the comments provided in response to CMS' published preliminary determinations. We understand the potential confusion presented by the creation of new HCPCS Level II codes without a payment determination. Therefore, based on the information provided in the application and after consideration of the comments we received, CMS is revising its preliminary coding determination and finalizing the decision to:

1. Maintain existing HCPCS Level II codes L6000, "Partial hand, thumb remaining," L6010, "Partial hand, little and/or ring finger remaining," and L6020, "Partial hand, no finger remaining." We intend to discontinue these three codes once HCPCS Level II code L6028 has been established as the new HCPCS Level II code for partial hands, which we intend to do as part of the second biannual HCPCS Level II non-drug and non-biological products coding cycle of 2025.

2. Revise existing 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" to instead read "Partial hand, finger, and thumb prosthesis without prosthetic digit(s)/thumb, amputation at metacarpal level, including flexible or non-flexible interface, molded to patient model, including palm, for use without external power and/or passive prosthetic digit/thumb, not including inserts described by l6692"

3. Make existing HCPCS Level II code L6028 invalid for Medicare use. While this code is intended to replace L6000, L6010, and L6020, we believe it is inappropriate for both new and old codes to remain valid in the code set concurrently. We intend to re-introduce L6028 as a valid for Medicare code in the second biannual HCPCS Level II non-drug and non-biological products coding cycle of 2025, at which point HCPCS Level II codes L6000, L6010, and L6020 would be discontinued.

4. Establish a new HCPCS Level II code L6034, "Partial hand, finger, and thumb prosthesis without prosthetic digit(s)/thumb, amputation at distal to metacarpal joint, including flexible or non-flexible interface, molded to patient model, for use without external power and/ or passive prosthetic digit/thumb, not including inserts described by l6692"

As outlined in the HCPCS Level II Preliminary Coding, Benefit Category, and Payment Determinations for the First Biannual 2025 HCPCS Coding Cycle, CMS recognizes the need to update existing HCPCS Level II codes L6000, L6010, and L6020 to better reflect current prosthetic technologies. The introduction of more detailed descriptors will help ensure that the HCPCS Level II code set accurately identifies the wide range of available prosthetic devices, including those with flexible or non-flexible interfaces and patient-specific molded designs.

CMS acknowledges the need for separate base codes to address the common designs of partial finger prostheses that do not extend into the palm. As a result, CMS established a new code specifically for partial hand and digit prostheses that do not include an interface over the palm.

Based on the comments received, CMS has determined that the current range of partial hand and digit prostheses includes two distinct categories:

1. Non-body-powered partial hand and digit prostheses that include an interface extending into the palm. These are typically for amputations at the metacarpal level.

2. Body-powered partial hand and digit prostheses that do not require a palm interface, generally used for amputations distal to the metacarpal joints.

Accordingly, CMS agrees to revise the language of HCPCS Level II code L6028 to more clearly describe non-body-powered prostheses with interfaces that extend into the palm at the metacarpal level. Furthermore, the revised descriptor for L6028 will clarify that it does not apply to the interfaces used for passive partial hand or digit prostheses intended for cosmetic purposes, as these are already appropriately coded under L6900, L6905, L6910, and L6915. HCPCS Level II code L6034 is similar in function to L6028 but designed to describe prosthetic devices used for amputations distal to the metacarpal joint. HCPCS Level II code L6034 will cover body-powered prostheses that are custom-molded and provide interface without extending over the palm. This new code will explicitly exclude any prostheses that are passive or cosmetic in nature.

CMS continues to support retaining the reference to HCPCS Level II code L6992 in the code language for L6028 and L6034. HCPCS Level II code L6992 ("Upper extremity addition, silicone gel insert or equal, with or without locking mechanism, each") does not explicitly distinguish between custom-fabricated and prefabricated liners. However, based on historical application and examples of products billed under this code, it appears to encompass molded, rolled custom silicone inserts frequently used in partial hand prostheses.

Final Medicare Benefit Category Determination

Prosthesis (Artificial Arm).

Final Medicare Payment Determination

No determination. We intend to address the payment determination for HCPCS Level II code L6028 as part of the Second Biannual 2025 HCPCS Level II coding cycle. We note that as HCPCS Level II code L6028 describes items that would currently be billed under HCPCS Level II codes L6000, L6010, or L6020, we plan to propose that the payment amount for HCPCS Level II code L6028 would be established as the weighted average of these three existing codes in accordance with 42 CFR 414.236(b).

In the meantime, the payment rules and pricing associated with existing HCPCS Level II codes L6000, L6010, and L6020 apply to these items, if covered. The current average 2025 fee schedule amounts for L6000, L6010, and L6020 are $1,808.07, $2,009.94, and $1,875.15, respectively.

The average fee schedule amount is the average of the 2025 fee schedule amounts for these codes for each of the 50 states, Washington DC, Puerto Rico, and the Virgin Islands. Fee schedule amounts are updated annually.

Pricing Indicator = 38

Non-Specific Custom-Made Terminal Device, Partial Digit - HCP241231PN7NF

Topic/Issue

Request to establish a new HCPCS Level II code to identify custom made terminal devices used in partial hand and finger prostheses.

Applicant's suggested language: LXXXX, “Terminal device, partial digit, custom static post, any material”

Summary of Applicant's Submission

The Upper Limb Prosthetics Society of the American Academy of Orthotists and Prosthetists submitted a request to establish a new HCPCS Level II code to identify terminal devices used in partial hand and finger prostheses. Terminal devices used in partial hand and finger prostheses are class I devices, exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The item described is a custom-fabricated terminal device created by a certified prosthetist to restore the anatomical length and shape of an amputated digit when the remaining length of the amputated digit is too long to accommodate another off-the-shelf terminal device. It is integrated onto the socket of a custom partial hand or partial finger prosthesis. This static post is rigid and non-articulated, designed to provide a stable surface for contact with other fingers, thereby assisting in the restoration of functional grasp without requiring excessive compensatory motions. Its purpose is to enhance the user’s ability to perform daily tasks by providing opposition and stabilization, enabling improved functional outcomes. The nearest equivalent existing HCPCS Level II code to the proposed code is L6703, “Terminal device, passive hand/mitt, any material, any size.” However, this existing code describes a passive hand or mitt, provided as an off-the-shelf component. In contrast, the proposed HCPCS Level II code for a partial digit custom static post is highly specific, tailored for individual digits, and custom-fabricated to meet the unique anatomical and functional needs of each individual. The static post is manufactured using advanced materials such as silicone, carbon fiber, and plastics, and employs both traditional and additive manufacturing techniques. This fabrication process requires a high degree of precision and clinical expertise to ensure proper fit, functionality, and integration with the custom socket. It takes 11.5 hours of clinical and technical time to evaluate, design, and fabricate a partial digit custom static post. Therefore, the proposed new HCPCS Level II code should be reimbursed at a rate equivalent to 11.5 hours or 46 units of the average reimbursement for prosthetic repair HCPCS Level II code L7520 plus the cost of materials.

CMS Preliminary HCPCS Coding Determination

CMS recognizes that the current HCPCS Level II code set does not encompass custom made passive or static partial finger prosthetics. As such, CMS is proposing to:

Establish a new HCPCS Level II code LXXX4, “Passive digit or thumb, full or partial, custom made, any material, initial or replacement, per single digit or thumb”

This new HCPCS Level II code LXXX4 would be used in conjunction with the revised code from the Second Biannual, 2024 HCPCS Coding Cycle, HCPCS Level II code L6028, “Partial hand with or without digit(s) amputation any level, flexible or non-flexible interface, molded to patient model, for use without external power, not including inserts described by

l6692” to describe a custom-made passive digit or thumb. HCPCS Level II code L6028 would serve as the base code for the interface of the custom-made passive prosthetic, while the proposed HCPCS Level II code LXXX4 would identify the specific passive digit or thumb based on the amputation level.

Preliminary Medicare Benefit Category Determination

Prosthetic.

Preliminary Medicare Payment Determination

No determination.

CMS is collectively reviewing the HCPCS Level II codes established in the Second Biannual 2024 HCPCS Level II coding cycle along with the HCPCS Level II codes proposed under this HCPCS Level II coding cycle and plans to make a payment determination once all of the codes have been finalized. As such, the payment determination for this item will be addressed at a subsequent HCPCS Level II public meeting.

As an alternative, we are seeking input on whether to: 1) finalize the coding determination for this item under this coding cycle (the First Biannual 2025 HCPCS public meeting cycle) but defer the effective date of the code until April 1, 2026, to align with a potential payment determination, or 2) defer a final coding determination on this item and finalize along with the payment determinations in a subsequent HCPCS Level II public meeting cycle.

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 and program instructions at section 60.3 of chapter 23 of the Medicare Claims Processing Manual (CMS Pub. 100-04).

Pricing Indicator = 38

Summary of Public Feedback

The Upper Limb Prosthetics Society of the American Academy of Orthotists and Prosthetists and other commenters generally agree with CMS’ published preliminary determinations. Commenters suggest finalizing the creation of HCPCS Level II code LXXX4 for custom static posts. However, the commenters also suggested that CMS reconsider creating a separate base code for partial finger prostheses because the designs are not interchangeable with full partial hand sockets and serve a clinically distinct role.

In its published preliminary Medicare payment determination, CMS sought input on whether to finalize the HCPCS coding determinations under this HCPCS Level II public meeting cycle but defer the effective date of the codes until April 1, 2026, to align with a potential payment determination, or finalize the coding determinations along with the payment determinations in a subsequent HCPCS Level II public meeting cycle. Commenters suggested that the coding determinations be finalized as normal under this current coding cycle with an effective date of October 1, 2025, instead of delaying the codes to align with a delayed payment determination. The commenters further suggested that the Medicare payment determinations should be finalized in the next coding cycle with an effective date of April 1,

2026, and established independently of the timeline for any other partial hand prosthetic code changes.

CMS Final HCPCS Coding Determination

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

Establish a new HCPCS Level II code L6039, "Passive prosthetic digit or thumb prosthesis not including hand restoration partial hand, full or partial, custom made, any material, initial or replacement, per single passive prosthetic digit or thumb"

This change reflects CMS' intention to classify the new HCPCS Level II code L6039 describing a complete prosthesis, not just an interface. As a result, the use of this code in conjunction with HCPCS Level II code L6028, as was introduced in previous coding cycles, will no longer be necessary or appropriate.

CMS' analysis indicates that passive partial hand prostheses typically include both a custom-molded interface and one or more passive prosthetic digits or thumbs. Because these devices function as integrated prosthetic systems rather than isolated components, they require a dedicated code and descriptor, separate from those intended for active prostheses or individual parts. Creating a standalone code for passive partial hand prostheses will support more accurate classification, ensure appropriate reimbursement, and provide clearer guidance to providers, payers, and manufacturers.

However, since passive prostheses could potentially be confused with hand restoration or cosmetic prosthetic devices that are already assigned to HCPCS Level II codes L6900, L6905, L6910, and L6915, the language of the new code will be crafted to prevent such misinterpretation. Passive partial hand prostheses are designed to offer basic support or assistance with light stabilizing functions, such as holding or pushing. While they do not provide active motion (as seen in body-powered or externally powered devices), they may still assist and aid functionally with tasks like opposition or grip stabilization.

In contrast, cosmetic prostheses and hand restorations under the HCPCS Level II code L6900 code series, established in the 1990s, are solely aesthetic. These devices are intended only to replicate the natural appearance of the hand and do not provide any support, function, or utility in daily activities.

Therefore, CMS has determined that the revised language for HCPCS Level II L6039 must clearly distinguish passive prosthetic digits or thumbs from cosmetic restorations, ensuring clarity in both clinical application and billing practices.

Final Medicare Benefit Category Determination

Prosthesis (Artificial Arm).

Final Medicare Payment Determination

No determination.

It is our intention that the payment determination for these items will be addressed during the Second Biannual 2025 HCPCS Level II coding cycle.

In the meantime, 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 and program instructions at section 60.3 of chapter 23 of the Medicare Claims Processing Manual (CMS Pub. 100-04).

Pricing Indicator = 38.

Aerofit - HCP2501013V3F9

Topic/Issue

Request to establish two new HCPCS Level II codes to identify Aerofit.

Applicant's suggested language:

1. LXXX1, “Addition to lower extremity, socket vents for use with breathable silicone socket insert”

2. LXXX2, “Addition to lower extremity, breathable silicone socket insert for use with vented socket”

Summary of Applicant's Submission

Ossur submitted a request to establish two new HCPCS Level II codes to identify Aerofit. Aerofit is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). Aerofit consists of two elements: (1) a breathable silicone liner created by additive manufacturing that is clinically proven to decrease relative humidity inside a liner/socket system when combined with (2) 6-12 vents that a prosthetist fabricates into the external socket frame to ensure that moisture gets evacuated outside the socket. The breathable liner and vented socket work together to reduce relative humidity on the skin compared to a closed (non-breathable) socket-liner system.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II code L5673, “Addition to lower extremity, below knee/above knee, custom fabricated from existing mold or prefabricated, socket insert, silicone gel, elastomeric or equal, for use with locking mechanism” describes the Aerofit breathable silicone socket insert. The breathable silicone socket insert is similar in nature to other devices in HCPCS Level II code L5673.

Existing HCPCS Level II codes L5200, “Above knee, molded socket, single axis constant friction knee, shin, sach foot” or L5321, “Above knee, molded socket, open end, sach foot, endoskeletal system, single axis knee” describes the Aerofit sockets.

In addition, existing HCPCS Level II code L5701, “Replacement, socket, above knee/knee disarticulation, including attachment plate, molded to patient model” describes the replacement socket, when necessary.

The Aerofit socket is similar in nature to other devices in HCPCS Level II codes L5200, L5321 and L5701.

Preliminary Medicare Benefit Category Determination

Prosthesis (Artificial Leg).

The current Medicare policy and prior established benefit category determination for HCPCS Level II codes L5673, L5200, L5701, and L5321 apply to Aerofit.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code L5673 apply to the Aerofit breathable silicone socket insert, if covered. The current average 2025 fee schedule amount for HCPCS Level II code L5673 is $895.15. The payment rules and pricing associated with the existing HCPCS Level II codes L5200 and L5321 apply to the Aerofit socket with vents, if covered. The current average 2025 fee schedule amount for HCPCS Level II codes L5200 and L5321 are $4,445.01 and $4,483.61, respectively. The payment rules and pricing associated with the existing HCPCS Level II code L5701 apply to the Aerofit replacement socket with vents, if covered. The current average 2025 fee schedule amount for HCPCS Level II code L5701 is $4,517.25.

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

Summary of Public Feedback

Ossur and other commenters disagreed with CMS' published preliminary determinations. The speaker stated that the Aerofit liner-socket system is an integrated solution that actively evacuates moisture from the skin-liner interface through a novel breathable liner and vented socket. The speaker disagreed that Aerofit is "similar in nature to other devices" described by existing liner and socket HCPCS Level II codes by providing two reasons. First, Aerofit functions differently from items described by existing codes, using the combination of both a breathable liner with three distinct layers and a vented socket to evacuate moisture. Ossur stated that no existing liner or socket codes describe this function. Second, Aerofit offers a significant therapeutic distinction from devices described by current HCPCS Level II codes. A broad body of research documents the myriad problems sweat-trapping liners and sockets create. In contrast, few studies show that Aerofit reduces relative humidity inside the liner-socket environment. The speaker stated, that together, Aerofit's different function and established significant therapeutic distinction warrant creation of new codes describing this system. Another speaker stated that peer reviewed literature describes the system as comprised of a liner with three distinct layers that wicks moisture from the skin to the liner socket interface, and a vented socket which actively vents moisture out of the system. Published ongoing research documents that compared with conventional sockets, this system reduces relative humidity, which in turn could promote safer and more effective use of prosthetic devices

Other speakers stated that people with lower-limb amputations face serious consequences from sweat inside a prosthetic socket- including skin breakdown, rashes, painful sores, and even the prosthesis falling off due to loss of suspension. This is not just discomfort- it can result in individuals removing their prosthesis mid- day, limiting their mobility, causing them to miss work, and in some cases, abandoning prosthetic use altogether. Commonly utilized solutions such as moisture wicking liners and removing the device several times a day does not completely address this challenge, especially in warmer weather conditions. Managing moisture in the socket is a medical necessity. Devices that address this problem support skin health, mobility, consistent prosthesis use, and reduce missed workdays and healthcare utilization. The speaker urged CMS to make a favorable determination on this moisture

evacuation system to help restore independence, function, and dignity to people with lower limb amputations.

CMS Final HCPCS Coding Determination

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

1. Assign existing HCPCS Level II codes L5200, "Above knee, molded socket, single axis constant friction knee, shin, sach foot" or L5321, "Above knee, molded socket, open end, sach foot, endoskeletal system, single axis knee" to describe the Aerofit sockets.

2. Assign existing HCPCS Level II code L5701, "Replacement, socket, above knee/knee disarticulation, including attachment plate, molded to patient model" to describe the Aerofit replacement socket, when necessary.

According to commenters, Aerofit sockets incorporate a vented design to help evacuate moisture and other currently available sockets incorporate moisture management features and are made from perforated silicone materials that enhance breathability. The current HCPCS Level II codes L5200, L5321, and L5701 are not limited to sockets without moisture management features and therefore describe the Aerofit socket. In addition, some currently available liners incorporate moisture management features and are made from perforated silicone materials that enhance breathability. We consider moisture management via ventilated sockets to be a technological refinement of sockets under these codes since all users would benefit from reduced moisture.

Our findings indicate that the evidence provided by the applicant does not directly measure or demonstrate reductions in sweat or heat. Rather, the evidence implies that socket discomfort is a common issue, which may be linked to various factors not necessarily related to thermal or moisture management. The studies presented suggest that vented socket designs reduce internal moisture, indicating that systems with active airflow could have similar effects. However, other ventilated socket designs such as those used in volume management systems already exist and, when combined with breathable and perforated liners, may offer the same benefit as Aerofit in preventing moisture buildup. To strengthen the clinical argument for Aerofit, further studies are needed, specifically those that include Aerofit-specific data, long-term usage outcomes, and patient-reported feedback. At present, the lack of peer-reviewed publications, objective clinical outcomes, and comparative data significantly limits the strength of evidence, the clinical utility, and the therapeutic claims associated with Aerofit.

Existing HCPCS Level II codes (L5200, L5321, L5701 for prosthetic systems and L5673, L5679 for breathable liners) already adequately cover similar moisture-management technologies and socket modifications, including products like Silcare Breathe, SmartTemp Gel, and SoftSkin Air prosthetic liners that incorporate comparable temperature regulation and perspiration reduction features. These liners incorporate features such as perforated silicone and phase change materials, which absorb and release thermal energy to regulate temperature and reduce perspiration, offering the same intended impact and effect as the

Aerofit liners. In conclusion, Aerofit does not demonstrate a significant therapeutic advantage over existing moisture-management solutions already covered under these established codes.

The revised HCPCS Level II code L5679 will describe the breathable silicone socket insert provided by Aerofit.

To ensure the HCPCS Level II codes accurately reflect the availability of breathable and perforated liners, CMS will be updating the descriptions of existing prefabricated and custom-fabricated liners made from existing molds. As such, CMS will also

3. Revise existing HCPCS Level II code L5679, "Addition to lower extremity, below knee/above knee, custom fabricated from existing mold or prefabricated, socket insert, silicone gel, elastomeric or equal, not for use with locking mechanism" to read "Addition to lower extremity, below knee/above knee, custom fabricated from existing mold or prefabricated, socket insert, silicone gel, elastomeric, or equal, with or without perforations, with or without breathable material, not for use with locking mechanism" to describe the Aerofit breathable silicone socket insert.

4. Revise existing HCPCS Level II code L5673, "Addition to lower extremity, below knee/above knee, custom fabricated from existing mold or prefabricated, socket insert, silicone gel, elastomeric or equal, for use with locking mechanism" to read "Addition to lower extremity, below knee/above knee, custom fabricated from existing mold or prefabricated, socket insert, silicone gel, elastomeric, or equal, with or without perforations, with or without breathable material, for use with locking mechanism."

Final Medicare Benefit Category Determination

Prosthesis (Artificial Leg).

The current Medicare policy and prior established benefit category determination for HCPCS Level II codes L5200, L5701, and L5321 apply to Aerofit.

Final Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II codes L5673 and L5679 apply to the Aerofit breathable silicone socket insert, if covered. The current average 2025 fee schedule amount for HCPCS Level II codes L5673 and L5679 are $895.15 and $745.93, respectively.

The payment rules and pricing associated with the existing HCPCS Level II codes L5200 and L5321 apply to the Aerofit socket with vents, if covered. The current average 2025 fee schedule amount for HCPCS Level II codes L5200 and L5321 are $4,445.01 and $4,483.61, respectively.

The payment rules and pricing associated with the existing HCPCS Level II code L5701 apply to the Aerofit replacement socket with vents, if covered. The current average 2025 fee schedule amount for HCPCS Level II code L5701 is $4,517.25.

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

Overlay Transtibial and Overlay Transfemoral - HCP241231FYCJQ

Topic/Issue

Request to establish a new HCPCS Level II code to identify Overlay Transtibial (TT) and Overlay Transfemoral (TF).

Applicant's suggested language: LXXXX, “Addition to lower extremity exoskeletal system, below knee or above knee pneumatic prosthetic socket insert w/ integrated air cells, w/ inflation/deflation mechanisms, for management of limb volume fluctuations and/or progressive changes to limb size and shape”

Summary of Applicant's Submission

Ethnocare Inc. submitted a request to establish a new HCPCS Level II code to describe Overlay Transtibial (TT) and Overlay Transfemoral (TF). Overlay TT and Overlay TF are prefabricated pneumatic transtibial/transfemoral prosthetic socket inserts with an integrated air expansion system and built-in inflation pump with release valves. Overlay TT and Overlay TF are exempt from the premarket notification procedures by the Food and Drug Administration (FDA). These prosthetic socket inserts with air inflation and deflation capabilities provide a different function than prosthetic liners and molded inner sockets. The Overlay pneumatic prosthetic socket inserts have a breathable and durable circumferential textile structure with an overall thickness of less than one millimeter. Overlay TT and Overlay TF are applied over the individual’s prosthetic liner, insert downward to the base of the existing socket, and extend above the socket’s proximal end. A built-in pump and release valve near the proximal end of the Overlay enables the individual to manually inflate or deflate an integrated series of interconnected air cells located on the posterior, medial, and lateral aspects of the insert. Pressurization of these air cells can achieve the functional equivalence of up to 15-ply of prosthetic socks. The individual can adjust the air pressure throughout the day to maintain a secure and comfortable fit between the socket and residual limb and reduce medial or lateral rotation of the limb inside the socket. Air pressure distributes to areas where there are voids and/or looseness between the limb and socket wall. Overlay TT and Overlay TF restore the secure uniform fit and distribution of loading forces present when the socket was originally fabricated. Overlay TT and Overlay TF enhance the individual’s ability and confidence to ambulate safely and comfortably. Individuals ambulating with ill-fitting or loose sockets alter their gait pattern which can increase their risk of falling. Additionally, an ill-fitting or loose socket can increase the risk of developing skin abrasions or wounds. The ability to use air pressure to restore and maintain socket-to-limb intimacy throughout the day is a reliable and efficient solution for individuals with above or below knee limb loss or limb difference. Overlay TT and Overlay TF enable users to avoid having to take off their clothes and prosthesis, as they must do when using prosthetic socks, thereby ensuring individuals can immediately tighten a loose or ill-fitting socket as needed even during physical activities. Certified prosthetists can dispense the Overlay TT and Overlay TF to resolve fit and comfort issues and extend the useful wear time of an existing socket.

CMS Preliminary HCPCS Coding Determination

Prosthetic socks are designed to offer a global reduction in pressure, distributing forces more evenly across the limb. In contrast, the Overlay TT and Overlay TF liners function similar to

a localized popliteal pad, targeting specific areas of the residual limb but not providing the same level of uniform pressure relief. Further, CMS believes there is a lack of sufficient evidence to definitively establish the effectiveness of the Overlay TT and Overlay TF liners compared to conventional prosthetic socks. Although some studies suggest potential benefits, such as enhanced comfort or improved volume management for transtibial amputees, the existing body of research is limited. Moreover, the available studies tend to be small in scale and narrow in focus. Without larger, more comprehensive studies, it remains difficult to draw definitive conclusions regarding the overall efficacy of the Overlay TT and Overlay TF liners compared to other prosthetic socks.

As a result, CMS believes that the Overlay TT and TF liners are not fundamentally different from other prosthetic socks. To more accurately reflect this, CMS proposes revising the current terminology for prosthetic socks to include "socks or equivalent." As such, CMS is proposing to:

1. Revise existing HCPCS Level II code L8420, "Prosthetic sock, multiple ply, below knee, each" to instead read "Prosthetic sock or equivalent, multiple ply, below knee, each"

2. Revise existing HCPCS Level II code L8430, "Prosthetic sock, multiple ply, above knee, each" to instead read "Prosthetic sock or equivalent, multiple ply, above knee, each"

3. Revise existing HCPCS Level II code L8470, "Prosthetic sock, single ply, fitting, below knee, each" to instead read "Prosthetic sock or equivalent, single ply, fitting, below knee, each"

4. Revise existing HCPCS Level II code L8480, "Prosthetic sock, single ply, fitting, above knee, each" to instead read "Prosthetic sock or equivalent, single ply, fitting, above knee, each"

These four revised HCPCS Level II codes describe Overlay TT and Overlay TF.

Preliminary Medicare Benefit Category Determination

Prosthesis (Artificial Leg).

The current Medicare policy and prior established benefit category determination of prosthetics for HCPCS Level II codes L8420, L8430, L8470, and L8480 apply to Overlay TT and Overlay TF.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II codes L8420, L8430, L8470, and L8480 apply to Overlay TT and Overlay TF. The current average 2025 fee schedule amount for each of these codes is as follows:

- HCPCS Level II code L8420 - $26.74
- HCPCS Level II code L8430 - $30.11
- HCPCS Level II code L8470 - $8.67

- HCPCS Level II code L8480 - $12.25

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

Summary of Public Feedback

Ethnocare, Inc. disagreed with CMS' published preliminary determinations suggesting that the Overlay Transtibial and Transfemoral products are "equivalent" to prosthetic socks. The speaker stated that the Overlay represents a fundamentally different technology with distinct therapeutic advantages. Traditional prosthetic socks are passive textile garments that uniformly add bulk around the limb through layering, requiring users to remove their prosthesis and guess the appropriate number of socks needed for proper fit, which creates safety risks and often results in uneven pressure distribution. In contrast, the Overlay is an air-cushion socket insert with an integrated inflation and deflation system that allows targeted volume compensation in specific anatomical regions while the prosthesis remains worn. The device uses air as a compressible fluid that naturally flows to areas requiring volume compensation, enabling precise adjustments without disrobing and significantly improving users' autonomy and compliance. The speaker stated that clinical evidence supports the Overlay's effectiveness, including peer-reviewed studies showing improved gait symmetry, enhanced stability, reduced hip flexion, and lower pain levels compared to prosthetic socks. Mechanical testing confirmed the device's ability to compensate for up to 6 mm of volume fluctuation and reduce internal limb movement. The speaker requested CMS recognize the Overlay under a new HCPCS Level II code with suggested language of LXXXX, "Addition to lower extremity, user adjustable, air, gel or fluid socket insert, residual limb volume management system." Alternatively, they proposed revising existing codes L5646 and L5648 to include equivalent socket inserts rather than misclassifying the technology under prosthetic sock codes, which could eliminate Medicare access to this clinically meaningful advancement in prosthetic care.

Another speaker stated that clinicians have been willing to pay manufacturer list prices for both TT and TF versions, with reportedly receiving reimbursements ranging from $600 to $900 from various payers. The commenters warned that denying a new code for the Overlay would significantly limit users' access to this innovative solution. Another speaker stated that companies with only HCPCS Level II miscellaneous codes (e.g., L5999) face reimbursement challenges that limit individual access to new prosthetic devices. Prosthetists often express concern about providing devices with L5999 codes, claiming poor insurance reimbursement rates.

CMS Final HCPCS Coding Determination

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

Establish new HCPCS Level II code L5657, "Addition to lower extremity prosthesis, manual/automated adjustable air, fluid, gel or equal socket insert for limb volume management, any materials" to describe Overlay Transtibial and Overlay Transfemoral.

After considering the public comments, CMS supports the creation of a new HCPCS Level II code to describe these types of volume management systems such as the Overlay Transtibial and Overlay Transfemoral specifically designed for use below the knee (transtibial) and above the knee (transfemoral). These products often take the place of multiple socks and unlike socks are adjustable/inflatable.

The new code language should be broad enough to describe not only the products currently on the market, such as the Overlay Transtibial and Overlay Transfemoral, but also future innovations that may come in the form of sleeves or similar designs. These products typically incorporate materials and mechanisms, such as pneumatic or fluid-based systems, that allow for manual or automated volume adjustment to effectively manage limb volume fluctuations.

Final Medicare Benefit Category Determination

Prosthesis (Artificial Leg).

Final Medicare Payment Determination

No determination. A preliminary payment determination for the new HCPCS Level II code L5657 will be presented at a future public meeting. Information on the payment determination process is available on our website[9].

[9] https://www.cms.gov/medicare/payment/fee-schedules/durable-medical-equipment-prosthetic-devices-prosthetics-orthotics-supplies/dmepos-payment-determinations-new-items-services

Milk Stork Breast Milk Shipping Products and Service - HCP250102QVE8D

Topic/Issue

Request to revise existing HCPCS Level II code A4287, “Disposable collection and storage bag for breast milk, any size, any type, each” to include breast milk storage coolers and shipping supplies and services.

Applicant's suggested language: A4287, “Breast milk storage bags and coolers, and shipping supplies and services for transport of expressed breast milk”

Summary of Applicant's Submission

Milk Stork submitted a request to revise existing HCPCS Level II code A4287 to include coolers and shipping for the transport of breast milk. The request proposes adding additional language as a natural extension, emphasizing the importance of safely storing and transporting expressed breast milk to maintain safe temperatures and viability prior to feeding per the Centers for Disease Control’s (CDC) Breast Milk Storage and Preparation guidelines. The Milk Stork cooler, Milk Cubby™, is reusable, durable and provides temperature-controlled storage for breast milk during shipping and delivery. Fresh breast milk storage poses a significant challenge for mothers separated from their infants, particularly those with babies in the neonatal intensive care unit (NICU) or those traveling back and forth from work/home to the hospital. The requested revision acknowledges that safe transportation of breast milk requires more than just storage bags, it also depends on cooling, storage, and shipping solutions that preserve milk integrity. This proposed change would enable equitable access to reimbursement for the costs of the overnight shipping of breast milk and the coolers, thus supporting optimal nutrition for infants regardless of location. Including these items and services under HCPCS Level II code A4287 would enhance the code’s utility, addressing the comprehensive needs of breastfeeding families and healthcare providers.

CMS Preliminary HCPCS Coding Determination

CMS has not identified a program operating need for Medicare or other insurers to revise existing HCPCS Level II code A4287, “Disposable collection and storage bag for breast milk, any size, any type, each,” to include breast milk storage coolers and shipping supplies and services. Existing HCPCS Level II code T2101, “Human breast milk processing, storage and distribution only” describes the products and services provided by Milk Stork.

Summary of Public Feedback

Milk Stork disagreed with CMS’ published preliminary determination to not revise existing HCPCS Level II code A4287, “Disposable collection and storage bag for breast milk, any size, any type, each,” to include breast milk storage coolers and shipping supplies and services, while instead recommending that existing HCPCS Level II code T2101, “Human breast milk processing, storage and distribution only” describes the products and services provided by Milk Stork. The speaker stated that HCPCS Level II code A4287 only accounted only for storage bags, one component of milk transport and preservation, and that leaving out coolers and shipping services left a critical gap based on CDC guidelines for Breast Milk Storage and Preparation which emphasizes maintaining integrity of the cold chain in transport and storage. The speaker explained that the mothers separated from their babies due to NICU

stays, military deployments or traveling for work makes preservation and delivery of breast milk a daily challenge. The speaker went on to add that breast milk must be kept at a consistent and cold temperature to prevent spoilage and bacterial growth and that the costs of not breastfeeding on the baby's immune system, development and inability to thrive show up for years to come. The speaker also commented that HCPCS Level II code T2101 pertains to milk banks and did not necessarily address mothers' efforts to store their own milk.

CMS Final HCPCS Coding Determination

We appreciate the comments provided in response to CMS' published preliminary determination. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary determination. CMS has not identified a program operating need for Medicare or other payers to revise existing HCPCS Level II code A4287, "Disposable collection and storage bag for breast milk, any size, any type, each" to include breast milk storage coolers and shipping supplies and services. Existing HCPCS Level II code T2101, "Human breast milk processing, storage and distribution only" includes the storage and distribution of human breast milk and based on the language is not limited to donor milk only. As such, it describes the products and services provided by Milk Stork.

While some payers may use this code for donor breast milk and associated services, inquiries regarding the billing and coverage of HCPCS Level II code T2101 should be directed to the insurer(s) in whose jurisdiction(s) claim(s) would be filed.

Cohealyx™ Collagen Dermal Matrix - HCP250101H5C7V

Topic/Issue

Request to establish a new HCPCS Level II code to identify Cohealyx™ Collagen Dermal Matrix.

Applicant's suggested language: AXXXX, “Cohealyx™ Collagen Dermal Matrix, per square centimeter”

Summary of Applicant's Submission

Collagen Matrix, Inc. submitted a request to establish a new HCPCS Level II code to identify Cohealyx™ Collagen Dermal Matrix. Cohealyx™ Collagen Dermal Matrix received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on December 19, 2024. This is a sterile, porous, resorbable collagen matrix engineered from purified collagen from bovine dermal tissue. It is non-pyrogenic and intended for single use only. The product is surgically applied and intended for the management of wounds by providing an environment that supports cellular repopulation and revascularization. It provides a moist wound environment and supportive extracellular matrix-like framework that rapidly absorbs blood and wound fluids, allowing for rapid infiltration of cells, blood, and other wound healing components. It provides structural support to support tissue regeneration and incorporates into the host tissue without inducing a prolonged foreign body response. The matrix has a fibrous structure similar to native extracellular matrix to support wound healing and revascularization. Cohealyx™ Collagen Dermal Matrix is indicated for the management of wounds including full thickness and partial thickness wounds; chronic wounds (e.g., pressure ulcers, venous ulcers, diabetic ulcers, chronic ulcers); surgical wounds (donor sites/grafts, post-Moh’s surgery, post-laser surgery, podiatric, wound dehiscence); trauma wounds (abrasions, lacerations, and skin tears); draining wounds; and partial thickness burns. The product is individually sealed within a pouch and packaged one per market unit.

CMS Preliminary HCPCS Coding Determination

Establish a new HCPCS Level II code AXXXX, "Cohealyx collagen dermal matrix, per square centimeter" to describe Cohealyx™ Collagen Dermal Matrix.

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

Collagen Matrix, Inc. agreed with CMS’ published preliminary determination.

CMS Final HCPCS Coding Determination

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

Establish new HCPCS Level II code A2036, "Cohealyx collagen dermal matrix, per square centimeter" to describe Cohealyx™ Collagen Dermal Matrix.

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.

G4Derm™ Plus - HCP2412316J8NR

Topic/Issue

Request to establish a new HCPCS Level II code to identify G4Derm™ Plus.

Applicant's suggested language: AXXXX, “G4Derm™ Plus, per ml”

Summary of Applicant’s Submission

Gel4Med, Inc. submitted a request to establish a new HCPCS Level II code to identify G4Derm™ Plus. G4Derm™ Plus received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on October 11, 2023. It is a sterile, synthetic wound matrix supplied in a prefilled syringe with a flexible applicator tip/nozzle for precise application to wounds. Utilizing proprietary self-assembling peptide technology, it forms a three-dimensional extracellular matrix (ECM)-like scaffold. This scaffold facilitates cell infiltration and attachment, capillary ingrowth, and soft tissue formation while providing a barrier to bacterial penetration. The product is shelf-stable for two years at room temperature and contains no human, animal, or plant-derived materials. G4Derm™ Plus provides a fully resorbable ECM-like scaffold to support wound healing. It ensures intimate contact with the wound bed, minimizing dead space, supporting cell attachment and revascularization, and providing an optimal healing environment. The structural matrix also acts as an antibacterial barrier, which may help mitigate infection by preventing bacterial colonization and biofilm reformation without the use of added antimicrobials. G4Derm™ Plus is an FDA-cleared peptide-based matrix designed to function as a resorbable ECM scaffold with an antibacterial barrier claim. G4Derm™ Plus offers precise placement and intimate wound bed coverage through a syringe delivery system and does not rely on human or animal-derived materials. G4Derm™ Plus is indicated for the local management of partial- and full-thickness wounds, including diabetic and pressure ulcers, lower extremity ulcers of venous, arterial, or mixed etiology, surgical wounds, and first-degree or partial-thickness burns, including dermabrasions and laser resurfacing. Upon application to the wound site, G4Derm™ Plus’ peptides self-assemble into a three-dimensional dermal scaffold that mimics the native ECM. By replicating the microarchitecture of native ECM, G4Derm™ Plus System facilitates the regrowth of dermal tissue and capillary networks, which are essential for wound healing. Furthermore, the cationic-rich peptide matrix in G4Derm™ Plus allows for broad-spectrum antibacterial protection while simultaneously providing a supportive environment for healthy tissue regrowth. G4Derm™ Plus is fully bioresorbable and completely integrates into the host tissues, where it is gradually replaced by the recipient’s own cells and ECM. It is supplied for single-use application. Reapplication may be performed as needed, based on wound progression and clinical judgment. It is applied topically, directly to the wound bed via a sterile prefilled syringe. G4Derm™ Plus is supplied in sterile, single-use, prefilled syringes contained within individual pouches. Each unit includes a sterile flexible applicator tip and is packaged in an outer carton with instructions for use.

CMS Preliminary HCPCS Coding Determination

Establish a new HCPCS Level II code AXXXX, "G4derm plus, per milliliter" to describe G4Derm™ Plus synthetic wound matrix.

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

Gel4Med, Inc. agreed with CMS' published preliminary determination.

CMS Final HCPCS Coding Determination

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

Establish new HCPCS Level II code A2037, "G4derm plus, per milliliter" to describe G4Derm™ Plus synthetic wound matrix.

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.

Redsense Dialysis Blood Loss Detection System - HCP2408250XJ78

Topic/Issue

Request to establish a new HCPCS Level II code to identify Redsense Dialysis Blood Loss Detection System.

Applicant's suggested language: XXXXX, “Dialysis Blood Loss Detection System – Includes sensor patch and alarm unit, per treatment session”

Summary of Applicant's Submission

Redsense submitted a request to establish a new HCPCS Level II code to identify Redsense Dialysis Blood Loss Detection System. Redsense Dialysis Blood Loss Detection System received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on October 18, 2007. Redsense Dialysis Blood Loss Detection System is a device designed to detect venous needle dislodgement during hemodialysis. The system includes a sensor patch and an alarm unit that provides real-time monitoring and immediate response to blood leakage, significantly enhancing safety by preventing potentially fatal blood loss. The new code would facilitate reimbursement by unbundled insurance plans and allow CMS to track the utilization of this safety device, with the potential to inform future bundled payment adjustments.

CMS Preliminary HCPCS Coding Determination

CMS has not identified a program operating need for Medicare or other insurers to establish a new HCPCS Level II code to identify Redsense Dialysis Blood Loss Detection System. This item is intended for use with a dialysis machine, which is typically dialysis treatment for end-stage renal disease (ESRD). For Medicare, when Redsense Dialysis Blood Loss Detection System is used for the treatment of ESRD covered under the ESRD prospective payment system (PPS), this product would be considered included in the ESRD PPS bundled payment.

Summary of Public Feedback

Redsense and other commenters disagreed with CMS’ published preliminary determination. The speaker noted that a current coding barrier obscures utilization in claims data and prevents CMS from tracking the clinical or economic impact, which can lead to payer inconsistency, claim denials, and reimbursement gaps. Another speaker pointed out that the ESRD PPS has not included monitoring of access during hemodialysis, except for requiring that the access remain uncovered and in view of dialysis personnel.

CMS Final HCPCS Coding Determination

We appreciate the comments provided in response to CMS’ published preliminary determination. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary determination. CMS has not identified a program operating need for Medicare or other insurers to establish a new HCPCS Level II code to identify Redsense Dialysis Blood Loss Detection System. This item is intended for use with a dialysis machine, which is typically dialysis treatment for ESRD. For Medicare, when Redsense Dialysis Blood Loss Detection System is used for the treatment of

ESRD covered under the ESRD prospective payment system (PPS), this product would be considered included in the ESRD PPS bundled payment.

Valves for Personal Breast Pump - HCP241231LF0VW

Topic/Issue

Request to establish a new HCPCS Level II code to identify replacement valves for personal breast pumps.

The applicant did not submit any suggested language.

Summary of Applicant's Submission

Symmetrical Health, LLC submitted a request to establish a new HCPCS Level II code to identify replacement valves for personal breast pumps. Breast pumps receive clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway. Valves attach to the underside of the breast shield, facilitating milk flow into the collection container while maintaining proper suction. Reduced suction is often the first indicator that the valves need replacing. It is recommended these valves should be replaced every 1-3 months, depending on usage. Failure to replace valves in a timely manner may result in decreased or lost suction, potentially impacting the user's milk supply. Replacement valves are sold in sets of two. Other replacement breast pump parts (bottle sets, breast shields, tubing, caps and locking rings) have specific billing codes to highlight the need of replacement. This allows providers to better define what equipment has been provided and is necessary. As highlighted above, valves are required for pump performance and currently can only be billed under a generic code.

CMS Preliminary HCPCS Coding Determination

Establish a new HCPCS Level II code AXXXX, "Valve for breast pump, replacement" to describe replacement valves for personal breast pumps.

Preliminary Medicare Benefit Category Determination

No DMEPOS benefit category when used with an electric breast pump; contractor discretion when used with a manual breast pump.

Electric breast pumps are not classified as DME. For manual breast pumps and related supplies, the Medicare Administrative Contractor processing claims for these items determines whether or not the pump is DME on a claim-by-claim basis.

HCPCS Level II code AXXXX is being added for replacement valves for breast pumps. In order for personal breast pump valves to fall under the DME benefit category, they would need to be essential accessories to a pump classified as DME.

Preliminary Medicare Payment Determination

There are currently two HCPCS Level II codes for breast pumps, with HCPCS Level II code E0602 for manual breast pumps using the pricing indicator 46 (contractor discretion), and HCPCS Level II code E0603 for electric breast pumps using the pricing indicator 00 (not payable or noncovered by Medicare). Therefore, payment for breast pump valves used with

manual breast pumps would be based on contractor discretion while breast pump valves used with electric breast pumps would be not payable or noncovered by Medicare.

Pricing Indicator = 46

Summary of Public Feedback

Symmetrical Health, LLC, and other commenters, agreed with CMS' HCPCS preliminary determination to establish a new HCPCS Level II code to describe replacement valves for personal breast pumps and acknowledged Medicare's benefit and payment determinations. The speaker described how valves for breast pumps act to maintain proper suction, which directly impacts the efficiency of milk expression, and manufacturers recommend replacing the valves every 1 to 3 months depending on use to ensure pump performance and optimal milk removal. According to the speaker, without a HCPCS Level II code, insurers are not covering replacement valves, which means many mothers are delaying replacing them due to cost. This leads to decreased suction of the pump which frustrates and discourages parents and thus jeopardizes the long-term success of breastfeeding. The speaker stated that creating a HCPCS Level II code would also align with the Women's Preventative Services Guidelines supported by Health Resources & Services Administration, which states that breastfeeding equipment and supplies, including pump parts and maintenance, must be covered without cost sharing under the Affordable Care Act. The speaker indicated that they would expect Medicare's benefit category and payment determinations to align with what they have been in the past.

CMS Final HCPCS Coding Determination

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

Establish a new HCPCS Level II code A4288, "Valve for breast pump, replacement" to describe replacement valves for personal breast pumps.

The establishment of a HCPCS Level II code does not guarantee coverage by payers. For inquiries regarding coverage, please contact the insurer(s) in whose jurisdiction(s) claim(s) would be filed.

Final Medicare Benefit Category Determination

No Medicare DMEPOS benefit category when used with an electric breast pump; contractor discretion when used with a manual breast pump.

Final Medicare Payment Determination

There are currently two HCPCS Level II codes for breast pumps: HCPCS Level II code E0602 for manual breast pumps with the pricing indicator 46 (contractor discretion), and HCPCS Level II code E0603 for electric breast pumps with the pricing indicator 00 (not payable or noncovered by Medicare). Therefore, payment for breast pump valves used with manual breast pumps would be based on contractor discretion. Local fee schedule amounts would be established by the DME MACs for use in paying any covered claims for this item.

Breast pump valves used with electric breast pumps would be not payable or noncovered by Medicare.

Pricing Indicator = 46

Lil Mixins™ Egg Powder - HCP2410230Q0YE

Topic/Issue

Request to establish a new HCPCS Level II code to identify Lil Mixins™ Egg Powder.

Applicant's suggested language: AXXXX, “Healthy infant early egg introduction supplement to reduce the risk of egg allergy (powder)”

Summary of Applicant's Submission

Lil Mixins submitted a request to establish a new HCPCS Level II code to identify Lil Mixins™ Egg Powder. Lil Mixins™ Egg Powder is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). This product is an early egg introduction dietary supplement used as an oral exposure for infants to well-cooked egg protein for early allergen introduction.

CMS Preliminary HCPCS Coding Determination

CMS has not identified a program operating need for Medicare or other insurers to establish a new HCPCS Level II code to identify Lil Mixins™ Egg Powder. We welcome information from the applicant and other insurers that are currently paying for this product to demonstrate a claims processing need for a unique HCPCS Level II code.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

Summary of Public Feedback

Lil Mixins disagreed with CMS’ published preliminary determinations. The speaker stated that the HCPCS Level II codes requested are specifically for new policies around food allergy prevention or early allergen introduction. The speaker commented that last year, Delaware passed a new Title 18 insurance code law which went into effect on January 1, 2025. This resulted in two categories of supplements: early peanut introduction dietary supplements and early well-cooked egg introduction dietary supplements. This new law was mandated for all of the insurance plans in Delaware. Both private and public plans, and Medicaid state plans for employees, as well as any plan operating in the state of Delaware, must cover at least one option of an early peanut introduction dietary supplement, and at least one option of an early well-cooked egg introduction dietary supplement. The speaker indicated that many of the private plans wish to put this under their health plan or the medical benefit, and the coverage for this law is limited to infants aged four to 12 months, and only with a prescription by a physician. This law would then necessitate new coding. Each of these products is really a one-time prescription. So, pediatricians would be able to write a prescription for a four-month visit or at a six-month visit, for example, and allow the parents to have coverage through age one for their infants. The law gives insurers a grace period until January 1, 2026. A number of discussions with both public and private payers have taken place, and they have not decided how they are going to deal with it, though there was a desire for consistent coding across the payers.

CMS Final HCPCS Coding Determination

We appreciate the comments provided in response to CMS' published preliminary determinations. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary coding determination. At this time, CMS has not identified a program operating need for Medicare or other insurers to establish a new HCPCS Level II code to identify Lil Mixins™ Egg Powder. Establishing a HCPCS Level II code while both private and public payers are still discussing how they would like to handle Delaware's new Title 18 insurance law would be premature. We welcome information from the applicant and other insurers that are currently paying for this product to demonstrate a claims processing need for a unique HCPCS Level II code in a subsequent coding cycle.

Final Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

Lil Mixins™ Peanut Powder - HCP241022FKXDQ

Topic/Issue

Request to establish a new HCPCS Level II code to identify Lil Mixins™ Peanut Powder.

Applicant's suggested language: AXXXX, “Healthy infant early peanut introduction supplement to reduce the risk of peanut allergy (powder)”

Summary of Applicant's Submission

Lil Mixins submitted a request to establish a new HCPCS Level II code to identify Lil Mixins™ Peanut Powder. Lil Mixins™ Peanut Powder is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). This product is an early peanut introduction dietary supplement used as an oral exposure for infants to peanut protein for early allergen introduction.

CMS Preliminary HCPCS Coding Determination

CMS has not identified a program operating need for Medicare or other insurers to establish a new HCPCS Level II code to identify Lil Mixins™ Peanut Powder. We welcome information from the applicant and other insurers that are currently paying for this product to demonstrate a claims processing need for a unique HCPCS Level II code.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

Summary of Public Feedback

Lil Mixins disagreed with CMS’ published preliminary determinations. The speaker stated that the HCPCS Level II codes requested are specifically for new policies around food allergy prevention or early allergen introduction. The speaker commented that last year, Delaware passed a new Title 18 insurance code law which went into effect on January 1, 2025. This resulted in two categories of supplements: early peanut introduction dietary supplements and early well-cooked egg introduction dietary supplements. This new law was mandated for all of the insurance plans in Delaware. Both private and public plans, and Medicaid state plans for employees, as well as any plan operating in the state of Delaware, must cover at least one option of an early peanut introduction dietary supplement, and at least one option of an early well-cooked egg introduction dietary supplement. The speaker indicated that many of the private plans wish to put this under their health plan or the medical benefit, and the coverage for this law is limited to infants aged four to 12 months, and only with a prescription by a physician. This law would then necessitate new coding. Each of these products is really a one-time prescription. So, pediatricians would be able to write a prescription for a four-month visit or at a six-month visit, for example, and allow the parents to have coverage through age one for their infants. The law gives insurers a grace period until January 1, 2026. A number of discussions with both public and private payers have taken place, and they have not decided how they are going to deal with it, though there was a desire for consistent coding across the payers.

CMS Final HCPCS Coding Determination

We appreciate the comments provided in response to CMS' published preliminary determinations. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary coding determination. At this time, CMS has not identified a program operating need for Medicare or other insurers to establish a new HCPCS Level II code to identify Lil Mixins™ Peanut Powder. Establishing a HCPCS Level II code while both private and public payers are still discussing how they would like to handle Delaware's new Title 18 insurance law would be premature. We welcome information from the applicant and other insurers that are currently paying for this product to demonstrate a claims processing need for a unique HCPCS Level II code in a subsequent coding cycle.

Final Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

Kate Farms High Protein Nutrition Shake - HCP250102ECVPJ

Topic/Issue

Request to establish a new HCPCS Level II code to identify Kate Farms High Protein Nutrition Shake.

Applicant's suggested language: BXXXX, “Enteral formula (EN), supplemental co-therapy or adjunctive EN therapy to medication(s), contains carbohydrates, fats, protein, vit/mins, reduced calorie (<0.7kcal/mL), high protein (>50% of daily value (DV) for protein), may be nutritionally complete, and includes fiber, 10g protein = 1 Unit”

Summary of Applicant's Submission

Kate Farms Inc. submitted a request to establish a new HCPCS Level II code to identify Kate Farms High Protein Nutrition Shake. Kate Farms High Protein Nutrition Shake is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). Kate Farms High Protein Nutrition Shake is an orally administered enteral nutrition product. Kate Farms High Protein Nutrition Shake is an enteral formula specifically developed to address the needs of individuals requiring supplemental co-therapy or adjunctive enteral nutrition therapy to medications. The intention of these products is to be used in conjunction with anti-obesity medications to target specific nutrient intake and subsequently reduce the rate of malnutrition as a complication of significant weight loss. Kate Farms High Protein Nutrition Shake is packaged in 325 mL packages and is available in cases of twelve.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II code A9270, “Non-covered item or service” describes Kate Farms High Protein Nutrition Shake. Kate Farms High Protein Nutrition Shake is orally administered and not via a feeding tube. Kate Farms High Protein Nutrition Shake is similar to other products in HCPCS Level II code A9270.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

Medicare pays for enteral nutritional therapy administered through feeding tubes under the prosthetic device benefit, with the feeding tube being the prosthetic device. This product is not administered via a feeding tube and does not fall under any of the DMEPOS benefit categories.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with existing HCPCS Level II code A9270 apply to this product.

No Medicare DMEPOS payment. Payment Indicator = 00

Summary of Public Feedback

Kate Farms Inc. disagreed with CMS' published preliminary determinations. The speaker stated that the Kate Farms High Protein Nutrition Shake provides high-quality protein that is not available in other enteral nutrition products. The speaker acknowledged that the adjunctive nutritional therapy provided by the Kate Farms High Protein Nutrition Shake is administered orally and therefore typically not covered by Medicare. However, the speaker noted that access to adjunctive therapy products can help advance health equity within this patient population.

CMS Final HCPCS Coding Determination

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

Existing HCPCS Level II code A9270, "Non-covered item or service" to describe Kate Farms High Protein Nutrition Shake.

To fall under a Medicare benefit, products listed within the HCPCS Level II enteral nutrition codes must have the option to be administered through a feeding tube. Since the Kate Farms High Protein Nutrition Shake is only orally administered, it is similar to other products in HCPCS Level II code A9270.

CMS is not aware of any other payers with a current need for a unique code for this product. The submitted policies (Tricare, AmeriHealth Caritas (Louisiana), CareSource (Ohio), Commonwealth Care Alliance (Massachusetts), Minnesota Medicaid, and Medi-Cal) only support coverage of oral nutrition supplements, nothing specific to this product or the product's indication for use with anti-obesity medication. In fact, for Medi-Cal, Kate Farms High Protein Nutrition Shake was not on the list of contracted enteral nutrition products eligible for coverage, while other Kate Farm products were listed. HCPCS Level II code B4155, "Enteral formula, nutritionally incomplete/modular nutrients, includes specific nutrients, carbohydrates (e.g., glucose polymers), proteins/amino acids (e.g., glutamine, arginine), fat (e.g., medium chain triglycerides) or combination, administered through an enteral feeding tube, 100 calories = 1 unit" in combination with the BO, "Orally administered nutrition, not by feeding tube" is available if other payers deem appropriate.

Final Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

Final Medicare Payment Determination

No Medicare DMEPOS payment. Payment Indicator = 00

RevoFit® Lamination Kit - HCP241230DU444

Topic/Issue

Request to establish a new HCPCS Level II code to identify RevoFit® Lamination Kit.

Applicant's suggested language: LXXXX, “Addition to lower extremity, user adjustable, mechanical, limb volume management system, custom fabricated (used for offloading orthosis)”

Summary of Applicant's Submission

Click Medical submitted a request to establish a new HCPCS Level II code to identify RevoFit® Lamination Kit (RF). RF is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). RF for orthoses is identical to the component approved under HCPCS Level II code L5783, “Addition to lower extremity, user adjustable, mechanical, residual limb volume management system,” including the fabrication process, complexity of clinical evaluation, and user benefits. RF allows individuals to make 1 mm volume changes to their devices, without activity of daily living (ADL) interruption, to match activity level and limb volume changes. Users can independently don and doff their devices, maintain skin integrity, and have security and confidence during ADLs. The patented RF is a kit of components that an orthotist adds to a custom fabricated orthosis. The orthotist determines areas of adjustability and adds RF during custom fabrication. Once delivered, the individual can tighten or loosen the orthosis to optimize the fit and function. Adjustable device volume allows the orthosis to fit a wider range of individual limb volumes. RF can extend the life of an orthosis, reducing replacement orthoses and visits to the orthotist. Traditional offloading orthoses cannot be compressed or expanded by the user and require adjustment by the orthotist. Conventional offloading orthoses can offload in the sagittal plane, while adding RF allows for axial offloading.

CMS Preliminary HCPCS Coding Determination

The RevoFit® Systems for lower limb prostheses and for upper limb prostheses and RevoFit® System for lower limb offloading orthoses use the same lamination kit. As such, CMS proposes to:

1. Discontinue existing HCPCS Level II code L5783, “Addition to lower extremity, user adjustable, mechanical, residual limb volume management system”

   Effective September 30, 2025

2. Discontinue existing HCPCS Level II code L7406, “Addition to upper extremity, user adjustable, mechanical, residual limb volume management system”

   Effective September 30, 2025

3. Establish a new HCPCS Level II code LXXXX, “Addition to extremity, user adjustable, mechanical, custom fabricated, limb volume management system (including lamination kit, etc.)” to describe RevoFit® Systems for upper and lower limb prosthesis.

HCPCS Level II code LXXXX can be used for both orthoses and prostheses for upper and lower limb volume adjustment systems. HCPCS Level II code LXXXX would be used in conjunction with a base code for either a lower limb prosthesis, upper limb prosthesis, or lower limb orthosis.

Preliminary Medicare Benefit Category Determination

Prosthesis (Artificial Leg).

Preliminary Medicare Payment Determination

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

In this case, new HCPCS Level II code LXXXX has a pricing history based on HCPCS Level II codes L5783 and L7406. Thus, the preliminary payment determination for new HCPCS Level II code LXXXX is to establish the fee schedule amount using the average of the existing fee schedule amounts for HCPCS Level II code L5783 and L7406 (in this case, the codes have the same payment amount, so there is no need to weight the average by allowed services).

The payment rules and pricing associated with the existing HCPCS Level II codes L5783 and L7406 apply to this product, if covered. The current average 2025 fee schedule amount for HCPCS Level II codes L5783 and L7406 is $3,088.30.

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

Summary of Public Feedback

Click Medical partially agreed with CMS' published preliminary determinations and provided few recommendations. They expressed gratitude for previously established HCPCS Level II codes L5783 and L7406 for prosthetic items, and for a newly proposed HCPCS Level II code for the RevoFit® volume management system in orthotic devices. The speaker disagreed with the CMS' preliminary determination to create a single L code to describe orthoses in addition to upper and lower extremity prosthetics, and, accordingly, to eliminate HCPCS Level II codes L5783 and L7406. They stated that a single code that crosses orthotic and prosthetic devices and upper and lower limb indications will create significant confusion for providers and payors, since this approach is unprecedented in the HCPCS Level II code set. As such, the speaker suggested establishing a new L code specifically to describe orthotic applications, and to keep existing HCPCS Level II codes L5783 and L7406, specific for

lower and upper extremity prosthetics, respectively. The speaker agreed with the language clarification which included the addition of the phrases "custom fabricated" and "including lamination kit" to the code descriptor. They agreed that this language would be an improvement for all three codes, it would provide clarity and consistency and would accurately describe the RevoFit® System in its various applications. The speaker further stated that the term "etc." in the proposed code descriptor should not be included as it invites confusion, and perhaps improper use of codes as intended. The speaker agreed to include the term "lamination kit" in the code descriptor as it would help to ensure that intent of the code is followed, and that the reimbursement is commensurate with the labor needed to create custom fabricated volume adjustable devices.

Another speaker stated that the individual codes, specific to upper and lower extremity prosthetics and a separate code for orthotic applications would help to avoid confusion for providers, coders, and insurers. The speaker stated that they are not aware of HCPCS Level II codes that broadly cover orthotic and prosthetic devices (for lower and upper extremity). They agreed with suggested additional descriptive language affirming that these complex adjustable devices are "custom fabricated" with the "included lamination kit." These specific phrases are appropriate for describing RevoFit® when integrated into prosthetics and orthotics and should be consistent in the descriptions of each of the three codes. The term "lamination kit" is a generic term simply describing "all component parts" necessary to integrate the RevoFit® System into a device during the lamination process. Lastly, the speaker expressed their gratitude for the understanding that the integration of the RevoFit® System into prostheses and orthoses, is delivered by the clinicians with the same clinical education and technical training, using the same materials, fabrication techniques and the same RevoFit® Lamination Kits across all device types. Additionally, with these similarities recognized, it is entirely appropriate that the stated reimbursement rate is set equivalent to HCPCS Level II codes L5783 and L7406.

CMS Final HCPCS Coding Determination[10]

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

1. Revise existing HCPCS Level II code L5783, "Addition to lower extremity, user adjustable, mechanical, residual limb volume management system" to read "Addition to lower extremity, user adjustable, mechanical, residual limb volume management system (with or without lamination kit)"

2. Revise existing HCPCS Level II code L7406, "Addition to upper extremity, user adjustable, mechanical, residual limb volume management system" to read "Addition to upper extremity prosthesis, user adjustable, mechanical, residual limb volume management system (with or without lamination kit)"

CMS agrees with public comments that using a single HCPCS Level II code to describe both orthotic and prosthetic devices across upper and lower limb indications would create significant confusion for providers and payers. Therefore, CMS has decided to revise existing

[10] Updated on November 14, 2025 to add further clarification for why CMS revised its final determination.

HCPCS Level II codes L5783 and L7406, which were previously established in the second biannual 2023 and 2024 coding cycles. CMS also concurs with commenters that revising the existing language is necessary to accurately reflect the full range of volume management systems currently in use whether they are integrated with lamination kits or provided as standalone solutions.

However, CMS does not support the proposed orthotic-specific code (LXXXX, “Addition to orthosis, user adjustable, mechanical, custom fabricated, volume management system, including lamination kit”) as comparable to the prosthetic application of RevoFit®. CMS revised its preliminary decision and ultimately chose not to proceed with the creation of a new orthotic-specific code after reviewing public comments and additional documentation submitted after and during the public meeting. While RevoFit® in prosthetics enables dynamic residual limb volume management throughout the day via mechanical adjustment systems (e.g., dial and cable-based mechanisms like the BOA Fit System), the same functional purpose is not evident in orthotic use.

Unlike prosthetics, volume changes in limbs fitted with orthoses are infrequent. In orthotic applications such as patellar tendon-bearing designs for offloading the foot and ankle, mechanical systems (e.g., dials) typically function as closure mechanisms, replacing traditional straps. Their purpose is to secure the device rather than accommodate anatomical volume fluctuations. In orthotic designs like patellar tendon-bearing AFOs, adjustable mechanical systems (e.g., dials) are primarily used as closure mechanisms, replacing traditional straps, rather than managing anatomical volume changes. As such, CMS concluded these features do not meet the definition of a "volume management system" and are more akin to upgraded closures similar in function to ski boot buckles. Therefore, CMS does not consider these orthotic configurations to meet the definition of "volume management systems," and a distinct code for such orthotic features is not warranted.

Final Medicare Benefit Category Determination

Prosthesis (Artificial Leg).

Final Medicare Payment Determination

The payment rules and pricing associated with existing HCPCS Level II codes L5783 and L7406 apply to these items, if covered. The current average 2025 fee schedule amounts for L5783 and L7406 are $3,088.30.

The average fee schedule amount is the average of the 2025 fee schedule amounts for these codes for each of the 50 states, Washington DC, Puerto Rico, and the Virgin Islands. Fee schedule amounts are updated annually.

Pricing Indicator = 38

LINK™ External Fixator - HCP2408147XDEB

Topic/Issue

Request to establish a new HCPCS Level II code to identify LINK™ External Fixator.

Applicant's suggested language: XXXXX, “Continuous dynamic percutaneous bone fixation device”

Summary of Applicant's Submission

Metric Medical Devices, Inc. submitted a request to establish a new HCPCS Level II code to identify LINK™ External Fixator. LINK™ External Fixator received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on May 29, 2024. The LINK™ External Fixator is not a traditional external fixator because it acts on bone pins in a continuously dynamic manner to reduce and compress a fracture, osteotomy or site of arthrodesis. It provides the same function as bone plates or screws but is applied percutaneously and in many cases avoids an open incision. Consequently, fractures of the foot, ankle, hand and wrist, and other sites can be treated upon first presentation at the physician’s office providing early treatment for the individual, convenience for the individual and the physician, and can be placed with a nerve block and local anesthetic. Minimally invasive bunions and fusion of small joints can be treated with the LINK™ External Fixator device in the same manner. This technology mimics that of a nitinol bone staple that provides continuous and dynamic compression to support bony fusion. Since this device is applied percutaneously with only 1.6 to 2.0 mm diameter bone pins, it leaves the soft tissue envelope intact, does not cut vascular structures, and due to the significantly lower surgical trauma it allows the healing response to focus on bony healing. The use of the LINK™ External Fixator in the doctor’s office has significant healthcare cost advantages too, as general anesthesia and operating room resources are often not needed, nor required.

CMS Preliminary HCPCS Coding Determination

LINK™ External Fixator is not suitable for inclusion in the HCPCS Level II code set because it is considered bundled into the facility payment. CMS has not identified a specific need for the LINK™ External Fixator to be separately paid, since we believe that a particular insurer may elect to pay for the service in which this device is used. For instance, Medicare would typically reflect the costs of the device in the payment for the procedure, if it is used, and as such it would not be separately payable and is bundled in the facility payment.

Summary of Public Feedback

Metric Medical Devices, Inc. disagreed with CMS’ published preliminary determination. The LINK™ External Fixator (LINK™) has the ability to provide dynamic compressions, by creating adjustable forces, and actively reducing a healing osseous wound. The LINK™ also has a tremendous number of applications, and it can be linked together in a sense, like an erector set, so as to create a complex external fixator. That will change shape, pull bones together and compress them while healing. This can be seen as a broad alternative to plates, screws, and staples. The speaker stated that providers are billing for this device using HCPCS Level II codes C1713, “Anchor/screw for opposing bone-to-bone or soft tissue-to-bone (implantable)” or C1889, “Implantable/insertable device, not otherwise classified.” The

speaker further stated that these codes are very broad, which limits the ability to utilize this technology in the physician's office, whereas the facility payment structure is only in the hospital setting. The HCPCS Level I Current Procedural Terminology® codes 20690 and 20692 have also been used to code this product. The speaker reiterated that this request is to obtain reimbursement for the LINK™, again for use in the physician's office, as well as to define and clarify its use for surgery centers and hospital patients. There is a lot of billing confusion around this product, which has created a problem entering the market. This device itself gives the physician the ability to treat patients earlier, more effectively, and more convenient for both patients and physicians. If physicians can begin to fix metatarsal and metacarpal fractures percutaneously in the office, this will create broad cost reductions, in the small bone internal fixation environment, potentially even eliminating operating room and anesthesia charges.

CMS Final HCPCS Coding Determination

We appreciate the comments provided in response to CMS' published preliminary determination. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary determination. At this time, LINK™ External Fixator is not suitable for inclusion in the HCPCS Level II code set because it is considered bundled into the facility payment. CMS has not identified a specific need for the LINK™ External Fixator to be separately paid, since we believe that a particular insurer may elect to pay for the service in which this device is used. For instance, Medicare would typically reflect the costs of the device in the payment for the procedure, if it is used, and as such it would not be separately payable and is bundled in the facility payment.

JUST WALK™ - HCP241231BFXL5

Topic/Issue

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

Applicant's suggested language: EXXXX, “Dynamic adjustable upper and lower extremity extension and flexion linear resistance device, includes all components and accessories”

Summary of Applicant's Submission

Chaban Medical submitted a request to establish a new HCPCS Level II code to identify JUST WALK™. JUST WALK™ is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). JUST WALK™ is a wearable/external dynamic adjustable medical device engineered to enhance gait coordination, balance, and upper limb coordination. It enhances proprioception, which is the body’s position awareness, further enabling natural relearning of proper movement patterns. JUST WALK™ guides the body through an intuitive rehabilitation journey. By stimulating the body’s natural movement instincts, it helps restore functional mobility effectively and efficiently. The fully mechanical neuromotor weighs just one pound and is designed to provide an ultra-portable neuromotor rehabilitation solution. This ergonomic wearable device integrates into the complete gait cycle, assisting with foot lift at step initiation and leveraging adjustable resistive forces (four levels) as the leg moves forward. This is a dual-action approach accelerating both neuroplasticity and muscle strengthening without excessive load bearing. This device provides effective treatment for individuals with orthopedic and neurological (e.g., stroke, traumatic brain injury, multiple sclerosis, Parkinson's disease, cerebral palsy, and older individuals at an increased risk of falls) disorders by applying dynamic adjustable linear resistance to the lower and upper limbs. Neurological injuries frequently manifest beyond single-organ involvement, commonly resulting in concurrent impairments of both upper and lower extremities. Due to its dynamic nature, JUST WALK™ is distinguished by its therapeutic capability to provide comprehensive treatment across both lower and upper body segments, addressing extension and flexion movements in multiple joints simultaneously (elbow, shoulder, knee, and ankle).

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II code A9300, “Exercise equipment” describes JUST WALK™.

JUST WALK™ is an external device that enables relearning of proper movement patterns for gait coordination, balance, and upper limb coordination. JUST WALK™ is equipped to provide resistance training aimed at strengthening the upper and lower limbs. An individual can wear the device while performing exercises aimed at improving stability and/or strengthening muscle mass. JUST WALK™’s proprioceptive training capability allows for a variety of exercises, including seated activities like knee and ankle flexion/extension, as well as upper limb rehabilitation with resistance. This demonstrates that the device is designed primarily as a rehabilitative tool to support exercise for individuals with neurological or orthopedic conditions, rather than being focused on improving joint range of motion. JUST WALK™ is similar to other devices in HCPCS Level II code A9300.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

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

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

All five of these conditions must be met for equipment to be classified as DME. However, JUST WALK™ does not meet one of the conditions that must be met for equipment to be classified as DME:

> **Is primarily and customarily used to serve a medical purpose** - While there are DME items commonly used in conjunction with rehabilitation, we believe the primary purpose of the JUST WALK™ is to enhance exercise sessions during the rehabilitation process. Per the applicant, the individual can wear the device while performing exercises aimed at improving stability and/or strengthening muscle mass in the lower and/or upper extremities. The individual can also perform supplementary exercises for muscle strengthening of lower and upper extremities if the product is mounted on an external fixture. The manufacturer's website markets the device as "The Wearable Resistance Gym: Anytime, Anywhere". The website goes on to say, "When muscle strengthening is the priority, Just Walk transforms into a cutting-edge wearable resistance gym, enabling strength and endurance training through functional, weight-bearing movements in standing or seated positions – all without excessive load impact."[11] There are also other products currently assigned under HCPCS Level II code A9300 (exercise equipment) on the Pricing Data Analysis and Coding (PDAC) Product Classification List, which similarly allow individuals to receive rehabilitation therapy and stimulate neuroplasticity to improve activities of daily living.
>
> The applicant has asserted that the JUST WALK™ is a dynamic adjustable extension/flexion device (e.g., HCPCS Level II code L1815), which are covered by Medicare as DME. However, we do not agree that the JUST WALK™ is a dynamic adjustable extension/flexion device. Dynamic adjustable extension/flexion devices provide stretching and work to increase range of motion, mainly to address joint contractures. Although the JUST WALK™ claims to offer treatment across both upper and lower body segments, addressing extension and flexion movements in multiple joints simultaneously (elbow, shoulder, knee, and ankle), we do not believe the device actually provides the same range of motion improvements as those other devices. The JUST WALK™ appears to be more focused on assisting with walking and reducing fall risk, and we have not seen information that would suggest it plays a

[11] https://www.chaban-medical.com/just-walk-page

significant role in joint rehabilitation like those dynamic adjustable extension/flexion devices. As explained by the applicant, JUST WALK™ is equipped to provide resistance training aimed at strengthening the upper and lower limbs. This is achieved through the use of resistance rollers, upper extremity handles, and external connections. The system not only aids in increasing muscle mass but also enhances joint approximation and proprioception. Furthermore, JUST WALK™'s proprioceptive training capability allows for a variety of exercises, including seated activities like knee and ankle flexion/extension, as well as upper limb rehabilitation with resistance. This demonstrates that the device is designed primarily as a rehabilitative tool to support exercise for individuals with neurological or orthopedic conditions, rather than being focused on improving joint range of motion.

After taking all of this information into account, we consider the JUST WALK™ to be a type of exercise equipment and as a result cannot be DME. Per National Coverage Determination (NCD) 280.1, exercise equipment is not DME because it is not primarily medical in nature. Chapter 15 of the Medicare Benefit Policy Manual (Pub. 100-2) elaborates on equipment presumptively nonmedical by saying, "Equipment which is primarily and customarily used for a nonmedical purpose may not be considered "medical" equipment for which payment can be made under the medical insurance program. This is true even though the item has some remote medically related use. For example, in the case of a cardiac individual, an air conditioner might possibly be used to lower room temperature to reduce fluid loss in the individual and to restore an environment conducive to maintenance of the proper fluid balance. Nevertheless, because the primary and customary use of an air conditioner is a nonmedical one, the air conditioner cannot be deemed to be medical equipment for which payment can be made."

Preliminary Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Summary of Public Feedback

Chaban Medical disagreed with CMS' published preliminary determinations. JUST WALK™ is a wearable and an external dynamic adjustable medical device that is engineered to treat individuals with orthopedic trauma and neurological disorders. It uses a closed-loop neuro-feedback mechanism of action, designed solely for impaired gait phase rehabilitation. The device itself works based on magnetic variable linear resistance levels, and the mechanical creation of resistance as the patient moves forward and is different from what currently exists on the market, such as fitness equipment. As an individual's leg moves forward and is lifted up, it creates a stable resistance, that helps the brain understand where the limb is spatially. This is known as enhanced proprioception, which allows the brain to be taught and relearn the intended movements that are required to ambulate. This device again operates by creating and changing stable resistance over the limbs, that enhances motor learning, muscle strength, and reteaches the brain. Pressure is created from the shoulders down to the waist and then tension from the legs up to the waist. The speaker stated that the medical purpose of this device is gait rehabilitation for in-home use, so it is not suitable to be used by a healthy person, as it has no training benefits. It is non-recreational and thus cannot serve as general fitness or exercise equipment.

The speaker further stated that this product require a prescription from a licensed therapist, who adjusts and optimizes the treatment to each individual patient. This product cannot be used by successive patients, and there is no rental and/or refurbishment program, at this point in time. Individuals can use it twice a day, for up to 10 to 15 minutes per day, to enhance gait coordination, balance, and upper limb coordination. From basic motions to complex physical activities, JUST WALK™ guides the patient's body through the whole walking cycle, swing to stance. The speaker reiterated that this device increases the proprioception sensation and stimulates the individual's own body to instinctively relearn correct natural motion throughout their entire rehabilitation journey from simple motion to complex physical functionality. This type of resistance cannot be achieved using elastic bands or springs, which alter their resistance based on extension and primarily target muscle mass rather than coordinated motor control. Unlike weights, which apply a fixed downward force, this system not only resists the patient's movement but also helps by supporting leg elevation during the walking cycle's swing phase, and applying upward resistance that stimulates foot lift during the step, and promotes joint approximation through targeted compression which again enhance proprioception.

CMS Final HCPCS Coding Determination

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

Existing HCPCS Level II code A9300, "Exercise equipment" to describe JUST WALK™.

JUST WALK™ is an external device that enables relearning of proper movement patterns for gait coordination, balance, and upper limb coordination. JUST WALK™ is equipped to provide resistance training aimed at strengthening the upper and lower limbs. An individual can wear the device while performing exercises aimed at improving stability and/or strengthening muscle mass. JUST WALK™'s proprioceptive training capability allows for a variety of exercises, including seated activities like knee and ankle flexion/extension, as well as upper limb rehabilitation with resistance. This demonstrates that the device is designed primarily as a rehabilitative tool to support exercise for individuals with neurological or orthopedic conditions, rather than being focused on improving joint range of motion. JUST WALK™ is similar to other devices in HCPCS Level II code A9300.

Final Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

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

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

5. Is appropriate for use in the home.

All five of these conditions must be met for equipment to be classified as DME. However, JUST WALK™ does not meet two of the conditions that must be met for equipment to be classified as DME:

Is primarily and customarily used to serve a medical purpose - We continue to consider the JUST WALK™ to be a type of exercise equipment and therefore it is not DME.

The applicant clarified in their written comments that the FDA classified the JUST WALK™ under 21 CFR 890.5370. § 890.5370 represents "Nonmeasuring exercise equipment". Per § 890.5370, "Nonmeasuring exercise equipment consist of devices intended for medical purposes, such as to redevelop muscles or restore motion to joints or for use as an adjunct treatment for obesity. Examples include a prone scooter board, parallel bars, a mechanical treadmill, an exercise table, and a manually propelled exercise bicycle."

The device's regulation classification name therefore supports the conclusion that the device is a type of exercise equipment; specifically, nonmeasuring exercise equipment. Parallel bars and treadmills are listed as examples of nonmeasuring exercise equipment under § 890.5370 and National Coverage Determination (NCD) 280.1 specifies both devices are exercise equipment and not DME. NCD 280.1 holds that treadmill exercisers are exercise equipment, and that they are not primarily medical in nature. NCD 280.1 considers parallel bars to be support exercise equipment. Therefore, there is precedent for which devices classified under 21 CFR 890.5370 are also listed in NCD 280.1 as exercise equipment rather than DME.

Items like the JUST WALK™ classified under § 890.5370 may be intended for a medical purpose, but they are not necessarily DME. For an item to be classified as DME, specific conditions must be met under 42 CFR 414.202. The specific condition that the JUST WALK™ does not meet is that the equipment must be primarily and customarily used to serve a medical purpose. While there are DME items commonly used in conjunction with rehabilitation, we believe the primary purpose of the JUST WALK™ is to enhance exercise sessions during the rehabilitation process.

After taking all of this information into account, we consider the JUST WALK™ to be a type of exercise equipment and as a result is not DME. As explained, per NCD 280.1, exercise equipment is not DME because it is not primarily medical in nature. Chapter 15 of the Medicare Benefit Policy Manual (Pub. 100-2) elaborates on equipment presumptively nonmedical by saying, "Equipment which is primarily and customarily used for a nonmedical purpose may not be considered 'medical' equipment for which payment can be made under the medical insurance program. This is true even though the item has some remote medically related use."

Generally is not useful to an individual in the absence of an illness or injury – In the public meeting the applicant claimed that the JUST WALK™ is not useful to an individual in the absence of an illness or injury. The applicant said that the device is not usable by healthy individuals, that there is no training benefit for healthy individuals, and that it is used by those with a neuromotor deficit. The applicant said

that those without functional limitations would not be able to properly use it, nor would they benefit from it. The applicant also said that the JUST WALK™ was designed for use by neurological and/or orthopedic patients.

Although the device may be used by neurological and/or orthopedic patients, we disagree with the applicant's assertion that the device lacks utility for those without an illness or injury. The device is classified under 21 CFR 890.5370 as "nonmeasuring exercise equipment," a category that includes devices with general fitness applications. Other equipment in this same classification—such as treadmills and exercise bicycles—are routinely used by healthy individuals for fitness, athletic training, and general wellness purposes. This classification suggests the device has broader use beyond those with specific medical conditions.

We indicated in our preliminary decision that the manufacturer's website markets the device as "The Wearable Resistance Gym: Anytime, Anywhere". The website goes on to say, "When muscle strengthening is the priority, Just Walk transforms into a cutting-edge wearable resistance gym, enabling strength and endurance training through functional, weight-bearing movements in standing or seated positions – all without excessive load impact."[12] We believe that these marketing materials also show that the device has broader use for general fitness purposes beyond those with specific medical conditions.

In addition, it is unclear if the JUST WALK™ meets the 3-year minimum lifetime requirement. The applicant attested in their written comments that the device is intended for use up to 3 years, that it is made of robust materials, and is suitable for daily multi-year use. However, we have reviewed lifetime testing results submitted by the applicant and based on the information in these results we are currently unable to conclude that the device has an expected life of at least 3 years. The testing results indicate components of the device fail prior to 3 years and we have concerns that this may indicate that the device does not have an expected life of at least 3 years.

We also continue to believe that the JUST WALK™ is not a dynamic adjustable extension/flexion device (e.g., HCPCS Level II code E1800). Such devices are prescriptive passive motion systems used post-surgically to prevent joint stiffness or restore isolated range of motion under controlled, passive conditions. These devices apply external, passive movement to a single joint without requiring active muscle engagement from the patient. In contrast, the JUST WALK™ system is designed for dynamic gait rehabilitation. It requires active patient participation, utilizes variable resistance, engages multiple joints, and focuses on whole-body coordination. Its clinical intent, mechanism of action, and therapy setting are therefore fundamentally different from such devices.

Final Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

[12] https://www.chaban-medical.com/just-walk-page

JUST WALK™ ASM SOLE - HCP250101M4ABE

Topic/Issue

Request to establish a new HCPCS Level II code to identify JUST WALK™ ASM SOLE.

Applicant's suggested language: AXXXX, “Just walk disposable asm soles”

Summary of Applicant's Submission

Chaban Medical submitted a request to establish a new HCPCS Level II supply code to identify JUST WALK™ ASM SOLE. JUST WALK™ is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). JUST WALK™ is a wearable/external dynamic adjustable medical device engineered to enhance gait coordination, balance, and upper limb coordination. This device provides effective treatment for individuals with orthopedic and neurological (e.g., stroke, traumatic brain injury, multiple sclerosis, Parkinson's disease, cerebral palsy, and older individuals at an increased risk of falls) disorders by applying dynamic adjustable linear resistance to the lower and upper limbs. For the operation of the system and the treatment of the lower limbs, it is necessary to connect the JUST WALK™ system's rollers mechanism to the system's sandal, which includes a consumable component, which is the sandal's disposable ASM sole.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II code A9300, “Exercise equipment” describes JUST WALK™ ASM SOLE.

JUST WALK™ is an external device that enables relearning of proper movement patterns for gait coordination, balance, and upper limb coordination. JUST WALK™ is equipped to provide resistance training aimed at strengthening the upper and lower limbs. An individual can wear the device while performing exercises aimed at improving stability and/or strengthening muscle mass. JUST WALK™’s proprioceptive training capability allows for a variety of exercises, including seated activities like knee and ankle flexion/extension, as well as upper limb rehabilitation with resistance. This demonstrates that the device is designed primarily as a rehabilitative tool to support exercise for individuals with neurological or orthopedic conditions, rather than being focused on improving joint range of motion. JUST WALK™ ASM SOLE is similar to other devices in HCPCS Level II code A9300.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

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

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

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

All five of these conditions must be met for equipment to be classified as DME. JUST WALK™ does not meet one of the conditions that must be met for equipment to be classified as DME:

> **Is primarily and customarily used to serve a medical purpose** - While there are DME items commonly used in conjunction with rehabilitation, we believe the primary purpose of the JUST WALK™ is to enhance exercise sessions during the rehabilitation process. Per the applicant, the individual can wear the device while performing exercises aimed at improving stability and/or strengthening muscle mass in the lower and/or upper extremities. The individual can also perform supplementary exercises for muscle strengthening of lower and upper extremities if the product is mounted on an external fixture. The manufacturer's website markets the device as "The Wearable Resistance Gym: Anytime, Anywhere". The website goes on to say, "When muscle strengthening is the priority, Just Walk transforms into a cutting-edge wearable resistance gym, enabling strength and endurance training through functional, weight-bearing movements in standing or seated positions – all without excessive load impact."[13] There are also other products currently assigned under HCPCS Level II code A9300 (exercise equipment) on the Pricing Data Analysis and Coding (PDAC) Product Classification List, which similarly allow individuals to receive rehabilitation therapy and stimulate neuroplasticity to improve activities of daily living.
>
> The applicant has asserted that the JUST WALK™ is a dynamic adjustable extension/flexion device (e.g., HCPCS Level II code L1815), which are covered by Medicare as DME. However, we do not agree that the JUST WALK™ is a dynamic adjustable extension/flexion device. Dynamic adjustable extension/flexion devices provide stretching and work to increase range of motion, mainly to address joint contractures. Although the JUST WALK™ claims to offer treatment across both upper and lower body segments, addressing extension and flexion movements in multiple joints simultaneously (elbow, shoulder, knee, and ankle), we do not believe the device actually provides the same range of motion improvements as those other devices. The JUST WALK™ appears to be more focused on assisting with walking and reducing fall risk, and we have not seen information that would suggest it plays a significant role in joint rehabilitation like those dynamic adjustable extension/flexion devices. As explained by the applicant, JUST WALK™ is equipped to provide resistance training aimed at strengthening the upper and lower limbs. This is achieved through the use of resistance rollers, upper extremity handles, and external connections. The system not only aids in increasing muscle mass but also enhances joint approximation and proprioception. Furthermore, JUST WALK™'s proprioceptive training capability allows for a variety of exercises, including seated activities like knee and ankle flexion/extension, as well as upper limb rehabilitation with resistance. This demonstrates that the device is designed primarily as a rehabilitative tool to support exercise for individuals with neurological or orthopedic conditions, rather than being focused on improving joint range of motion.

[13] https://www.chaban-medical.com/just-walk-page

After taking all of this information into account, we consider the JUST WALK™ to be a type of exercise equipment and as a result cannot be DME. Per National Coverage Determination (NCD) 280.1, exercise equipment is not DME because it is not primarily medical in nature. Chapter 15 of the Medicare Benefit Policy Manual (Pub. 100-2) elaborates on equipment presumptively nonmedical by saying, "Equipment which is primarily and customarily used for a nonmedical purpose may not be considered "medical" equipment for which payment can be made under the medical insurance program. This is true even though the item has some remote medically related use. For example, in the case of a cardiac individual, an air conditioner might possibly be used to lower room temperature to reduce fluid loss in the individual and to restore an environment conducive to maintenance of the proper fluid balance. Nevertheless, because the primary and customary use of an air conditioner is a nonmedical one, the air conditioner cannot be deemed to be medical equipment for which payment can be made."

Preliminary Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Summary of Public Feedback

Chaban Medical disagreed with CMS' published preliminary determinations. JUST WALK™ is a wearable and an external dynamic adjustable medical device that is engineered to treat individuals with orthopedic trauma and neurological disorders. It uses a closed-loop neuro-feedback mechanism of action, designed solely for impaired gait phase rehabilitation. The device itself works based on magnetic variable linear resistance levels, and the mechanical creation of resistance as the patient moves forward and is different from what currently exists on the market, such as fitness equipment. As an individual's leg moves forward and is lifted up, it creates a stable resistance, that helps the brain understand where the limb is spatially. This is known as enhanced proprioception, which allows the brain to be taught and relearn the intended movements that are required to ambulate. This device again operates by creating and changing stable resistance over the limbs, that enhances motor learning, muscle strength, and reteaches the brain. Pressure is created from the shoulders down to the waist and then tension from the legs up to the waist. The speaker stated that the medical purpose of this device is gait rehabilitation for in-home use, so it is not suitable to be used by a healthy person, as it has no training benefits. It is non-recreational and thus cannot serve as general fitness or exercise equipment.

The speaker further stated that this product require a prescription from a licensed therapist, who adjusts and optimizes the treatment to each individual patient. This product cannot be used by successive patients, and there is no rental and/or refurbishment program, at this point in time. Individuals can use it twice a day, for up to 10 to 15 minutes per day, to enhance gait coordination, balance, and upper limb coordination. From basic motions to complex physical activities, JUST WALK™ guides the patient's body through the whole walking cycle, swing to stance. The speaker reiterated that this device increases the proprioception sensation and stimulates the individual's own body to instinctively relearn correct natural motion throughout their entire rehabilitation journey from simple motion to complex physical functionality. This type of resistance cannot be achieved using elastic bands or springs, which alter their resistance based on extension and primarily target muscle mass rather than coordinated motor control. Unlike weights, which apply a fixed downward force, this system

not only resists the patient's movement but also helps by supporting leg elevation during the walking cycle's swing phase and applying upward resistance that stimulates foot lift during the step and promotes joint approximation through targeted compression which again enhance proprioception.

CMS Final HCPCS Coding Determination

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

Existing HCPCS Level II code A9300, "Exercise equipment" to describe JUST WALK™ ASM SOLE.

JUST WALK™ is an external device that enables relearning of proper movement patterns for gait coordination, balance, and upper limb coordination. JUST WALK™ is equipped to provide resistance training aimed at strengthening the upper and lower limbs. An individual can wear the device while performing exercises aimed at improving stability and/or strengthening muscle mass. JUST WALK™'s proprioceptive training capability allows for a variety of exercises, including seated activities like knee and ankle flexion/extension, as well as upper limb rehabilitation with resistance. This demonstrates that the device is designed primarily as a rehabilitative tool to support exercise for individuals with neurological or orthopedic conditions, rather than being focused on improving joint range of motion. JUST WALK™ is similar to other devices in HCPCS Level II code A9300.

Final Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

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

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

All five of these conditions must be met for equipment to be classified as DME. However, JUST WALK™ does not meet two of the conditions that must be met for equipment to be classified as DME:

> **Is primarily and customarily used to serve a medical purpose** - We continue to consider the JUST WALK™ to be a type of exercise equipment and therefore it is not DME.

The applicant clarified in their written comments that the FDA classified the JUST WALK™ under 21 CFR 890.5370. § 890.5370 represents “Nonmeasuring exercise equipment”. Per § 890.5370, “Nonmeasuring exercise equipment consist of devices intended for medical purposes, such as to redevelop muscles or restore motion to joints or for use as an adjunct treatment for obesity. Examples include a prone scooter board, parallel bars, a mechanical treadmill, an exercise table, and a manually propelled exercise bicycle.”

The device’s regulation classification name therefore supports the conclusion that the device is a type of exercise equipment; specifically, nonmeasuring exercise equipment. Parallel bars and treadmills are listed as examples of nonmeasuring exercise equipment under § 890.5370 and National Coverage Determination (NCD) 280.1 specifies both devices are exercise equipment and not DME. NCD 280.1 holds that treadmill exercisers are exercise equipment, and that they are not primarily medical in nature. NCD 280.1 considers parallel bars to be support exercise equipment. Therefore, there is precedent for which devices classified under 21 CFR 890.5370 are also listed in NCD 280.1 as exercise equipment rather than DME.

Items like the JUST WALK™ classified under § 890.5370 may be intended for a medical purpose, but they are not necessarily DME. For an item to be classified as DME, specific conditions must be met under 42 CFR 414.202. The specific condition that the JUST WALK™ does not meet is that the equipment must be primarily and customarily used to serve a medical purpose. While there are DME items commonly used in conjunction with rehabilitation, we believe the primary purpose of the JUST WALK™ is to enhance exercise sessions during the rehabilitation process.

After taking all of this information into account, we consider the JUST WALK™ to be a type of exercise equipment and as a result is not DME. As explained, per NCD 280.1, exercise equipment is not DME because it is not primarily medical in nature. Chapter 15 of the Medicare Benefit Policy Manual (Pub. 100-2) elaborates on equipment presumptively nonmedical by saying, “Equipment which is primarily and customarily used for a nonmedical purpose may not be considered ‘medical’ equipment for which payment can be made under the medical insurance program. This is true even though the item has some remote medically related use.”

Generally is not useful to an individual in the absence of an illness or injury – In the public meeting the applicant claimed that the JUST WALK™ is not useful to an individual in the absence of an illness or injury. The applicant said that the device is not usable by healthy individuals, that there is no training benefit for healthy individuals, and that it is used by those with a neuromotor deficit. The applicant said that those without functional limitations would not be able to properly use it, nor would they benefit from it. The applicant also said that the JUST WALK™ was designed for use by neurological and/or orthopedic patients.

Although the device may be used by neurological and/or orthopedic patients, we disagree with the applicant's assertion that the device lacks utility for those without an illness or injury. The device is classified under 21 CFR 890.5370 as "nonmeasuring exercise equipment," a category that includes devices with general fitness applications. Other equipment in this same classification—such as treadmills and exercise bicycles—are routinely used by healthy individuals for fitness, athletic

training, and general wellness purposes. This classification suggests the device has broader use beyond those with specific medical conditions.

We indicated in our preliminary decision that the manufacturer's website markets the device as "The Wearable Resistance Gym: Anytime, Anywhere". The website goes on to say, "When muscle strengthening is the priority, Just Walk transforms into a cutting-edge wearable resistance gym, enabling strength and endurance training through functional, weight-bearing movements in standing or seated positions – all without excessive load impact."[14] We believe that these marketing materials also show that the device has broader use for general fitness purposes beyond those with specific medical conditions.

In addition, it is unclear if the JUST WALK™ meets the 3-year minimum lifetime requirement. The applicant attested in their written comments that the device is intended for use up to 3 years, that it is made of robust materials, and is suitable for daily multi-year use. However, we have reviewed lifetime testing results submitted by the applicant and based on the information in these results we are currently unable to conclude that the device has an expected life of at least 3 years. The testing results indicate components of the device fail prior to 3 years and we have concerns that this may indicate that the device does not have an expected life of at least 3 years.

We also continue to believe that the JUST WALK™ is not a dynamic adjustable extension/flexion device (e.g., HCPCS Level II code E1800). Such devices are prescriptive passive motion systems used post-surgically to prevent joint stiffness or restore isolated range of motion under controlled, passive conditions. These devices apply external, passive movement to a single joint without requiring active muscle engagement from the patient. In contrast, the JUST WALK™ system is designed for dynamic gait rehabilitation. It requires active patient participation, utilizes variable resistance, engages multiple joints, and focuses on whole-body coordination. Its clinical intent, mechanism of action, and therapy setting are therefore fundamentally different from such devices.

Final Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

[14] https://www.chaban-medical.com/just-walk-page

Peristeen® Plus Transanal Irrigation System - HCP2406251AW47

Topic/Issue

Request for Medicare payment determination for Peristeen® Plus Transanal Irrigation System (TAI).

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 clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway 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 Final HCPCS Coding Determination

CMS revised HCPCS Level II code A4459, “Manual transanal irrigation system, includes water reservoir, pump, tubing, and accessories, without catheter, any type” to differentiate between enema systems and transanal irrigation systems, effective April 1, 2025.

Medicare Benefit Category Determination

CMS determined that Peristeen® Plus Transanal Irrigation System is a prosthetic device, effective April 1, 2025.

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.

To determine whether TAI devices described under HCPCS Level II code A4459 are comparable to items with existing codes, we undertook a detailed examination of its physical and mechanical components along with its function and intended use and additional attributes. We carefully reviewed the existing HCPCS Level II codes as part of our payment review and did not find any codes that adequately compare to the TAI devices. We believe this device is not comparable to existing codes and for this reason, have determined that the gap-filling methodology is appropriate for establishing fees for this device.

To develop an appropriate Medicare payment amount in accordance with the gap filling procedure, we must identify appropriate commercial pricing for the underlying items. Only verifiable supplier or commercial pricing may be used for gap-filling purposes (84 FR 60739). We have found several internet retail prices for items that would be classified in HCPCS Level II code A4459, as shown in the below table. In addition, we identified payment information from the Veterans Administration (VA) Supply Schedule for the Coloplast Peristeen® Plus device that we verified against the Federal Supply Schedule, and used in establishing the payment determination. For two products, the internet retail pricing included a certain number of catheters which are not included in the HCPCS Level II code A4459. In these instances, we backed out the cost of the rectal catheters from the TAI device and accessory internet pricing. The median of these prices is $235.42.

Product Name	**Model**	**Price**	**Source Date**	**Source**
Peristeen Plus Anal Irrigation System (Catheter Not Included)	29152	$266.94	02/2025	https://medicalmonks.com/product/peristeen-plus-anal-irrigation-system/?srsltid=AfmBOoro1FCwc_oK8nCX498ZwYTn0zp_pOOPhsI_3Sx3m-Skb5hZMhuO
Peristeen Plus Trananal Irrigation Kits (Catheter Not Included)	29152	$382.99	02/2025	https://rpsmedcare.com/product-details/coloplast-corp-peristeen-plus-transanal-irrigation-kits-29152-1-each
Peristeen Plus Transanal Irrigation System without catheters	29152	$361.08	02/2025	https://www.binsons.com/product/peristeen-plus-transanal-irrigation-system?srsltid=AfmBOoqkgTluK1QxYcoEPVtlg1Q6OnKcqoj_Zk-SqysRUK3LmgU-RbTJ

Product Name	Model	Price	Source Date	Source
Navina Classic Manual Pump System	6900640 *	$234.01	02/2025	https://curemedrx.com/products/rectal-refill-catheter-navina-classic-regular?_pos=1&_sid=1aadcf61b&_ss=r&variant=44382592991459
Navina Classic System	6900640 *	$246.17	02/2025	https://www.adwdiabetes.com/product/26798/wellspect-navina-classic-system-regular-refill?srsltid=AfmBOoqu6oyPxVNNP7xy7GKpyY-Bpmku3EXlLOvwBQp2RizrA6khNgeZ
Navina Classic System	6900640 *	$236.83	02/2025	https://www.suprememed.com/rectal-refill-catheter-navina-classic/
Aquaflush Lite TransAnal Irrigation System	AFLS*	$130.75	02/2025	https://medicalmonks.com/product/aquaflush-lite-trans-anal-irrigation-system/?srsltid=AfmBOoqWM2qXVpDT7jPRWYUoSrPt9ciwJwKsmxiFez4owEV3nxbIpny2
Aquaflush Transanal Irrigation Standard Starter Set	AFLS*	$157.65	02/2025	https://medicalmega.com/Aquaflush-Transanal-Irrigation-Standard-Starter-Set
Aquaflush Irrigation System, Anal Starter	AFLS*	$199.99	02/2025	https://curemedrx.com/products/irrigator-bowel-starter-system-aquaflush?srsltid=AfmBOooB3lJZcA91N6H7dO9-_N7c3YaH7m7CkSqrnc-ff53WzryFkLVq&variant=44382563696867
Peristeen Plus Anal Irrigation System (Catheter Not Included)**	29152	$123.78	02/2025	https://www.vendorportal.ecms.va.gov/NAC/MedSurg/Details?lognumber=8503414&type=fss

*Pricing for these models subtracts payment for the number of catheters that are included in the system.
**Pricing from the Veterans Administration (VA) Supply Schedule

After applying the annual deflation and update factors to the median price of $235.42, the 2025 purchase payment amount for HCPCS Level II code A4459 would be approximately $157.27. Payment would be made on a purchase basis in accordance with section 1834(h)(1)(A) of the Social Security Act. Fee schedules are updated annually.

Pricing Indicator = 38

Summary of Public Feedback

Coloplast, Corp. and other commenters disagreed with CMS' published preliminary payment determination for HCPCS Level II code A4459. The speaker and several commenters objected to the payment amount, suggesting that CMS should include a broader array of payment sources in the pricing to better represent current payment levels by payers. They recommended incorporating publicly available state Medicaid fee schedule amounts in the pricing array and provided fee schedule amounts for HCPCS Level II code A4459 from seven state Medicaid plans: Colorado, Georgia, Idaho, New Hampshire, Pennsylvania, Utah, and Wisconsin. Commenters noted that the preliminary payment determination amounts appear to be significantly lower than other payers' rates and indicated that the inclusion of state Medicaid fee schedule amounts will assure better access to these devices.

The speaker also recommended applying an appropriate mark-up to the VA Supply Schedule pricing used in the preliminary determination, arguing that VA prices do not capture the total cost to deliver, service and support a device. They referenced a 1999 CMS proposed notice that applied a 67 percent mark-up to VA wholesale prices (64 FR 44227) as precedent for this adjustment.

Additionally, commenters recommended that CMS include only pricing information for TAI devices in the gap-filling payment calculations, suggesting that non-TAI devices should be excluded from the pricing array (i.e., Aquaflush Lite TransAnal Irrigation System; Aquaflush Transanal Irrigation Standard Starter Set; and Aquaflush Irrigation System, Anal Starter). Other commenters noted that the preliminary determination payment amount is less than their product costs and would restrict providers' ability to supply these bowel management products.

Final Medicare Payment Determination

We appreciate the comments provided in response to CMS' published preliminary payment recommendation. After careful consideration of all comments received, CMS is finalizing its preliminary payment determination to establish the Medicare payment amounts in accordance with the "gap filling" methodology regulations at 42 CFR 414.238(c) based on internet pricing and payment information from the Veterans Administration (VA) Supply Schedule.

The preliminary payment determination is based on internet retail pricing as well as non-Medicare payer data and is therefore in compliance with current regulations at 42 CFR 414.238(c). We note anecdotally that we reviewed publicly available state Medicaid fee schedule amounts following the public meeting and noticed some inconsistencies in the listed amounts, including a notably high fee of $2,415.34 for the single system described by HCPCS Level II code A4459 We note that internet retail pricing has been a longstanding method of pricing for Medicare DMEPOS items that has not hindered beneficiary access. We repeat that use of this pricing is in compliance with current regulations at 42 CFR 414.238(c), and we have determined that no errors were made in establishing the preliminary fee schedule amounts.

The applicant recommended applying a markup to VA Supply Schedule pricing, citing a 1999 CMS precedent of a 67 percent markup on VA wholesale prices. However, our preliminary payment determination uses VA Supply Schedule pricing for the Coloplast Peristeen® Plus device - the same pricing available on the Federal Supply Schedule - rather

than wholesale prices. The VA pays suppliers for veterans to have appropriate access to these systems and we have not seen evidence that beneficiaries experience difficulties accessing these items through the VA. The Supply Schedule pricing already includes delivery and the Coloplast Peristeen® Plus product labeling provides detailed usage guidance upon receipt of the product. We are not aware of additional VA service and support costs that would be necessary for this purchased product. The VA Supply Schedule pricing is non-Medicare payer data and therefore is an appropriate source for commercial pricing information in accordance with regulations at §414.238.

While we appreciate the comments received, we disagree with the assertion that the preliminary payment determination calculations include devices that are not TAI devices. In the Second Biannual 2024 HCPCS Level II coding cycle, we determined that TAI devices with cone-based rectal catheters that have a sealing function can be classified under the prosthetic devices benefit category. All the balloon and cone-based rectal catheter TAI systems included in the preliminary payment determination pricing array are appropriate and meet the descriptor for HCPCS Level II code A4459.

Therefore, we are finalizing our preliminary payment determination with the gap-filled fee schedule amounts established as discussed in the preliminary payment determination. The median of the internet and VA Supply Schedule pricing for HCPCS Level II A4459 is $235.42. The annual deflation factors, specified in program instructions, are applied to the current pricing and the deflated amount is then increased by the update factors specified in section 1834(h)(4) of the Act. The average 2025 purchase fee schedule amount for HCPCS Level II code A4459 would be approximately $157.27. Payment for HCPCS Level II code A4459 would be made on a purchase basis. Fee schedules are updated annually.

Pricing Indicator = 38

Peristeen® Plus Transanal Irrigation System - HCP240625E95UJ

Topic/Issue

Request for Medicare payment determination for HCPCS Level II code A4453, “Rectal balloon catheter for use with a transanal irrigation device, original issue and replacement.”

Applicant's Summary

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 r received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway 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 Final HCPCS Coding Determination

CMS revised HCPCS Level II code A4453, “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, effective April 1, 2025.

Medicare Benefit Category Determination

CMS determined that rectal balloon and cone catheters used with TAI devices are prosthetic devices, effective April 1, 2025.

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 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 determine whether rectal catheters used with TAI devices described under HCPCS Level II code A4453 are comparable to items with existing codes, we undertook a detailed examination of the catheter's physical and mechanical components along with its function and intended use and additional attributes. We carefully reviewed the existing HCPCS Level II codes as part of our payment review and did not find any codes that adequately compare to the TAI rectal catheters. We believe this device is not comparable to existing codes and for this reason, have determined that the gap-filling methodology is appropriate for establishing fees for this device.

To develop an appropriate Medicare payment amount in accordance with the gap filling procedure, we must identify appropriate commercial pricing for the underlying items. Only verifiable supplier or commercial pricing may be used for gap-filling purposes (84 FR 60739). We have found several internet retail prices for items that would be classified in HCPCS Level II code A4459, as shown in the below table. In addition, we identified payment information from the Veterans Administration (VA) Supply Schedule for Coloplast Peristeen® Plus that we verified against the Federal Supply Schedule, and used in establishing the payment determination. We note that some of the monthly rectal catheter retail prices as well as the Federal Supply Schedule pricing included payment for a single water reservoir. The median of these prices for a single rectal catheter is $20.56.

Product Name	**Model**	**Price**	**Source Date**	**Source**
Peristeen Plus Balloon Catheter Accessory	29142	$23.38	02/2025	https://www.discountcatheters.com/coloplast-29142-peristeen-plus-accessory-unit-regular-contains-1-water-bag-without-lid-and-15-single-use-rectal-catheters-bx
Peristeen Plus Balloon Catheter Accessory	29142	$23.38	02/2025	https://www.stomabags.com/coloplast-29142-peristeen-plus-accessory-unit-regular-contains-1-water-bag-without-lid-and-15-single-use-rectal-catheters
Peristeen Plus Balloon Catheter Accessory Unit	29142	$23.38	02/2025	https://www.onlinelivingaids.com/coloplast-29142-peristeen-plus-accessory-unit-regular-contains-1-water-bag-without-lid-and-15-single-use-rectal-catheters
Navina Catheter, Regular	6894040	$29.89	02/2025	https://www.atcmedical.com/AH6894040/product.aspx

Product Name	Model	Price	Source Date	Source
Navina Rectal Catheter, Regular	6894040	$20.68	02/2025	https://www.medicaleshop.com/navina-rectal-catheter-regular-10box?srsltid=AfmBOoqRrQtPThHFgh4ndsG6pC7OV89krd6v8Wj2A0L2b_e5v8QwafzE
Navina Catheter, Regular or Small	6894040	$20.44	02/2025	https://www.stomabags.com/wellspect-healthcare-6894040-wellspectnavina-catheter-regular
Aquaflush Lite Transanal Irrigation Cone Refill Pack	AFLA	$10.33	02/2025	https://medicalmonks.com/product/aquaflush-lite-trans-anal-irrigation-system/?srsltid=AfmBOop-o2A1a0FJxjIaoUQ4h-iWBZNjYCdP5RvmFb7S0S6hOc6n2BeT
Aquaflush Lite Refill Cone Kit	AFLA	$15.90	02/2025	https://www.adwdiabetes.com/product/24622/aquaflush-transanal-irrigation-refill-cones-kit-standard-size?srsltid=AfmBOoqzI8JiQP_VN2906kqu7e9JyKwVPugLd6jxzn6CckEUcRBxv_i5
Aquaflush Refill Cones	AFLA	$13.66	02/2025	https://www.discountcatheters.com/hr-pharmaceuticals-afla-aquaflush-transanal-irrigation-refill-cones-kit-standard-size-includes-15-refill-cones-and-15-lubricant-packets-ea
Peristeen Plus Catheters Kit *	29142	$16.42	02/2025	https://www.vendorportal.ecms.va.gov/NAC/MedSurg/Details?lognumber=8503412&type=fss

*Pricing from the Veterans Administration (VA) Supply Schedule

After applying the annual deflation and update factors to the median price of $20.56, the 2025 purchase payment amount for HCPCS Level II code A4453 would be approximately $13.76. Payment would be made on a purchase basis in accordance with section 1834(h)(1)(A) of the Social Security Act. Fee schedules are updated annually.

Pricing Indicator = 38

Summary of Public Feedback

Coloplast, Corp. and other commenters disagreed with CMS' published preliminary payment determination for HCPCS Level II code A4453. The speaker and several commenters objected to the payment amount, suggesting that CMS should include a broader array of payment sources to better represent current payment levels by payers. They recommended incorporating publicly available state Medicaid fee schedule amounts in the pricing array and provided fee schedule amounts for HCPCS Level II code A4453 from seven state Medicaid plans: Colorado, Georgia, Idaho, New Hampshire, Pennsylvania, Utah, and Wisconsin.

Commenters noted that the preliminary payment decision amounts appear to be significantly lower than other payers' rates and suggested that the inclusion of state Medicaid fee schedule amounts will assure better access to these devices.

The speaker also recommended applying an appropriate mark-up to the VA Supply Schedule pricing used in the preliminary decision, arguing that VA prices do not capture the total cost to deliver, service and support a device. They referenced a 1999 CMS proposed notice that applied a 67 percent mark-up to VA wholesale prices (64 FR 44227) as precedent for this adjustment. Another commenter advised that the Supply Schedule rates are inappropriate for gap-filling use because they are based on volume guarantees, exclusive contracts, and payment certainty which do not apply to traditional Medicare DMEPOS suppliers.

Additionally, commenters recommended that CMS include only pricing information for TAI devices in the gap-filling payment calculations, suggesting that non-TAI devices should be excluded from the pricing array (i.e., Aquaflush Lite Transanal Irrigation Cone Refill Pack; Aquaflush Lite Refill Cone Kit; and Aquaflush Refill Cones). Other commenters noted that the preliminary decision payment amount is less than their product costs and would restrict providers' ability to supply these bowel management products. One commenter felt that CMS should adjust the pricing multiplier to at least three times the internet retail prices used in the A4453 preliminary payment determination to represent all the additional cost required for an accredited organization to supply Medicare beneficiaries. The pricing multiplier would reflect the full regulatory burden of Medicare participation, delayed or uncertain payment terms, higher cost of capital and labor and alignment with the payment for other supply categories.

Final Medicare Payment Determination

We appreciate the comments provided in response to CMS' published preliminary payment recommendation. After careful consideration of all comments received, CMS is finalizing its preliminary payment determination to establish the Medicare payment amounts in accordance with the "gap filling" methodology regulations at 42 CFR 414.238(c) based on internet pricing and payment information from the Veterans Administration (VA) Supply Schedule.

The preliminary payment determination is based on internet retail pricing as well as non-Medicare payer data and is therefore in compliance with current regulations at 42 CFR 414.238(c). We note anecdotally that we reviewed publicly available state Medicaid fee schedule amounts following the public meeting and noticed some inconsistencies in the listed amounts, including fees of $1,140 and $2,233.55 for the catheter described by HCPCS Level II code A4453. We note that internet retail pricing has been a longstanding method of pricing for Medicare DMEPOS items that has not hindered beneficiary access. We repeat that use of this pricing is in compliance with current regulations at 42 CFR 414.238(c), and we have determined that no errors were made in establishing the preliminary fee schedule amounts.

The applicant recommended applying a markup to VA Supply Schedule pricing, citing a 1999 CMS precedent of a 67 percent markup on VA wholesale prices. However, our preliminary payment determination uses VA Supply Schedule pricing for the Coloplast Peristeen® Plus balloon rectal catheter-the same pricing available on the Federal Supply Schedule-rather than wholesale prices. The VA pays suppliers for veterans to have appropriate access to these catheters and we have not seen evidence that beneficiaries experience difficulties accessing these items through the VA. The Supply Schedule pricing

already includes delivery and the Coloplast Peristeen® Plus product labeling provides detailed usage guidance upon receipt of the product. We are not aware of additional VA service and support costs that would be necessary for this purchased product. The VA Supply Schedule pricing is non-Medicare payer data and therefore is an appropriate source for commercial pricing information in accordance with regulations at §414.238.

While we appreciate the comments received, we disagree with the assertion that the preliminary payment determination calculations include devices that are not TAI devices. In the Second Biannual 2024 HCPCS Level II coding cycle, we determined that TAI devices with cone-based rectal catheters that have a sealing function can be classified under the prosthetic devices benefit category. All the balloon and cone-based TAI system rectal catheters included in the preliminary payment determination pricing array are appropriate and meet the descriptor for HCPCS Level II code A4453.

Therefore, we are finalizing our preliminary payment determination with the gap-filled fee schedule amounts established as discussed in the preliminary payment determination. The median of the internet and VA Supply Schedule pricing for HCPCS Level II code A4453 is $20.56. The annual deflation factors, specified in program instructions, are applied to the current pricing and the deflated amount is then increased by the update factors specified in section 1834(h)(4) of the Act. The average 2025 purchase fee schedule amount for HCPCS Level II code A4453 would be approximately $13.76. Payment for HCPCS Level II code A4453 would be made on a purchase basis. Fee schedules are updated annually.

Pricing Indicator = 38

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. Rollz Motion is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). 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 previously 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. 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 Determination

CMS deferred the application for Rollz Motion in the Second Biannual 2024 HCPCS Level II coding cycle for additional consideration of the information provided in the application and research regarding the intended use and purpose of the equipment. After further analysis of Rollz Motion, we are now revising our preliminary coding determination to the following:

Establish a new HCPCS Level II code EXXXX, “Combination wheeled walker with seat and transport chair, folding, adjustable or fixed height” to describe the Rollz Motion.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

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

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

All five of these conditions must be met for equipment to be classified as DME. The Rollz Motion does not meet one of these conditions as follows:

> **Is appropriate for use in the home** - The Rollz Motion is described as a 2-in-1 product that provides both walker and wheelchair functions. It permits a user to ambulate independently when used as a walker and the user may sit down and be pushed by a caregiver when fatigued. The product's features include 4 large wheels, heavy duty, foldable, adjustable handlebars, back and seat to accommodate use as a walker or a wheelchair. The product is described as helpful for any environment including crossing doorsteps and curbs outside the home with a tilt function to lift wheels over the uneven terrain. Since the intended functions and capabilities of Rollz Motion are for use outside the home, the Rollz Motion does not fall within the DME benefit category.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Summary of Public Feedback

Rollz Mobility US Inc. partially disagreed with CMS' published preliminary determinations. Commenters supported the coding determination; however, it was noted that the Rollz Motion "performance" model is intended for outdoor use while the "regular" model is intended to be used indoors and therefore complies with all conditions for the DME benefit category.

CMS Final HCPCS Coding Decision

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

Establish a new HCPCS Level II code E0150, "Combination wheeled walker with seat and transport chair, folding, adjustable or fixed height" to describe the Rollz Motion.

Final Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

We appreciate the clarification that the Rollz Motion product associated with this application is the Rollz Motion, and not the Rollz Motion Performance. As explained in the Preliminary Medicare Benefit Category Determination, an item or service must be appropriate for use in the home. Rollz Motion permits a user to ambulate independently for longer distances when used as a walker and when fatigued, the individual may sit down and/or be pushed by a caregiver. We still consider the intended functions and capabilities of Rollz Motion to be for use outside the home, and the product marketing supports this conclusion. For example, the product website states "The Rollz Motion is made to support an active life so that you can still enjoy going out even with limited mobility" and it "is designed for those who refuse to let limited mobility hinder their adventures. Perfect for traveling, attending events, or simply enjoying a day out, this walker wheelchair combo keeps you on the move."

Final Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Power Assist Device - HCP250102G1G9P

Topic/Issue

Request to revise the existing HCPCS Level II code E0986, “Manual wheelchair accessory, push-rim activated power assist system” to reflect the technological advancements to power assist devices.

Applicant's suggested language: E0986, “Manual wheelchair accessory, power assist device”

Summary of Applicant's Submission

The National Coalition for Assistive and Rehabilitation Technology submitted a request to revise the existing HCPCS Level II code E0986 to reflect the technological advancements to power assist devices. A power-assisted wheelchair consists of an electric power add-on device (e.g., powered-wheels and/or a front-end/rear-end/under-chair attachment) that connects to a manual wheelchair's (MWC) frame to mitigate the physical load of MWC propulsion as needed. When HCPCS Level II code E0986 was originally established in 2004, it described one type of add-on power assist device in which the conventional propulsion wheels were replaced with motorized ones. The motor and batteries were in the hub of the wheel and activated by the wheelchair user executing force on the pushrim. Design innovation over the past 20 years has resulted in the development of more advanced control methods and mounting options for the add-on devices that create power-assisted wheelchairs that are no longer described by the existing HCPCS Level II code. A review of the add-on power assist devices currently coded under the code E0986, recognizes that each item is a manual wheelchair accessory, power assist device and has considered the design innovation of the array of control methods and mounting options that comprise these devices. From a clinical perspective, individuals with disabilities and complex medical conditions who have an intermittent need for powered mobility to perform and/or participate in their activities of daily living participate in a specialty evaluation by a licensed/certified medical professional who has specific training and experience in rehabilitation wheelchair evaluations who determines the most appropriate access method and mounting mechanism of the power add-on device for the individual.

CMS Preliminary HCPCS Coding Determination

Revise existing HCPCS Level II code E0986, “Manual wheelchair accessory, push-rim activated power assist system” to instead read, “Manual wheelchair accessory, power assist system” to describe the power assist systems for manual wheelchairs.

CMS proposes keeping the word “system” in the code descriptor to capture the entire accessory that might be needed to convert a manual wheelchair into a motorized one.

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

The current Medicare policy and prior established Medicare benefit category determination for HCPCS Level II code E0986 apply to this item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code E0986 apply to this product, if covered. Payment for existing HCPCS Level II code E0986 is made on a capped rental basis. Therefore, the 2025 monthly capped rental fee schedule amount would be approximately $679.65 on average for months 1 through 3, and approximately $509.74 on average for months 4 through 13, resulting in a total capped payment of $7,136.35 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 $815.56 on average for months 1 through 3, and approximately $509.74 on average for months 4 through 13, resulting in a total capped payment of $8,563.38 should there be 13 months of continuous use. Fee schedules are updated annually.

Pricing Indicator = 36

Summary of Public Feedback

The National Coalition for Assistive and Rehabilitation Technology agreed with CMS' published preliminary determinations. They agreed to remove the verbiage "push-rim activated" from HCPCS Level II code E0986 to now read "Manual wheelchair, power assist system". The speaker appreciated the CMS' recognition that design innovation and technology advancements have led to the development of an array power assist devices that may be attached, activated or engaged to temporarily transform a manual wheelchair to a power mobility device (PMD) and provide the beneficiary with intermittent assistance of power, on an as needed basis, and then return it to a MWC configuration. The speaker agreed to keep the word "system" in the code descriptor to capture the entire accessory, which includes the wheels, motors, batteries, a charger, a control mechanism, and the mounting hardware. However, they disagreed with the CMS' rationale in retaining the word "system" based on the premise that it "might be needed to convert a MWC into a motorized one." A power assist system temporarily transforms the MWC to a PMD for intermittent use only, and it does not permanently convert the MWC to a PMD. The speaker also agreed with CMS' preliminary payment rules and pricing determination associated with the existing HCPCS Level II code E0986, if covered.

CMS Final HCPCS Coding Determination

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

Revise existing HCPCS Level II code E0986, "Manual wheelchair accessory, push-rim activated power assist system" to instead read, "Manual wheelchair accessory, power assist system" to describe the power assist systems for manual wheelchairs.

We are finalizing our preliminary coding determination to retain the word "system" in the code descriptor to capture the entire accessory. We note that our preliminary determination language regarding converting a MWC into a PMD was not intended to imply that the system

could not be removed/deactivated but rather to describe how this option for an MWC provides a power assist feature to the wheelchair.

Final Medicare Benefit Category Determination

Durable Medical Equipment.

The current Medicare policy and prior established Medicare benefit category determination for HCPCS Level II code E0986 apply to this item.

Final Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code E0986 apply to this product, if covered. Payment for existing HCPCS Level II code E0986 is made on a capped rental basis. Therefore, the 2025 monthly capped rental fee schedule amount would be approximately $679.65 on average for months 1 through 3, and approximately $509.74 on average for months 4 through 13, resulting in a total capped payment of $7,136.35 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 $815.56 on average for months 1 through 3, and approximately $509.74 on average for months 4 through 13, resulting in a total capped payment of $8,563.38 should there be 13 months of continuous use. Fee schedules are updated annually.

Pricing Indicator = 36

HCPCS Level II Code E0984 - HCP2501018V97U

Topic/Issue

Request to discontinue existing HCPCS Level II code E0984, “Manual wheelchair accessory, power add-on to convert manual wheelchair to motorized wheelchair, tiller control.”

Summary of Applicant's Submission

The National Coalition for Assistive and Rehabilitation Technology submitted a request to discontinue existing HCPCS Level II code E0984. This code is deemed "not reasonable and necessary" for Medicare coverage in the Power Mobility Device Local Coverage Determination L33789. The three products listed on the Pricing, Data Analysis and Coding product classification list under HCPCS Level II code E0984 are no longer manufactured by Stand Aid of Iowa or Rio Mobility. Medicare utilization does not support retention of the code as there were only four units allowed between the years 2004 - 2009 and zero units were allowed since the year 2010. There are no products manufactured in the United States that convert a manual wheelchair to a tiller control motorized (power) mobility device. While the ability to provide an "alternative drive control" method for a power assist device is clinically relevant, a complete conversion of a manual wheelchair to a tiller control power mobility device is not, as this would be deemed a change in medical condition and warrant the recommendation of a dedicated power mobility device instead.

CMS Preliminary HCPCS Coding Determination

The HCPCS Level II coding system is a standardized system for identifying items and services. These codes are for the use of all private and public health insurers. It is not a methodology or system for making coverage or payment determinations, and the existence of a code does not, in itself, determine coverage or non-coverage for an item or service. Insurers have flexibility to determine their coverage and payment policies regarding what code(s) may be reported on a claim to describe the product. Even though the existing HCPCS Level II code E0984 was deemed "not reasonable and necessary" for coverage by Medicare, there are private insurers who might use the code. Additionally, HCPCS Level II codes may apply to products that are manufactured outside of the United States (U.S.) but could be available within the U.S. market. When an existing code becomes obsolete or is duplicative of another code, CMS may discontinue the code. We are aware that Medicaid has existing coverage policies related to HCPCS Level II code E0984. We welcome information from other insurers to demonstrate a need to discontinue existing HCPCS Level II code E0984.

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

The current Medicare policy and prior established Medicare benefit category determination for HCPCS Level II code E0984 apply to this item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code E0984 apply to this product, if covered. Payment for existing HCPCS Level II code E0984 is made

on a capped rental basis. Therefore, the 2025 monthly capped rental fee schedule amount would be approximately $252.11 on average for months 1 through 3, and approximately $189.08 on average for months 4 through 13, resulting in a total capped payment of $2,647.13 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

Summary of Public Feedback

The National Coalition for Assistive and Rehabilitation Technology disagreed with CMS' published preliminary determination to retain HCPCS Level II codes E0983 and E0984. The speaker stated that HCPCS Level II codes E0983 and E0984 are legacy codes that are obsolete in today's environment. They stated that there is no code verified medical products available or anticipated to be made available in the U.S. that convert a manual wheelchair (MWC) to a power mobility device (PMD), thereby meeting these code definitions. They further stated that there has been zero utilization of either of these two HCPCS Level II codes within the Medicare program since 2010; in addition, Medicare has deemed HCPCS Level II codes E0983 and E0984 "not reasonable and necessary." The speaker stated that 49/50 state Medicaid programs either do not cover or do not have coverage criteria published for these two codes; and the one state Medicaid program that does list criteria for coverage cautions against its use. Clinically, a change in medical condition that necessitates the individual's MWC to be converted to a PMD is better met by an independently tested, code verified PMD. Finally, the HCPCS Level II codes E0983 and E0984 are duplicative of current PMD codes and are unnecessary.

CMS Final HCPCS Coding Determination

We appreciate the comments provided in response to CMS' published preliminary determinations. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary coding determination. CMS has not identified a need to discontinue existing HCPCS Level II code E0984. We are aware that Medicaid has existing coverage policies related to HCPCS Level II code E0984. At this time, we have not heard any insurers demonstrate a need to discontinue existing HCPCS Level II code E0984.

Final Medicare Benefit Category Determination

Durable Medical Equipment.

The current Medicare policy and prior established Medicare benefit category determination for HCPCS Level II code E0984 apply to this item.

Final Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code E0984 apply to this product, if covered. Payment for existing HCPCS Level II code E0984 is made

on a capped rental basis. Therefore, the 2025 monthly capped rental fee schedule amount would be approximately $252.11 on average for months 1 through 3, and approximately $189.08 on average for months 4 through 13, resulting in a total capped payment of $2,647.13 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

HCPCS Level II Code E0983 - HCP250101D2GTH

Topic/Issue

Request to discontinue existing HCPCS Level II code E0983, “Manual wheelchair accessory, power add-on to convert manual wheelchair to motorized wheelchair, joystick control.”

Summary of Applicant's Submission

The National Coalition for Assistive and Rehabilitation Technology submitted a request to discontinue existing HCPCS Level II code E0983. This code is deemed "not reasonable and necessary" for coverage in the Power Mobility Device Local Coverage Determination L33789. The three products listed on the Pricing, Data Analysis and Coding product classification list under HCPCS Level II code E0983 are no longer manufactured by Frank Mobility Systems Inc. Medicare utilization does not support retention of the code as there were only twenty-three units allowed between the years 2004 - 2009 and zero units allowed since the year 2010. There are no products manufactured in the United States that convert a manual wheelchair to a joystick control motorized (power) mobility device. While the ability to provide an "alternative drive control" method for a power assist device is clinically relevant, a complete conversion of a manual wheelchair to a joystick control power mobility device is not, as this would be deemed a change in medical condition and warrant the recommendation of a dedicated power mobility device instead.

CMS Preliminary HCPCS Coding Determination

The HCPCS Level II coding system is a standardized system for identifying items and services. These codes are for the use of all private and public health insurers. It is not a methodology or system for making coverage or payment determinations, and the existence of a code does not, in itself, determine coverage or non-coverage for an item or service. Insurers have flexibility to determine their coverage and payment policies regarding what code(s) may be reported on a claim to describe the product. Even though the existing HCPCS Level II code E0983 was deemed "not reasonable and necessary" for coverage by Medicare, there are private insurers who might use the code. Additionally, HCPCS Level II codes may apply to products that are manufactured outside of the United States (U.S.), but available within the U.S. market (e.g., Alber E-fix M35 and Astris PME Light Drive Power Folding System). When an existing code becomes obsolete or is duplicative of another code, CMS may discontinue the code. We are aware that Medicaid has existing coverage policies related to HCPCS Level II code E0983. We welcome information from other insurers to demonstrate a need to discontinue existing HCPCS Level II code E0983.

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

The current Medicare policy and prior established Medicare benefit category determination for HCPCS Level II code E0983 apply to this item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code E0983 apply to this product, if covered. Payment for existing HCPCS Level II code E0983 is made on a capped rental basis. Therefore, the 2025 monthly capped rental fee schedule amount would be approximately $341.84 on average for months 1 through 3, and approximately $256.38 on average for months 4 through 13, resulting in a total capped payment of $3,589.32 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

Summary of Public Feedback

The National Coalition for Assistive and Rehabilitation Technology disagreed with CMS' published preliminary determinations to retain HCPCS Level II codes E0983 and E0984. The speaker stated that HCPCS Level II codes E0983 and E0984 are legacy codes that are obsolete in today's environment. They stated that there is no code verified medical products available or anticipated to be made available in the U.S. that convert a manual wheelchair (MWC) to a power mobility device (PMD), thereby meeting these code definitions. They further stated that there has been zero utilization of either of these two HCPCS Level II codes within the Medicare program since 2010; in addition, Medicare has deemed HCPCS Level II codes E0983 and E0984 "not reasonable and necessary." The speaker stated that 49/50 state Medicaid programs either do not cover or do not have coverage criteria published for these two codes; and the one state Medicaid program that does list criteria for coverage cautions against its use. Clinically, a change in medical condition that necessitates the individual's MWC to be converted to a PMD is better met by an independently tested, code verified PMD. Finally, the HCPCS Level II codes E0983 and E0984 are duplicative of current PMD codes and are unnecessary.

CMS Final HCPCS Coding Determination

We appreciate the comments provided in response to CMS' published preliminary determinations. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary coding determination. CMS has not identified the need to discontinue existing HCPCS Level II code E0983. We are aware that Medicaid has existing coverage policies related to HCPCS Level II code E0983. At this time, we have not heard any insurers demonstrate a need to discontinue existing HCPCS Level II code E0983.

Final Medicare Benefit Category Determination

Durable Medical Equipment.

The current Medicare policy and prior established Medicare benefit category determination for HCPCS Level II code E0983 apply to this item.

Final Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code E0983 apply to this product, if covered. Payment for existing HCPCS Level II code E0983 is made on a capped rental basis. Therefore, the 2025 monthly capped rental fee schedule amount would be approximately $341.84 on average for months 1 through 3, and approximately $256.38 on average for months 4 through 13, resulting in a total capped payment of $3,589.32 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

InnovaMatrix® FD - HCP241114UJG47

Topic/Issue

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

Applicant's suggested language: XXXXX, “Innovamatrix fd, per square centimeter”

Summary of Applicant's Submission

Convatec Triad Life Sciences, LLC submitted a request to establish a new HCPCS Level II code to identify InnovaMatrix® FD. InnovaMatrix® FD received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on June 26, 2024. InnovaMatrix® FD is a sterile, single use, medical device consisting of extracellular matrix derived from porcine placental material. InnovaMatrix® FD is composed of collagen, elastin, laminin, fibronectin, hyaluronic acid and sulfated glycosaminoglycans and is produced in sheet form in a variety of sizes. This biodegradable wound matrix provides a protective cover to the wound. InnovaMatrix® FD is intended for management of variety wounds such as pressure ulcers, diabetic ulcers, vascular ulcers, tunneled/undermined wounds, surgical wounds, trauma wounds and draining wounds. It is applied on a wound after the wound bed is prepared using standard debridement methods. InnovaMatrix® FD is supplied terminally sterile, in a single use package, and in a variety of sizes up to 25 square centimeters.

CMS Preliminary HCPCS Coding Determination

Establish a new HCPCS Level II code AXXXX, “Innovamatrix fd, per square centimeter” to describe InnovaMatrix® FD.

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

Convatec Triad Life Sciences, LLC agreed with CMS’ published preliminary determination.

CMS Final HCPCS Coding Determination

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

Establish a new HCPCS Level II code A2039, “Innovamatrix fd, per square centimeter” to describe InnovaMatrix® FD.

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.

GSH Immunity® - HCP240930D7YRX

Topic/Issue

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

The applicant did not submit any suggested language.

Summary of Applicant's Submission

GSH Labs Inc. submitted a request to establish a new HCPCS Level II code to identify GSH Immunity®. GSH Immunity® is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). GSH Immunity® is a nutraceutical (bonded cysteine supplement) glutathione precursor powdered product. GSH Immunity® is a natural food protein concentrate which assists the body in maintaining optimal concentrations of glutathione by supplying the precursors required for intracellular glutathione synthesis and is clinically proven to raise glutathione values. Glutathione is a tightly regulated intracellular constituent and is limited in its production by negative feedback inhibition of its own synthesis through the enzyme gamma-glutamylcysteine synthetase, thus greatly minimizing any possibility of overdose. Glutathione augmentation is a strategy developed to address glutathione deficiency, high oxidative stress, immune deficiency, and xenobiotic overload in which glutathione plays a part in detoxifying the xenobiotic in question. Glutathione deficiency states include but are not limited to human immunodeficiency virus, acquired immunodeficiency syndrome, infectious hepatitis, certain types of cancers, cataracts, Alzheimer’s Disease, Parkinson's, chronic obstructive pulmonary disease, asthma, radiation, and poisoning by acetaminophen.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II code B4155, “Enteral formula, nutritionally incomplete/modular nutrients, includes specific nutrients, carbohydrates (e.g., glucose polymers), proteins/amino acids (e.g., glutamine, arginine), fat (e.g., medium chain triglycerides) or combination, administered through an enteral feeding tube, 100 calories = 1 unit” together with modifier BO “administered orally and not by a feeding tube” describes GSH Immunity®.

Preliminary Medicare Benefit Category Determination

Enteral nutrient falling under the prosthetic device benefit if administered via a feeding tube and all other requirements for coverage as a prosthetic device and enteral nutritional therapy are met. No Medicare DMEPOS benefit category, when administered orally.

Medicare pays for enteral nutritional therapy administered through feeding tubes under the prosthetic device benefit category, with the feeding tube being the prosthetic device. However, Medicare does not pay for oral nutrition. Therefore, only when administered with a feeding tube is this item is classified as enteral nutrition.

Preliminary Medicare Payment Determination

If covered as an enteral nutrient administered through feeding tubes, the payment rules and pricing associated with existing HCPCS Level II code B4155 apply to this product. The

current average 2025 fee schedule amount for HCPCS Level II code B4155 is $0.92 (non-rural) and $1.03 (rural).

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 = 39

Summary of Public Feedback

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

CMS Final HCPCS Coding Determination

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

Existing HCPCS Level II code B4155, "Enteral formula, nutritionally incomplete/modular nutrients, includes specific nutrients, carbohydrates (e.g., glucose polymers), proteins/amino acids (e.g., glutamine, arginine), fat (e.g., medium chain triglycerides) or combination, administered through an enteral feeding tube, 100 calories = 1 unit" together with modifier BO "administered orally and not by a feeding tube" to describe GSH Immunity®.

Final Medicare Benefit Category Determination

Enteral nutrient falling under the prosthetic device benefit if administered via a feeding tube and all other requirements for coverage as a prosthetic device and enteral nutritional therapy are met. No Medicare DMEPOS benefit category, when administered orally.

Final Medicare Payment Determination

If covered as an enteral nutrient administered through feeding tubes, the payment rules and pricing associated with existing HCPCS Level II code B4155 apply to this product. The current average 2025 fee schedule amount for HCPCS Level II code B4155 is $0.92 (non-rural) and $1.03 (rural).

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 = 39

Digital Hearing Aid - HCP240828XBMU1

Topic/Issue

Request to establish four new modifiers to be used with existing HCPCS Level II code V5261, “Hearing aid, digital, binaural, bte” to further define digital hearing aid technology levels.

Applicant's suggested language:

1. XX, “Hearing aid, digital, binaural, BTE Essential level”
2. XX, “Hearing aid, digital, binaural, BTE Standard level”
3. XX, “Hearing aid, digital, binaural, BTE Advanced level”
4. XX, “Hearing aid, digital, binaural, BTE Premium level”

Summary of Applicant's Submission

Hearing Healthcare Centers of NC LLC. submitted a request to establish four new HCPCS modifiers to be used with HCPCS Level II code V5261 to further define digital hearing aid technology levels. Manufacturers of hearing aids use different technologies in making hearing aids. These modifiers can differentiate the levels of technology inside the hearing aid. Some of the digital hearing aids have sensor technology, Bluetooth connectivity, sudden sound stabilizers, environmental programs, directional microphones, tinnitus support, neural noise suppression, rechargeable battery or disposable battery and more. The cost per hearing aid can range from $200 to $4,000 depending on the technology used in the hearing aid (such as, customization, speech understanding, sound quality, and connectivity). Reimbursement for hearing aids is too low and insurers do not pay for claims or appeals filed for higher reimbursement based on technology.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II code V5261, “Hearing aid, digital, binaural, bte” describes digital hearing aids. CMS has not identified a program operating need for Medicare or other insurers to further stratify the hearing aid technology levels (such as, customization, speech understanding, sound quality, and connectivity). For Medicare, hearing aids and examinations are excluded from coverage by statute. We welcome information from the applicant and other insurers that are currently paying for this item to demonstrate a claims processing need to expand HCPCS Level II codes for hearing aids. Further, comments from manufacturers regarding different products on the market and how manufacturers have engaged with payers about these different products would be informative.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

Section 1862(a)(7) of the Social Security Act excludes hearing aids from Medicare coverage.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with existing HCPCS Level II code V5261 apply to this product.

No Medicare payment. Pricing Indicator = 00

Summary of Public Feedback

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

CMS Final HCPCS Coding Determination

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

Existing HCPCS Level II code V5261, "Hearing aid, digital, binaural, bte" to describe digital hearing aids.

For Medicare, hearing aids and examinations are excluded from coverage by statute. CMS has not identified a program operating need for Medicare or other insurers to further stratify the hearing aid technology levels (such as, customization, speech understanding, sound quality, and connectivity).

Final Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

Section 1862(a)(7) of the Social Security Act excludes hearing aids from Medicare coverage.

Final Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

SnoreHook - HCP241021CPG1M

Topic/Issue

Request to be assigned to existing HCPCS Level II code E0486, “Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, custom fabricated, includes fitting and adjustment” for SnoreHook.

The applicant did not submit any suggested language.

Summary of Applicant's Submission

Boyd Research submitted a request to be assigned to existing HCPCS Level II code E0486 for SnoreHook. SnoreHook received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on May 3, 2005. SnoreHook was assigned to HCPCS Level II code E0486 for nine years. Then, Boyd Research was advised by outside counsel that the company might simultaneously receive HCPCS Level II code K1027, “Oral device/appliance used to reduce upper airway collapsibility, without fixed mechanical hinge, custom fabricated, includes fitting and adjustment” in addition to HCPCS Level II code E0486. As such, Boyd Research applied to CMS to be assigned HCPCS Level II code K1027. CMS assigned SnoreHook to HCPCS Level II code K1027 on October 1, 2024. Therefore, SnoreHook was no longer allowed to be billed under HCPCS Level II code E0486.

CMS Preliminary HCPCS Coding Determination

In the First Biannual 2024 HCPCS Level II Coding Cycle (prior application HCP2312035AJRX), CMS concluded that existing HCPCS Level II code K1027, “Oral device/appliance used to reduce upper airway collapsibility, without fixed mechanical hinge, custom fabricated, includes fitting and adjustment” describes SnoreHook. CMS determined that the SnoreHook appliance does not feature a fixed, inseparable hinge that always remains integrated, including during adjustments. CMS continues to believe that HCPCS Level II code K1027 describes SnoreHook. SnoreHook is similar to other devices in existing HCPCS Level II code K1027.

Preliminary Medicare Benefit Category Determination

No determination.

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

Preliminary Medicare Payment Determination

No determination.

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

Pricing Indicator = 99 (Value not established)

Summary of Public Feedback

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

CMS Final HCPCS Coding Determination

No Determination.

Based on the information provided in the application and after consideration that no comments were received, CMS is not making a final coding determination regarding this device and is withdrawing any previous coding determinations related to oral sleep apnea devices until the issues related to the Medicare benefit category for these devices are resolved by CMS. In the meantime, determinations regarding coding for these items and all oral sleep apnea devices will be made by the DME Medicare Administrative Contractors (MACs).

Final Medicare Benefit Category Determination

No determination.

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

Final Medicare Payment Determination

No determination.

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

Pricing Indicator = 99 (Value not established)

SnoreHook Fixed-Hinge - HCP241215FRGLN

Topic/Issue

Request to be assigned to existing HCPCS Level II code E0486, “Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, custom fabricated, includes fitting and adjustment” for the SnoreHook Fixed-Hinge.

The applicant did not submit any suggested language.

Summary of Applicant's Submission

Boyd Research submitted a request to be assigned an existing HCPCS Level II code E0486 for the SnoreHook Fixed-Hinge. SnoreHook Fixed-Hinge received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on May 3, 2005. SnoreHook Fixed-Hinge is for the treatment of mild to moderate obstructive sleep apnea. SnoreHook Fixed-Hinge advances the mandible to maintain an open airway and it is a single, reusable device. SnoreHook Fixed-Hinge is custom fabricated by a dental lab and delivered by a licensed dental practitioner.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II code K1027, “Oral device/appliance used to reduce upper airway collapsibility, without fixed mechanical hinge, custom fabricated, includes fitting and adjustment” describes the SnoreHook Fixed-Hinge. CMS believes the SnoreHook Fixed-Hinge appliance does not feature a fixed, inseparable hinge that always remains integrated, including during adjustments. SnoreHook Fixed-Hinge is similar to other devices in existing HCPCS Level II code K1027.

Preliminary Medicare Benefit Category Determination

No determination.

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

Preliminary Medicare Payment Determination

No determination.

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

Pricing Indicator = 99 (Value not established)

Summary of Public Feedback

Boyd Research disagreed with CMS' published preliminary determinations. They commented that the SnoreHook Fixed-Hinge is functionally identical in design to TAP-3 Elite, manufactured by Airway Management, which is coded within HCPCS Level II code E0486. They stated that both devices upon coupling the hooking mechanism with the opposing channel, a fixed hinge is created, making the un-coupling of the upper and lower splints impossible while in use.

CMS Final HCPCS Coding Determination

No Determination.

We appreciate the comment provided in response to CMS' published preliminary determinations. Based on the information provided in the application and after consideration of the comment we received, CMS is not making a final coding determination regarding this device and is withdrawing any previous coding determinations related to oral sleep apnea devices until the issues related to the Medicare benefit category for these devices are resolved by CMS. In the meantime, determinations regarding coding for these items and all oral sleep apnea devices will be made by the DME Medicare Administrative Contractors (MACs).

Final Medicare Benefit Category Determination

No determination.

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

Final Medicare Payment Determination

No determination.

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

Pricing Indicator = 99 (Value not established)

PhysioHab Shoulder Rehab Brace - HCP241223ARCKR

Topic/Issue

Request to establish a new HCPCS Level II code to identify PhysioHab Shoulder Rehab brace.

Applicant's suggested language: XXXXX, "Shoulder Orthosis (SO), scapula restrainer to prevent scapular hiking and retraction of shoulder blades; canvas, webbing, with adjustable tension control cables, prefabricated, off-the-shelf"

Summary of Applicant's Submission

PhysioHab LLC submitted a request to establish a new HCPCS Level II code to identify PhysioHab Shoulder Rehab brace. PhysioHab Shoulder Rehab brace is a class I device, exempt from premarket notification requirements by the Food and Drug Administration (FDA). PhysioHab Shoulder Rehab brace is a scapula restrainer designed to prevent scapular hiking or shoulder shrugs and retraction of shoulder blades to prevent the individual from engaging in unwanted movements during physical therapy rehab sessions following injury or surgery that may compromise recovering range of motion. Made of canvas, webbing, and adjustable tension control cables, the PhysioHab Shoulder Rehab brace is designed to emulate the same "hand on trapezius area" function that the therapist applies to the body. Individuals can rehab at any time and do so in an anatomically correct manner as the trapezius is "locked down" to prevent the upward compensatory shoulder shrug movements (i.e., shoulder hiking) as well as securing retraction of the shoulder blades in the mid-back area of the trapezius. Following shoulder injury or surgery, it is difficult and painful to properly move/use the arm/shoulder. As a result, the body compensates, and individuals may rely too much on the scapula to help move the arm during rehab. This is problematic because following shoulder injury or surgery the shoulder joint/shoulder capsule must be rehabilitated properly to regain full range of motion and strength. If "shoulder hiking" takes place, it falsifies rehab efforts because the individual is moving the arm and "creating shoulder movement" with the scapula rather than the shoulder joint. The shoulder joint should be driving all shoulder/arm movement that is not overhead. When the individual relies on a scapula to be the primary form of moving the shoulder, below head level, it will produce poor outcomes with short- and long-term consequences, both physical and financial. The scapula is commonly referred to as the shoulder blade. It is the triangular-shaped bone on each side of the upper back. The socket of the shoulder joint is a part of the scapula. There are only three muscles that are responsible for enabling the movement of the shoulder blade. The trapezius muscle implants into the collarbone. It is responsible for the movement of the shoulder and head. The levator muscle is a small, thin muscle. It arises from the vertebrae of the neck. A small tendon attaches the levator to the upper area of the shoulder blade. This muscle is responsible for pulling up the scapula, which allows for the shrugging movement of the shoulders. The rhomboideus is two muscles, the major and minor, located deep in the base of the shoulder blade. These muscles are responsible for raising the shoulder blade and moving it backward. The muscles that move the shoulder forward come from the breast. Upward movements are controlled by muscles located in the neck. Normally the scapula will slide flat on the ribcage and rotate normally when an individual brings arms overhead. The scapula helps keep the shoulder centered in its socket and minimizes stress on the subacromial.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II code A4467, “Belt, strap, sleeve, garment, or covering, any type” describes PhysioHab Shoulder Rehab brace. PhysioHab Shoulder Rehab brace 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.

The current Medicare policy and prior established benefit category determination for HCPCS Level II code A4467 apply to PhysioHab Shoulder Rehab brace.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Summary of Public Feedback

PhysioHab LLC disagreed with CMS’ published preliminary determinations. The speaker maintained that the PhysioHab Shoulder Rehab brace is a training device that falls outside of the parameters of elastic bandages and compression garments, primarily constructed of elastic materials, due to the PhysioHab Shoulder Rehab brace's anchor component, which is durable. Furthermore, the speaker stated that tightening the tension knob on the tensioner until sufficient tension is achieved is what facilitates the prevention of scapular movement and does not immobilize the shoulder joint.

CMS Final HCPCS Coding Determination

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

Existing HCPCS Level II code A4566, “Shoulder sling or vest design, abduction restrainer, with or without swathe control, prefabricated, includes fitting and adjustment” to describe the PhysioHab Shoulder Rehab brace.

PhysioHab Shoulder Rehab brace is primarily made of elastic material and is similar to other devices in the existing HCPCS Level II code A4566**.** The PhysioHab Shoulder Rehab brace is marketed as a shoulder strap that prevents scapular movement by adjusting the tension of the device’s shoulder and thigh straps. The tightening motion is no different than an adjustment made to tighten the straps of a sling. The increased tension does not change the composition of the materials used to construct, nor does it make the PhysioHab Shoulder Rehab brace semi-rigid.

Final Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

The current Medicare policy and prior established benefit category determination for HCPCS Level II code A4566 apply to PhysioHab Shoulder Rehab brace.

Final Medicare Payment Determination

No Medicare DMEPOS payment. Pricing Indicator = 00

Embracer Vest - HCP241231MD9DY

Topic/Issue

Request to establish a new HCPCS Level II code to identify Embracer Vest.

The applicant did not submit any suggested language.

Summary of Applicant's Submission

Medical Technology Solutions, LLC submitted a request to establish a new HCPCS Level II code to identify Embracer Vest. Embracer Vest is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). Embracer Vest is constructed with a combination of antimicrobial and wicking white fabric in 88% polyester and 12% spandex ratio for compression purposes. Embracer Vest is used by individuals during the post-surgical recovery after any thoracic surgery including, but not limited to, thoracotomy, open heart, open chest, heart valve repair, and breast removal. All individuals undergoing any thoracic surgery, ideally before the surgery, will be fitted by hospital personnel with an appropriate size of vest. Embracer Vest is recommended to be worn up to 24 hours per day according to the individual's comfort level, for 3-5 days post-operatively. It is to be administered by the attending physician with a prescription order.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II code A4467, "Belt, strap, sleeve, garment, or covering, any type" describes Embracer Vest. When this item is used in hospital inpatient facility, for Medicare purposes, if this product were covered, it would be included within the hospital bundled payment.

The applicant compares Embracer Vest to another garment called the Heart Hugger. They state that the Heart Hugger is paid using HCPCS Level II code L0450. However, HCPCS Level II code L0450 is for devices covered under the benefit category for leg, arm, neck, and back braces and requires code verification by the Medicare contractor for Pricing, Data Analysis and Coding (PDAC), per the spinal orthosis Policy Article A52500. To our knowledge, the Heart Hugger has not received a code verification.

Embracer Vest is similar to other devices in HCPCS Level II code A4467.

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 A4467 apply to the Embracer Vest.

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 determinations.

CMS Final HCPCS Coding Determination

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

Existing HCPCS Level II code A4467, "Belt, strap, sleeve, garment, or covering, any type" to describe Embracer Vest.

When this item is used in a hospital inpatient facility, for Medicare purposes, if this product were covered, it would be included within the hospital bundled payment. Embracer Vest is similar to other devices in HCPCS Level II code A4467.

Final Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

The current Medicare policy and prior established benefit category determination for HCPCS Level II code A4467 apply to the Embracer Vest.

Final Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

TheraBionic® P1 System - HCP241230K09W1

Topic/Issue

Request to revise the existing HCPCS Level II code, E0767, “Intrabuccal, systemic delivery of amplitude modulated, radiofrequency electromagnetic field device, for cancer treatment, includes all accessories” by removing the phrase(s) ‘intrabuccal, systemic delivery’ and/or ‘all accessories’ and by adding the phrase(s) ‘therapeutic device’ and/or ‘docking station and power cord’ to describe the TheraBionic® P1 System.

Applicant's suggested language: E0767, “Intrabuccal, systemic delivery of amplitude-modulated, radiofrequency electromagnetic field device, for cancer treatment; therapeutic device, docking station and power cord” or “Amplitude-modulated, radiofrequency electromagnetic field device, for cancer treatment; therapeutic device, etc.”

Summary of Applicant's Submission

TheraBionic, Inc. submitted a request to revise the existing HCPCS Level II code E0767 to further describe the TheraBionic® P1 System without the non-durable accessories. The TheraBionic® P1 System was granted humanitarian device exemption (HDE) as a humanitarian use device (HUD) by the Food and Drug Administration (FDA) on September 26, 2023. The TheraBionic® P1 System is intended for use in individuals with advanced hepatocellular cancer who have failed first and second-line therapy. The TheraBionic® P1 System is a multi-component system consisting of a therapeutic device with docking station, a spoon-shaped antenna, and an activation card. The durable component is the therapeutic device, which includes a battery-driven amplitude-modulated radiofrequency electromagnetic field generator and the docking station (charger) with a power supply. The nondurable components necessary for the function of the durable medical equipment (DME) are the spoon-shaped antenna that is inserted in the individual’s mouth and connects to the therapeutic device through an attached coaxial cable, and an activation card that allows a defined number of therapeutic sessions as prescribed by the physician, which is usually three 1-hour sessions per day. The activation card is replaced each month and the spoon-shaped antenna every six months (or as required). When these supplies are included in HCPCS Level II code E0767, the classification as a capped rental prohibits the individual from accessing these supplies after the capped rental period is completed. The accessories necessary for the effective use of the device, the activation card and spoon-shaped antenna with coaxial cable, fall under the DME benefit category as supplies and should be removed from the existing HCPCS Level II code E0767 so they can each be billed and receive payment under separate HCPCS Level II codes.

CMS Preliminary HCPCS Coding Determination

CMS established HCPCS Level II code HCPCS Level II code E0767, “Intrabuccal, systemic delivery of amplitude modulated, radiofrequency electromagnetic field device, for cancer treatment, includes all accessories” to describe the TheraBionic® P1 System, effective April 1, 2025.

Based on the application, the activation card is replaced each month, and the spoon-shaped antenna is replaced as necessary. We believe that the routine replacement needs of the accessories for this device are no different than what would be expected for any other item of

DME and therefore would not be separately payable for Medicare. We welcome information from the applicant and other insurers who are currently paying for this product to demonstrate a claims processing need for a revision to the existing HCPCS Level II code E0767.

Preliminary Medicare Benefit Category Determination

CMS determined that the TheraBionic® P1 System is Durable Medical Equipment, effective October 1, 2024.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code E0767 apply to the TheraBionic® P1 System, if covered. At this time, we do not have verifiable information from supplier invoices or non-Medicare payer data that would support the establishment of a national Medicare fee schedule amount. As such, should the purchase price for this item exceed $150 in the base period, payment would be made on a capped rental basis in accordance with our regulations at 42 CFR 414.229. Should the purchase price for this item be less than $150 in the base period, payment would be made on a rental or purchase basis in accordance with our regulations at 42 CFR 414.220. Local fee schedule amounts would be established by the DME MACs for use in paying any covered claims for this item.

Pricing Indicator = 46

Summary of Public Feedback

TheraBionic, Inc. acknowledged CMS' published preliminary determinations. They commented that they intend to provide additional information and feedback from other insurers later this year, since no patient has yet been billed for the TheraBionic® P1 System.

CMS Final HCPCS Coding Determination

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

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

Final Medicare Benefit Category Determination

Durable Medical Equipment. As stated in the Preliminary Medicare Benefit Category Determination, the benefit category for the TheraBionic® P1 System went into effect October 1, 2024.

Final Medicare Payment Determination

Local fee schedule amounts would be established by the DME MACs for use in paying any covered claims under HCPCS Level II code E0767.

Pricing Indicator = 46

TheraBionic® P1 Spoon-Shaped Antenna - HCP241230FC2GR

Topic/Issue

Request to establish a new HCPCS Level II code to identify the TheraBionic® P1 spoon-shaped antenna.

Applicant's suggested language: AXXXX, “Spoon-shaped antenna with a coaxial cable for amplitude-modulated, radiofrequency electromagnetic field device, each”

Summary of Applicant's Submission

TheraBionic, Inc. submitted a request to establish a new HCPCS Level II code to describe the spoon-shaped antenna associated with the use of the TheraBionic® P1 System. The TheraBionic® P1 System was granted humanitarian device exemption (HDE) as a humanitarian use device (HUD) by the Food and Drug Administration (FDA) on September 26, 2023. The TheraBionic® P1 System is intended for use in individuals with advanced hepatocellular cancer who have failed first and second-line therapy. The TheraBionic® P1 System is a multi-component system consisting of a therapeutic device with docking station, a spoon-shaped antenna, and an activation card. The durable component is the therapeutic device, which includes a battery-driven amplitude-modulated (AM) radiofrequency (RF) electromagnetic field (EMF) generator and the docking station (charger) with a power supply. The nondurable components necessary for the function of the durable medical equipment (DME) are the spoon-shaped antenna that is inserted in the individual’s mouth and connects to the therapeutic device through an attached coaxial cable, and an activation card that allows a defined number of therapeutic sessions as prescribed by the physician, which is usually three 1-hour sessions per day. The stainless-steel spoon-shaped mouthpiece is connected to the TheraBionic® P1 therapeutic device by a 1.5 meter long 50-ohm coaxial cable, which matches the impedance within the therapeutic device with the spoon-shaped antenna holder and generates the AM RF EMF treatment. The spoon is the only point of contact between the device and the individual and results in systemic delivery of low and safe levels of AM RF EMF from head to toe, targeting hepatocellular cancer cells. The spoon-shaped antenna with coaxial cable is an accessory necessary for the effective use of the device. A separate HCPCS Level II code describing the spoon-shaped antenna will allow access to its replacement after the capped rental period ends.

CMS Preliminary HCPCS Coding Determination

Based on the information provided in the application, only one TheraBionic® P1 antenna is intended to be used by an individual for multiple treatments. The applicant indicated that most individuals keep their original TheraBionic® P1 antenna for a lifetime of treatments. Furthermore, we note that based on the available data, most patients only use the TheraBionic® P1 System during the initial 13-month period during which payment is made on a rental bases for Medicare, and during this period the rental payment is expected to include all necessary supplies and accessories. CMS believes that the rare instance of needing a replacement TheraBionic® P1 antenna does not require a unique HCPCS Level II code. As such, existing code HCPCS Level II code A9999, “Miscellaneous dme supply or accessory, not otherwise specified,” can be utilized in the event a replacement TheraBionic® P1 antenna is needed after thirteen months of continuous use when the DME capped rental period ends.

Preliminary Medicare Benefit Category Determination

The TheraBionic® P1 antenna is a part of the TheraBionic® P1 System. CMS determined that the TheraBionic® P1 System is Durable Medical Equipment, effective October 1, 2024.

In the event a replacement TheraBionic® P1 antenna is needed, then the current Medicare policy and prior established benefit category determination for HCPCS Level II code A9999 apply.

Preliminary Medicare Payment Determination

The TheraBionic® P1 antenna is a part of the TheraBonic® P1 System (HCPCS Level II code E0767) and when purchased as a part of the system, is not separately payable. However, in the event a replacement TheraBionic® P1 antenna is needed, then the payment rules and pricing associated with the existing HCPCS Level II code A9999 apply to the replacement TheraBionic® P1 antenna, if covered.

Local fee schedule amounts would be established by the DME MACs for use in paying any covered claims submitted using HCPCS Level II code A9999.

Pricing Indicator = 46

Summary of Public Feedback

TheraBionic, Inc. acknowledged CMS' published preliminary determinations.

CMS Final HCPCS Coding Determination

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

Existing HCPCS Level II code A9999, "Miscellaneous dme supply or accessory, not otherwise specified," in the event a replacement TheraBionic® P1 antenna is needed after thirteen months of continuous use when the DME capped rental period ends.

Final Medicare Benefit Category Determination

The TheraBionic® P1 antenna is a part of the TheraBionic® P1 System. CMS determined that the TheraBionic® P1 System is Durable Medical Equipment, effective October 1, 2024.

In the event a replacement TheraBionic® P1 antenna is needed, then the current Medicare policy and prior established benefit category determination for HCPCS Level II code A9999 apply.

Final Medicare Payment Determination

As stated in the Preliminary Medicare Payment Determination, the TheraBionic® P1 antenna is a part of the TheraBonic® P1 System (HCPCS Level II code E0767) and when purchased

as a part of the system, is not separately payable. However, in the event a replacement TheraBionic® P1 antenna is needed, then the payment rules and pricing associated with the existing HCPCS Level II code A9999 apply to the replacement TheraBionic® P1 antenna, if covered.

Local fee schedule amounts would be established by the DME MACs for use in paying any covered claims submitted using HCPCS Level II code A9999.

Pricing Indicator = 46

TheraBionic® P1 Activation Card - HCP241230TCC1H

Topic/Issue

Request to establish a new HCPCS Level II code to describe the activation card associated with the TheraBionic® P1 System.

Applicant's suggested language: AXXXX, “Activation Card for amplitude-modulated, radiofrequency electromagnetic field device, each”

Summary of Applicant's Submission

TheraBionic Inc. submitted a request to establish a new HCPCS Level II code to describe the activation card associated with the TheraBionic® P1 System. The TheraBionic® P1 System was granted humanitarian device exemption (HDE) as a humanitarian use device (HUD) by the Food and Drug Administration (FDA) on September 26, 2023. The TheraBionic® P1 System is intended for use in individuals with advanced hepatocellular cancer who have failed first and second-line therapy. The TheraBionic® P1 System is a multi-component system consisting of a therapeutic device with docking station, a spoon-shaped antenna, and an activation card. The durable component is the therapeutic device, which includes a battery-driven amplitude-modulated radiofrequency electromagnetic field generator and the docking station (charger) with a power supply. The nondurable components necessary for the function of the durable medical equipment (DME) are the spoon-shaped antenna that is inserted in the individual’s mouth and connects to the therapeutic device through an attached coaxial cable, and an activation card that allows a defined number of therapeutic sessions as prescribed by the physician, which is usually three 1-hour sessions per day. The therapeutic device has an internal clock or timer that tracks the treatment usage time. An activation card, a simple integrated circuit with read-only memory, is used to control the individual’s access to treatment time. This process allows the clinician to monitor treatment sessions up to three 1-hour sessions per day and limit access to treatment if it is deemed no longer medically indicated. When the activation card is inserted into the docking station, it wirelessly transfers the 93-hour authorization to the therapeutic device's memory, which then allows the device to operate until the allocated time is exhausted. Without a new activation card and allocation of 93-hours of new time to the therapeutic device, the device stops functioning and will no longer deliver treatment to the individual. As an accessory that is necessary for the effective allocation of treatment time to the therapeutic device, the activation card falls under the DME benefit category as a supply. A separate HCPCS Level II code describing the activation card will allow access to its replacement after the capped rental period ends.

CMS Preliminary HCPCS Coding Determination

Based on the information provided in the application, CMS believes the TheraBionic® P1 activation card does not require a new HCPCS Level II code because the intended function of each card is not separately payable by Medicare. While we understand that the activation card used to control access to the prescribed number of treatments must be periodically refreshed with additional authorized treatment sessions, provisioning the prescribed number of treatment sessions would not be separately payable. Overall, for Medicare, we believe that that servicing and refurbishment needs for this device are no different than what would be expected for any other item of DME. As such, all the necessary TheraBionic® P1 activation cards are to be included in the TheraBionic® P1 System as described by existing HCPCS

Level II code E0767, “Intrabuccal, systemic delivery of amplitude modulated, radiofrequency electromagnetic field device, for cancer treatment, includes all accessories.”

Preliminary Medicare Benefit Category Determination

The TheraBionic® P1 activation card is a part of the TheraBionic® P1 System. CMS determined that the TheraBionic® P1 System is Durable Medical Equipment, effective October 1, 2024.

Preliminary Medicare Payment Determination

The TheraBionic® P1 activation card is a part of the TheraBionic® P1 System (HCPCS Level II code E0767) and is not separately payable.

The payment rules and pricing associated with the existing HCPCS Level II code E0767 apply to the TheraBionic® P1 System, if covered. At this time, we do not have verifiable information from supplier invoices or non-Medicare payer data that would support the establishment of a national Medicare fee schedule amount. As such, should the purchase price for this item exceed $150 in the base period, payment would be made on a capped rental basis in accordance with our regulations at 42 CFR 414.229. Should the purchase price for this item be less than $150 in the base period, payment would be made on a rental or purchase basis in accordance with our regulations at 42 CFR 414.220. Local fee schedule amounts would be established by the DME MACs for use in paying any covered claims for this item.

Pricing Indicator = 46

Summary of Public Feedback

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

CMS Final HCPCS Coding Determination

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

Existing HCPCS Level II code E0767, “Intrabuccal, systemic delivery of amplitude modulated, radiofrequency electromagnetic field device, for cancer treatment, includes all accessories” to describe all the necessary TheraBionic® P1 activation cards that would be utilized with the TheraBionic® P1 System.

Final Medicare Benefit Category Determination

The TheraBionic® P1 activation card is a part of the TheraBionic® P1 System. CMS determined that the TheraBionic® P1 System is Durable Medical Equipment, effective October 1, 2024.

Final Medicare Payment Determination

As stated in the Preliminary Medicare Payment Determination, the TheraBionic® P1 activation card is a part of the TheraBionic® P1 System (HCPCS Level II code E0767) and is not separately payable. Local fee schedule amounts would be established by the DME MACs for use in paying any covered claims under HCPCS Level II code E0767.

Pricing Indicator = 46

Reliefband® Reletex™ - HCP24071167NY5

Topic/Issue

Request to establish a new HCPCS Level II code to identify Reliefband® Reletex™.

Applicant's suggested language: XXXXX, “FDA approved nerve stimulator, Reletex, with non-replaceable batteries for treatment of nausea and vomiting (transcutaneous electrical acupoint stimulation)”

Summary of Applicant's Submission

Reliefband® Technologies LLC submitted a request to establish a new HCPCS Level II code to identify Reliefband® Reletex™. Reliefband® NST™, and various models, received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on March 16, 2000. Reliefband® Reletex™ is a pulse generator that utilizes neuromodulation technology to stimulate the median nerve for the treatment and prevention of nausea and vomiting, related to motion sickness, physician diagnosed migraines, anxiety, morning sickness, chemotherapy, and post-operative nausea. Reliefband® Reletex™ is a prescription device. Reliefband® Reletex™ emits electrical pulses that stimulate the underlying median nerve which travel through the body’s natural neuropathways, from the median nerve to the vagus nerve, to the emetic center of the brain, down to the stomach to normalize erratic stomach rhythms that cause nausea. Reliefband® Reletex™ is a single use device and can function with a set of non-replaceable/non-rechargeable batteries for approximately 150 hours when used on setting 3. Individuals experience less nausea when Reliefband® Reletex™ is added as an adjunct to anti-emetics. Individuals can easily activate and adjust the level of stimulation, depending on the intensity of their symptoms. Reliefband® Reletex™ is free from the unwanted side effects associated with anti-emetics drugs and potential drug to drug interactions. The onset of action begins within minutes of activation of Reliefband® Reletex™. Reliefband® Reletex™ has the same mechanism of action as the replaceable battery models except that this model has a non-replaceable battery.

CMS Preliminary HCPCS Coding Determination

Revise existing HCPCS Level II code E0765, “Fda approved nerve stimulator, with replaceable batteries, for treatment of nausea and vomiting” to instead read “Fda approved nerve stimulator, for treatment of nausea and vomiting” to describe Reliefband® Reletex™.

Reliefband® Reletex™ is a neuromodulation nerve stimulator for the treatment and prevention of nausea and vomiting, related to motion sickness, physician diagnosed migraines, anxiety, morning sickness, chemotherapy, and post-operative nausea. CMS believes a revision to the existing HCPCS Level II code E0765 is appropriate because the one major difference between the devices is the power source. For Medicare, we are unaware of any devices currently utilizing HCPCS Level II code E0765, as there have been no paid claims since at least 2017. In addition, there are no items on the Product Classification List for HCPCS Level II code E0765. Thus, we propose to revise the existing HCPCS Level II code E0765 instead of establishing a new code.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

HCPCS Level II code E0765 was previously classified as DME. However, no claims have been paid on this code since at least 2017 and currently there are no devices included in the Product Classification List. Therefore, we are re-classifying this code as no longer falling within a Medicare DMEPOS benefit category.

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

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

All five of these conditions must be met for equipment to be classified as DME. The Reliefband® Reletex™ does not meet the following condition:

> **Primarily and customarily used to serve a medical purpose** - We note that the Reliefband® products are advertised as being effective in treating nausea and vomiting in venues including amusement parks and for situations such as car, train, air, and sea sickness. As such, we have concluded that the Reliefband® Reletex™ is not primarily and customarily use to serve a medical purpose.
>
> **Can withstand repeated use** – The Reliefband® Reletex™ is a single-patient use item, as explained in the application. Also, as explained in the application, it is not intended to be rented. DME is a benefit for rental of equipment and therefore DME items must be able to withstand repeated use by successive patients. The regulation is in accordance with section 1861(s)(6) of the Social Security Act which sets forth the DME benefit including rental of DME, although purchase of DME items is allowed in limited situations such as section 1834(a)(4) of the Social Security Act for custom DME.

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 determinations.

CMS Final HCPCS Coding Determination

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

Revise existing HCPCS Level II code E0765, "Fda approved nerve stimulator, with replaceable batteries, for treatment of nausea and vomiting" to instead read "Fda approved nerve stimulator, for treatment of nausea and vomiting" to describe Reliefband® Reletex™.

Reliefband® Reletex™ is a neuromodulation nerve stimulator for the treatment and prevention of nausea and vomiting, related to motion sickness, physician diagnosed migraines, anxiety, morning sickness, chemotherapy, and post-operative nausea. CMS believes a revision to the existing HCPCS Level II code E0765 is appropriate because the one major difference between the Reliefband® devices is the power source. For Medicare, we are unaware of any devices currently utilizing HCPCS Level II code E0765, as there have been no paid claims since at least 2017. In addition, there are no items on the Product Classification List for HCPCS Level II code E0765. Thus, CMS will revise the existing HCPCS Level II code E0765 instead of establishing a new code.

Final Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

HCPCS Level II code E0765 was previously classified as DME. However, no claims have been paid on this code since at least 2017 and currently there are no devices included in the Product Classification List. Therefore, we are re-classifying this code as no longer falling within a Medicare DMEPOS benefit category.

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

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

All five of these conditions must be met for equipment to be classified as DME. The Reliefband® Reletex™ does not meet the following conditions:

> **Primarily and customarily used to serve a medical purpose** - We note that the Reliefband® products are advertised as being effective in treating nausea and vomiting in venues including amusement parks and for situations such as car, train, air, and sea sickness. As such, we have concluded that the Reliefband® Reletex™ is not primarily and customarily use to serve a medical purpose.
>
> **Can withstand repeated use** – The Reliefband® Reletex™ is a single-patient use item, as explained in the application. Also, as explained in the application, it is not intended to be rented. DME is a benefit for rental of equipment and therefore DME

items must be able to withstand repeated use by successive patients. The regulation is in accordance with section 1861(s)(6) of the Social Security Act which sets forth the DME benefit including rental of DME, although purchase of DME items is allowed in limited situations such as section 1834(a)(4) of the Social Security Act for custom DME.

Final Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Reliefband® Sport - HCP240712880LP

Topic/Issue

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

Applicant's suggested language: XXXXX, “FDA approved nerve stimulator, Reliefband® Sport, (USB Rechargable), for treatment of nausea and vomiting (transcutaneous electrical acupoint stimulation)”

Summary of Applicant's Submission

Reliefband® Technologies LLC submitted a request to establish a new Level II HCPCS code to identify Reliefband® Sport. Reliefband® 1.5 and Reliefband® 2.0 received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on August 30, 2019. Reliefband® Sport has the same mechanism of action as the Reliefband® 1.5 and 2.0 over the counter devices. The Reliefband® devices are non-invasive, non-sterile neuromodulation nerve stimulation therapy device, indicated for the treatment of nausea associated with motion sickness, seasickness, anxiety, morning sickness, hangovers, physician-diagnosed migraines, chemotherapy and water sports. Reliefband® Sport is waterproof and provides 30 hours of consistent use from one full charge. Reliefband® Sport is added as an adjunct to anti-emetics. Reliefband® Sport is worn on the underside of the wrist and can be toggled between six levels of therapy. Reliefband® Sport gently stimulates the median nerve on the underside of the wrist, using the body’s neural pathways to send messages to the brain to stop nausea and vomiting. The Reliefband® Sport device emits a low-level electrical current across two small electrodes on its underside. Reliefband® Sport therapy is controlled by the individual using the device, worn in 30-minute increments. It works naturally, without the side effects of drugs, simply slip it on, adjust the intensity and it starts working within minutes. Reliefband® Sport is available in black or soft grey and it has Universal Serial Bus rechargeable capability.

CMS Preliminary HCPCS Coding Determination

Revise existing HCPCS Level II code E0765, “Fda approved nerve stimulator, with replaceable batteries, for treatment of nausea and vomiting” to instead read “Fda approved nerve stimulator, for treatment of nausea and vomiting” to describe Reliefband® Sport.

Reliefband® Sport is a neuromodulation nerve stimulator for the treatment of nausea associated with motion sickness, seasickness, anxiety, morning sickness, hangovers, physician-diagnosed migraines, chemotherapy and water sports. CMS believes a revision to the existing HCPCS Level II code E0765 is appropriate because the one major difference between the devices is the power source. For Medicare, we are unaware of any devices currently utilizing HCPCS Level II code E0765, as there have been no paid claims since at least 2017. In addition, there are no items on the Product Classification List for HCPCS Level II code E0765. Thus, we propose to revise the existing HCPCS Level II code E0765 instead of establishing a new code.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

HCPCS Level II code E0765 was previously classified as DME. However, no claims have been paid on this code since at least 2017 and currently there are no devices included in the Product Classification List. Therefore, we are re-classifying this code as no longer falling within a Medicare DMEPOS benefit category.

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

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

All five of these conditions must be met for equipment to be classified as DME. The Reliefband® Sport does not meet the following conditions:

Primarily and customarily used to serve a medical purpose - We note that the Reliefband® products are advertised as being effective in treating nausea and vomiting in venues including amusement parks and for situations such as car, train, air, and sea sickness. As such, we have concluded that the Reliefband® Sport is not primarily and customarily use to serve a medical purpose.

Can withstand repeated use – The Reliefband® Sport is a single-patient use item, as explained in the application. Also, as explained in the application, it is not intended to be rented. DME is a benefit for rental of equipment and therefore DME items must be able to withstand repeated use by successive patients. The regulation is in accordance with section 1861(s)(6) of the Social Security Act which sets forth the DME benefit including rental of DME, although purchase of DME items is allowed in limited situations such as section 1834(a)(4) of the Social Security Act for custom DME.

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 determinations.

CMS Final HCPCS Coding Determination

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

Revise existing HCPCS Level II code E0765, “Fda approved nerve stimulator, with replaceable batteries, for treatment of nausea and vomiting” to instead read “Fda approved nerve stimulator, for treatment of nausea and vomiting” to describe Reliefband® Sport.

Reliefband® Sport is a neuromodulation nerve stimulator for the treatment of nausea associated with motion sickness, seasickness, anxiety, morning sickness, hangovers, physician-diagnosed migraines, chemotherapy and water sports. CMS believes a revision to the existing HCPCS Level II code E0765 is appropriate because the one major difference between the Reliefband® devices is the power source. For Medicare, we are unaware of any devices currently utilizing HCPCS Level II code E0765, as there have been no paid claims since at least 2017. In addition, there are no items on the Product Classification List for HCPCS Level II code E0765. Thus, CMS will revise the existing HCPCS Level II code E0765 instead of establishing a new code.

Final Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

HCPCS Level II code E0765 was previously classified as DME. However, no claims have been paid on this code since at least 2017 and currently there are no devices included in the Pricing Data Analysis and Coding (PDAC) Product Classification List. Therefore, we are re-classifying this code as no longer falling within a Medicare DMEPOS benefit category.

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

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

All five of these conditions must be met for equipment to be classified as DME. The Reliefband® Sport does not meet the following conditions:

Primarily and customarily used to serve a medical purpose - We note that the Reliefband® products are advertised as being effective in treating nausea and vomiting in venues including amusement parks and for situations such as car, train, air, and sea sickness. As such, we have concluded that the Reliefband® Sport is not primarily and customarily use to serve a medical purpose.

Can withstand repeated use – The Reliefband® Sport is a single-patient use item, as explained in the application. Also, as explained in the application, it is not intended to be rented. DME is a benefit for rental of equipment and therefore DME items must be able to withstand repeated use by successive patients. The regulation is in accordance with section 1861(s)(6) of the Social Security Act which sets forth the DME benefit including rental of DME, although purchase of DME items is allowed in limited situations such as section 1834(a)(4) of the Social Security Act for custom DME.

Final Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Appendix A: DMEPOS Payment Categories

The Social Security Act separates DMEPOS into different Medicare payment categories, each with its own unique payment rules. The pricing indicator codes in the HCPCS identify which major payment category a HCPCS Level II code falls under. The pricing indicator codes applicable to DMEPOS.

Pricing = 00 Service Not Separately Priced

Items or services described by the HCPCS Level II codes that are either not covered under Medicare Part B or for which payment is bundled into the payment some other Medicare service or procedure.

Pricing = 31 Frequently Serviced Items

Payment is generally made on a monthly rental fee schedule basis for items such as ventilators that require frequent and substantial servicing in order to avoid risk to the patient's health. Payment for E0935 is based on a daily rental fee schedule basis since coverage of this device is limited to 21 days.

Pricing = 32 Inexpensive and Other Routinely Purchased Items

Payment is made on a purchase or rental fee schedule basis. This category includes items that have a purchase price of $150 or less, were purchased 75 percent of the time or more from July 1986 through June 1987, or which are accessories used in conjunction with a nebulizer, aspirator, continuous airway pressure device, or respiratory assist device. The beneficiary has the option to acquire the item on a purchase or monthly rental basis. Total payments for the item cannot exceed the purchase fee schedule amount for the item.

Pricing = 33 Oxygen and Oxygen Equipment

Monthly fee schedule payments are made for furnishing oxygen and oxygen equipment. This monthly payment includes payment for all stationary oxygen equipment, supplies, and accessories and delivery of oxygen contents (stationary and portable). A monthly add-on to this payment is made for portable oxygen equipment only for those beneficiaries who require portable oxygen. The monthly payments for oxygen equipment cap after the 36th monthly payment is made, after which payment for the ongoing delivery of contents continues for gaseous or liquid systems.

Pricing = 34 Supplies Necessary for the Effective Use of DME

Payment is made on a purchase fee schedule basis for supplies necessary for the effective use of DME (e.g., lancets that draw blood for use in blood glucose monitor).

Pricing = 35 Surgical Dressings

Payment is made on a purchase fee schedule basis for surgical dressings.

Pricing = 36 Capped Rental Items

Payment is made on a monthly rental fee schedule basis. The beneficiary takes over ownership of the item after the 13th rental payment is made. The rental fee for capped rental items, other than power wheelchairs, for each of the first 3 months of rental is equal to 10 percent of the purchase fee for the item. The rental fee for months 4 through 13 is equal to 7.5 percent of the purchase fee for the item. The rental fee for power wheelchairs for each of the first 3 months of rental is equal to 15 percent of the purchase fee for the item. The rental fee for power wheelchairs for months 4 through 13 is equal to 6 percent of the purchase fee for the item. Complex rehabilitative power wheelchairs can also be purchased in the first month.

Pricing = 37 Ostomy, Tracheostomy and Urological Supplies
Payment is made on a purchase fee schedule basis for ostomy, tracheostomy and urological supplies.

Pricing = 38 Orthotics, Prosthetics, Prosthetic Devices, and Vision Services (Prosthetic Lenses)
Payment is made on a purchase fee schedule basis for orthotics, prosthetics, and prosthetic devices & lenses.

Pricing = 39 Parenteral and Enteral Nutrition (PEN)
Payment is made on a purchase fee schedule basis for parenteral and enteral nutrients and supplies. Payment is made on a purchase or rental fee schedule basis for parenteral and enteral equipment. The beneficiary has the option to acquire the item on a purchase or monthly rental basis.

Pricing = 40 Lymphedema Compression Treatment Items
Payment is made on a purchase basis for lymphedema compression treatment items.

Pricing = 45 Customized DME
Payment is made for lump-sum purchase of DME that meets the Medicare regulatory definition of customized DME at 42 CFR 414.224. The payment amount is based on the carrier's individual consideration of the item and judgment of a reasonable payment amount, which, at a minimum, includes a review of the costs of labor and material used in constructing the equipment.

Pricing = 46 Carrier Priced Item
The allowed payment amount for covered items is based on local carrier pricing (e.g., local fee schedule amounts or reasonable charges or other carrier pricing method.