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

Centers for Medicare & Medicaid Services' (CMS') First Biannual 2025 Healthcare Common Procedure Coding System (HCPCS) Public Meeting Agenda

Hybrid Meeting – Remote and in-person participation
Monday, June 2, 2025
9:00 am – 5:00 pm, eastern time (ET)

CMS Multi-Purpose Room
7500 Security Boulevard
Baltimore, Maryland, 21244-1850

8:15 am, ET:
• Arrival and sign-in for those attending in-person.

8:45 am, ET:
• Zoom meeting login for both June 2, 2025 and June 3, 2025:
https://cms.zoomgov.com/j/1616543000?pwd=EjbcsEeWVs2neTC119CaTf5aUR2J7k.1
•Passcode: 390172 Webinar ID: 161 654 3000 Dial: 833-568-8864 US Toll Free

9:00 am, ET:
• Welcome
• Background and purpose of meeting
• Meeting format and ground rules

Each agenda item includes a written overview of the applicant's request, CMS' preliminary coding determination, as well as CMS' preliminary benefit category and payment determination, if applicable. Preliminary determinations are not final or binding upon any insurer and are subject to change. Meeting participants will hear presentations about each agenda item from the registered primary speaker and any registered 5-minute speakers. Speaker presentations will be followed by an opportunity for questions regarding that particular agenda item. The public meeting provides an opportunity for interested parties to provide additional input related to requests to modify the HCPCS Level II code set. Final determinations are not made at the public meeting. CMS' final coding, benefit category, and payment determinations will be published on CMS' HCPCS website at: https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Prior-Years-CMS-HCPCSLevelII-Coding-Decisions-Narrative-Summary around August 2025 and will be effective October 1, 2025, unless otherwise specified.

This document includes a summary of each HCPCS Level II code application being presented on Monday, June 2, 2025, with an overflow date of Tuesday, June 3, 2025 to be held virtually, if necessary. The same Zoom link above will be utilized if the overflow date is necessary. The information provided in each summary reflects claims made by the applicant and should not be construed as a statement of fact or an endorsement by the federal government.

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Preliminary determinations for the HCPCS Level II Public Meeting on Monday, June 2, 2025, with an overflow date of Tuesday, June 3, 2025, to be held virtually, if necessary.

Agenda Item # 1
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.

Agenda Item # 2
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.

Agenda Item # 3
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 Dressing is 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

Agenda Item # 4
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

Agenda Item # 5
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

Agenda Item # 6
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

Agenda Item # 6
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

Agenda Item # 7
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 patients 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 patient use? Also, what is the typical or recommended total duration of treatment and how often does the typical patient 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.

Agenda Item # 7
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.

Agenda Item # 8
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) for the 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

Agenda Item # 8
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:

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, 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

Agenda Item # 8
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

Agenda Item # 9
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

Agenda Item # 9
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

Agenda Item # 9
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

Agenda Item # 9
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 the 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

Agenda Item # 9
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

Agenda Item # 10
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

Agenda Item # 10
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

Agenda Item # 11
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

Agenda Item # 12
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

Agenda Item # 13
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 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 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.

Agenda Item # 14
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.

Agenda Item # 15
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.

Agenda Item # 16
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.

Agenda Item # 17
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

Agenda Item # 18
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.

Agenda Item # 18
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.

Agenda Item # 19
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

Kent 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

Agenda Item # 20
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.
Effective October 1, 2025

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

Agenda Item # 21
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.

Agenda Item # 22
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."[1] 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

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

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

Agenda Item # 22
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."[2] 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.

[2] 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

Agenda Item # 23
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 Decision

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

Agenda Item # 23
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 Decision

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

Agenda Item # 24
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 previous mentioned features. This allows users to stay as active as possible using the Rollz Motion as a rollator and they can transform it into a wheelchair whenever they need more support. This benefits rehabilitation and achieving a more active lifestyle. Over 8.5 million people in the United States of all ages with diseases like Multiple Sclerosis, Parkinson's or Amytrophic Lateral Sclerosis, or those simply having serious mobility issues may benefit greatly from a combination product like the Rollz Motion. 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

Agenda Item # 25
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

Agenda Item # 25
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 years 2004 - 2009 and zero units were allowed since 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 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, of 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 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

Agenda Item # 25
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 years 2004 - 2009 and zero units allowed since 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 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, of 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 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

Agenda Item # 26
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.

Agenda Item # 27
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

Agenda Item # 28
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

Agenda Item # 29
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 bill 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)

Agenda Item # 29
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)

Agenda Item # 30
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

Agenda Item # 31
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

Agenda Item # 32
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

Agenda Item # 32
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

Agenda Item # 32
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

Agenda Item # 33
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

Agenda Item # 34
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

Agenda Item # 35
HCPCS Level II Codes for Various FDA Approvals under the 505(b)(2) or Biologics License Application (BLA) Pathways and Products "Not Otherwise Classified" - HCP220517FAENJ

Topic/Issue

We are requesting public comment on the language in the code descriptors for the new HCPCS Level II codes that we established in CMS' Fourth Quarter of 2023 and First, Second and Third Quarters of 2024 Drug and Biological HCPCS code application review cycles, per our postings at https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Prior-YearsCMSHCPCSLevelII-Coding-Decisions-Narrative-Summary.

Summary of Applicant's Submission

CMS has been reviewing its approach for establishing HCPCS Level II codes to identify products approved under the 505(b)(2) New Drug Application (NDA) or the Biologics License Application (BLA) pathways after October 2003. These products are not rated as therapeutically equivalent to their reference listed drug in the Food and Drug Administration's (FDA) Orange Book, and are therefore considered single source products. Also, this effort will help reduce use of the not otherwise classified (NOC) codes.

In order to conform with the general approach used for the assignment of products paid under section 1847A of the Social Security Act (the Act) to HCPCS Level II codes as described at the following CMS link: https://www.cms.gov/files/document/frequently-asked-questionssingle-source-drugs-and-biologicals.pdf. CMS is making several code changes, including manufacturer specific codes to identify products approved under separate 505(b)(2) NDA or BLA pathways. Since the products are approved under separate 505(b)(2) NDAs and are not rated as therapeutically equivalent by the FDA in the Orange Book[3], they are single source drugs based on the statutory definition of "single source drug" in section 1847A(c)(6) of the Act. Because these are single source drugs, there is a programmatic need for each product to have a unique billing and payment code.

In cases where certain products meet the statutory definition of "multiple source drug" in section 1847A(c)(6) of the Act, CMS will remove the brand name of the drug from any existing HCPCS Level II code as needed as it will accommodate any associated generic product(s), if approved and marketed, that are rated as therapeutically equivalent.

Due to the complexity and nuanced nature of the differences between each product, we encourage providers to rely on the Average Sales Price (ASP) HCPCS-National Drug Code (NDC) crosswalk[4] to identify the correct billing and payment code for each applicable product.

[3] The FDA's Orange Book, officially entitled, Approved Drug Products With Therapeutic Equivalence Evaluations, identifies drug products approved on the basis of safety and effectiveness by the FDA, and is published at the following FDA link: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm.
[4] The ASP crosswalks are maintained by CMS on a quarterly basis to support ASP-based Medicare Part B payments only. The quarterly ASP crosswalks are published at the following CMS link: https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/2022-asp-drug-pricing-files.

CMS Final HCPCS Coding Decision

We established or revised ten HCPCS Level II codes within the fourth quarter (Q4) of 2024,effective April 1, 2025, and thirteen HCPCS Level II codes within the first quarter (Q1) of 2025, effective July 1, 2025, to separately identify products approved by the FDA after October 2003, and not rated as therapeutically equivalent to a reference listed product in an existing code.

We seek comment on these code descriptors.

See Appendix A for a complete list of new HCPCS Level II codes that we are establishing.

CMS intends to continue our review in subsequent HCPCS code application quarterly cycles to separately identify products approved under the 505(b)(2) NDA or the BLA pathways after October 2003, and not rated as therapeutically equivalent to a reference listed product in an existing code, as well as products that have been “not otherwise classified”.

Appendix A: HCPCS Level II Codes for Products Approved by the FDA Under the 505(b)(2) NDA or BLA Pathways and Products "Not Otherwise Classified"

HCPCS Code	Action	Long Descriptor
J1271	Add	Injection, doxycycline hyclate, 1 mg
J0281	Add	Injection, aminocaproic acid, 1 gram
J1299	Add	Injection, eculizumab, 2 mg
J1308	Add	Injection, famotidine, 0.25 mg
J1808	Add	Injection, folic acid, 0.1 mg
J1938	Add	Injection, furosemide, 1 mg
J2804	Add	Injection, rifampin, 1 mg
J2865	Add	Injection, sulfamethoxazole 5 mg and trimethoprim 1 mg
J7521	Add	Tacrolimus, granules, oral suspension, 0.1 mg
Q5152	Add	Injection, eculizumab-aeeb (bkemv), biosimilar, 2 mg
J0165	Add	Injection, epinephrine, not otherwise specified, 0.1 mg
J0166	Add	Injection, epinephrine (bpi), not therapeutically equivalent to j0165, 0.1 mg
J0167	Add	Injection, epinephrine (hospira), not therapeutically equivalent to j0165, 0.1 mg
J0168	Add	Injection, epinephrine (international medication systems), not therapeutically equivalent to j0165, 0.1 mg
J0169	Add	Injection, epinephrine (adrenalin), not therapeutically equivalent to j0165, 0.1 mg
J0616	Add	Injection, metoprolol tartrate, 1 mg
J0618	Add	Injection, calcium chloride, 2 mg
J1163	Add	Injection, diltiazem hydrochloride, 0.5 mg
J2312	Add	Injection, naloxone hydrochloride, not otherwise specified, 0.01 mg
J2313	Add	Injection, naloxone hydrochloride (zimhi), 0.01 mg
J3373	Add	Injection, vancomycin hydrochloride, 10 mg
J3375	Add	Injection, vancomycin hydrochloride (xellia), not therapeutically equivalent to j3373, 10 mg
J9292	Revise	From "Injection, pemetrexed (avyxa), not therapeutically equivalent to j9305, 10 mg" to instead read "Injection, pemetrexed dipotassium, 10 mg"
J9342	Add	Injection, thiotepa, not otherwise specified, 1 mg

Appendix B: 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.