

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



**Centers for Medicare & Medicaid Services' (CMS') Second Biannual 2026 Healthcare
Common Procedure Coding System (HCPCS) Public Meeting Agenda**

**Hybrid Meeting – Remote and in-person participation
Monday, November 2, 2026
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:

- Teams meeting login for both November 2, 2026, and November 3, 2026, if necessary:
<https://teams.microsoft.com/meet/250068995786790?p=Nzh5p6SqrDNWnK05cZ>
Meeting ID: 250 068 995 786 790 Passcode: jU9VK9XS
Phone: (888) 588-2610 (Toll-free) Phone conference ID: 102 735 428#

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 February 2027 and will be effective April 1, 2027, unless otherwise specified.

This document includes a summary of each HCPCS Level II code application being presented on Monday, November 2, 2026, with an overflow date of Tuesday, November 3, 2026, to be held virtually, if 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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Red Blood Cells, Leukocytes Reduced, Oxygen/Carbon Dioxide Reduced, Irradiated, - HCP260602QB8LG

Topic/Issue

Request to establish a new HCPCS Level II code to identify red blood cells (RBCs), leukocytes reduced (LR), oxygen/carbon dioxide (O2/CO2) reduced, irradiated.

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

Summary of Applicant's Submission

Hemanext submitted a request to establish a new HCPCS Level II code to identify RBCs, LR, O2/CO2 reduced, irradiated. RBCs, LR, O2/CO2 reduced, irradiated was approved by the Food and Drug Administration (FDA) under a De Novo classification on September 15, 2023. The RBCs, LR, O2/CO2 reduced, irradiated blood component product is manufactured from RBCs, LR, O2/CO2 reduced blood components and is further processed using the standard FDA-authorized dose of X-ray or gamma irradiation to render residual T lymphocytes incapable of proliferation, thereby reducing the risk of transfusion-associated graft-versus-host disease in susceptible individuals.

CMS Preliminary HCPCS Coding Determination

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

Revise Existing HCPCS Level II Code H0005 - HCP260226GXRW1

Topic/Issue

Request to revise existing HCPCS Level II code H0005, “Alcohol and/or drug services; group counseling by a clinician” to incorporate language specifying 15-minute increments.

Applicant's suggested language: H0005, “Alcohol and/or drug services; group counseling by a clinician, 15 minutes”

Summary of Applicant's Submission

The Department of Human Services, State of Minnesota (MN), submitted a request to revise existing HCPCS Level II code H0005 to incorporate language specifying 15-minute increments. A state law was recently passed for substance use disorder services to correspond to a 15-minute unit. Within the list of services, there is a need for 15-minute group counseling session. The existing HCPCS Level II code H0005 is not a time-based code. The state law requires the commissioner of human services to establish six new billing codes for nonresidential substance use disorder individual and group counseling, individual and group psychoeducation, and individual and group recovery support services. The commissioner must identify reimbursement rates for the newly defined codes and update the substance use disorder fee schedule. The State of Minnesota is requesting that the new HCPCS Level II code corresponds to a 15-minute unit and become effective for services provided on or after July 1, 2026, or upon federal approval, whichever is later.

CMS Preliminary HCPCS Coding Determination

Establish a new HCPCS Level II code HXXXX, “Alcohol and/or drug services; group counseling by a clinician, 15 minutes”

HCPCS Level II code HXXXX will directly address Minnesota's need for a 15-minute unit of service for group counseling, consistent with the State's recently enacted legislation. Because other payers may have already established their own billing policies around existing HCPCS Level II code H0005, which may not reflect a specific 15-minute time increment, CMS is not proposing any changes to the existing HCPCS Level II code. This approach allows Minnesota's 15-minute billing requirement to be met through a new, distinct code while preserving the flexibility other payers currently have under HCPCS Level II code H0005.

Plus™ Nutritional Cookie - HCP260629GRT01

Topic/Issue

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

Applicant's suggested language: XXXXX, “Enteral formula, nutritionally complete with intact nutrients in solid cookie form, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, orally administered, per 100 calories”

Summary of Applicant's Submission

Thrive Nutrition, LLC submitted a request to establish a new HCPCS Level II code to identify Plus™ Nutritional Cookie. Plus™ Nutritional Cookie is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). Plus™ Nutritional Cookies are ready-to-eat cookies supplied in a container containing four servings (eight cookies total). Each serving consists of two cookies (50 g) and provides 220 calories, 10–11 g of protein, 12 g of total fat, 19 g of total carbohydrate (including 2 g of dietary fiber and 9 g of total sugars), along with a complete profile of vitamins and minerals. The function of Plus™ Nutritional Cookies is to provide supplemental or complete oral nutrition for individuals who require increased caloric and nutrient intake due to disease-related malnutrition, cachexia, post-surgical recovery, or mild-to-moderate dysphagia but who cannot or will not tolerate liquid oral nutritional supplements. Indications for use include the dietary management of individuals with functional gastrointestinal tracts who require palatable, nutrient-dense oral nutrition to prevent further weight loss, support recovery, and improve compliance. The product delivers balanced intact nutrients in a convenient solid form that enhances user acceptance and adherence compared with liquid oral nutritional supplements.

CMS Preliminary HCPCS Coding Determination

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

Plus™ Nutritional Cookie is an orally administered nutritional product intended for individuals who require increased caloric and nutrient intake due to disease-related malnutrition. It is not intended for administration via a feeding tube. Like other items and services classified under HCPCS Level II code A9270, Plus™ Nutritional Cookie does not fall under an existing Medicare benefit category or is excluded from Medicare coverage by statute and is non-covered for Medicare. We have not identified a processing need for Medicare or other payers for a unique HCPCS Level II code for this item or service. Other payers may use HCPCS Level II code A9270 or other HCPCS Level II codes as they deem appropriate. 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.

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 is not enteral nutritional therapy. We also do not believe this product falls under any other DMEPOS benefit category.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code A9270 apply to this product. Items or services described by HCPCS Level II code A9270 are not covered under Medicare Part B.

No Medicare payment. Pricing Indicator = 00

PSACH Care™ - HCP2605205WA0H

Topic/Issue

Request to establish a new HCPCS Level II code to identify PSACH Care.

The applicant did not submit any suggested language.

Summary of Applicant's Submission

Solace Nutrition submitted a request to establish a new HCPCS Level II code to identify PSACH Care™. PSACH Care™ is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). PSACH Care™ is a medical food for the dietary management of joint degeneration and discomfort associated with pseudoachondroplasia and other forms of skeletal dysplasia. PSACH Care™ enhances the absorption of curcumin by nearly 40-fold at a much lower dose than standard 95% curcumin. Each softgel contains 400 mg of PSACH Care™ and is administered orally either as a softgel or by removing the contents of the softgel and mixing them with moist foods or thick liquids.

CMS Preliminary HCPCS Coding Determination

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

PSACH Care™ is orally administered medical food used for dietary management and is not administered via a feeding tube. Like other items and services classified under HCPCS Level II code A9270, PSACH Care™ does not fall under an existing Medicare benefit category or is excluded from Medicare coverage by statute and is non-covered for Medicare. We have not identified a processing need for Medicare or other payers for a unique HCPCS Level II code for this item or service. Other payers may use HCPCS Level II code A9270 or other HCPCS Level II codes as they deem appropriate. 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.

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 is not enteral nutritional therapy. We also do not believe this product falls under any other DMEPOS benefit category.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code A9270 apply to this product. Items or services described by HCPCS Level II code A9270 are not covered under Medicare Part B.

No Medicare payment. Pricing Indicator = 00

Crescel™ Skin Renewal Cream - HCP2606299X13F

Topic/Issue

Request to establish a new HCPCS Level II code to identify Crescel™ skin renewal cream.

Applicant's suggested language: XXXXX, "Biobotanical skin renewal cream, supporting skin hydration, skin barrier function, skin integrity, and overall skin condition, per gram"

Summary of Applicant's Submission

Crescel LLC submitted a request to establish a new HCPCS Level II code to identify Crescel™ skin renewal cream. Crescel™ skin renewal cream is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). Crescel™ skin renewal cream is a non-drug topical bio botanical skin renewal cream designed to support skin hydration, skin barrier function, skin integrity, and overall skin condition as part of routine clinical care.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II code A6250, "Skin sealants, protectants, moisturizers, ointments, any type, any size" describes Crescel™ skin renewal cream.

CMS understands that Crescel™ skin renewal cream supports skin integrity, skin barrier function, and overall skin condition in individuals experiencing skin compromise associated with chronic medical conditions, injury, or environmental stressors. Crescel™ skin renewal cream is similar to other products in HCPCS Level II code A6250.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code A6250 apply to this product. Items or services described by HCPCS Level II code A6250 are not covered under Medicare Part B.

No Medicare payment. Pricing Indicator = 00

ClearikonFLEX™ - HCP260625AV6BF

Topic/Issue

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

Applicant's suggested language: AXXXX, "ClearikonFLEX"

Summary of Applicant's Submission

Clear Care Products, Inc. submitted a request to establish a new HCPCS Level II code to identify ClearikonFLEX™. ClearikonFLEX™ received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on June 7, 2026. ClearikonFLEX™ is a sterile, multi-component wound bandage system supplied as a single packaged item. The system consists of a skin-adhering frame incorporating a silicone pressure-sensitive adhesive and a removable window component that is pre-installed on the frame at the time of purchase. The window component attaches to the frame using a high-density hook-and-loop mechanism and may be repeatedly removed and resealed, allowing wound or ulcer dressing changes without removal of the bandage frame from the individual. ClearikonFLEX™ adheres directly to the skin and functions as a primary wound management system, damage and disturbance to the wound and surrounding areas is avoided by negating the need for constant pulling off of adhesive bandages. The ClearikonFLEX™ system is not a gauze, film, hydrocolloid, alginate, or composite dressing as described by the existing HCPCS Level II codes and is not intended solely as a secondary securing device.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II codes A6257, "Transparent film, sterile, 16 sq. in. or less, each dressing", and A6258, "Transparent film, sterile, more than 16 sq. in. but less than or equal to 48 sq. in., each dressing", depending on size, describes ClearikonFLEX™.

ClearikonFLEX™ is a peelable window or flap that allows for daily wound inspection and targeted treatment without requiring full removal of the base bandage. It is a sterile wound management surgical dressing device intended for use with a separately selected primary wound dressing.

It is our understanding that ClearikonFLEX™ does not exceed 48 square inches. As such, HCPCS Level II code A6259, "Transparent film, sterile, more than 48 sq. in., each dressing" is currently not applicable for describing ClearikonFLEX™, as the product does not meet the size threshold required for billing under this code.

Preliminary Medicare Benefit Category Determination

Surgical Dressings.

Based on the information submitted, this is a sterile wound management device intended for use with a separately selected primary wound dressing. The device is applied to intact peri-wound skin to secure, cover, and protect an underlying primary dressing while permitting access to the wound through a resealable window. The applicant states that the device does not contact the wound bed and functions as a secondary dressing. Accordingly, we believe

this item falls within the Medicare benefit category for surgical dressings in accordance with section 100 of chapter 15 of the Medicare Benefit Policy Manual.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II codes A6257 and A6258 apply to this product, if covered. The current average 2026 fee schedule amount for each unit of HCPCS Level II code A6257 is \$2.19. The current average 2026 fee schedule amount for each unit of HCPCS Level II code A6258 is \$6.17.

The average fee schedule amount is the average of the 2026 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 = 35

ECM3™ - HCP2606305WD0M

Topic/Issue

Request to establish a new HCPCS Level II code to identify ECM3™.

Applicant's suggested language: AXXXX, “ECM3™ Extra Cellular Matrix Particles, per square centimeter”

Summary of Applicant's Submission

Maiden Biosciences Inc. submitted a request to establish a new HCPCS Level II code to identify ECM3™. ECM3™ received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on April 25, 2025. ECM3™ is indicated for the management of wounds including full thickness and partial thickness wounds, pressure (stage I-IV) and venous ulcers, ulcers caused by mixed vascular etiologies, venous stasis and diabetic ulcers, first degree and superficial second-degree burns, cuts, abrasions and surgical wounds. ECM3™ are comprised of 100% pure bovine type I collagen without any artificial substances. The particles have been engineered to maintain their original triple helix structure, which supports biocompatibility with enhanced support and stability. The particles are used dry to absorb excess wound exudate, and in the case of chronic non exudating wounds are moistened with sterile water; depending on the wound type either application transforms into a soft conformable gel sheet, that protects the wound and maintains a moist wound environment. It is typically applied to chronic wounds after being moistened with sterile water & replaced every 72 hours. ECM3™ is categorized as surface device for breached or compromised surface with permanent duration. It is applied topically directly to the affected area as a direct contact primary wound covering that is secured into place with a suitable secondary dressing and can be applied to a wound either in the dry state or pre-hydrated with sterile saline. ECM3™ is sterile and intended for one time use. It is packaged in sterile single use 0.5-, 1-, 2-or 5-gram Tyvek®/poly pouch packaging.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II code A6010, “Collagen based wound filler, dry form, sterile, per gram of collagen” describes ECM3™.

ECM3™ is a bovine collagen matrix powder similar to other products in HCPCS Level II code A6010.

Preliminary Medicare Benefit Category Determination

Surgical Dressings.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code A6010 apply to this product, if covered. The current average 2026 fee schedule amount for HCPCS Level II code A6010 is \$44.31.

The average fee schedule amount is the average of the 2026 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 = 35

ECM3™ Extra Cellular Matrix - HCP260508WKU3E

Topic/Issue

Request to establish a new HCPCS Level II code to identify ECM3™ Extra Cellular Matrix.

Applicant's suggested language: AXXXX, "ECM3™ Extra Cellular Matrix, per square centimeter"

Summary of Applicant's Submission

Maiden Biosciences Inc. submitted a request to establish a new HCPCS Level II code to identify ECM3™ Extra Cellular Matrix. ECM3™ Extra Cellular Matrix received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on August 5, 2022. It is indicated for use in the management of wounds including partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, ulcers caused by mixed vascular etiologies, partial thickness burns, donor sites and other bleeding surface wounds, abrasions, traumatic wounds healing by secondary intention, and dehiscent surgical incisions. It is comprised of a porous matrix of cross-linked biodegradable bovine type-1 collagen. The dressing is used dry to absorb excess wound exudate and in the case of chronic non exudating wounds are moistened with sterile water, depending on the wound type either application transforms into a soft conformable gel sheet. ECM3™ Extra Cellular Matrix is typically applied to chronic wounds after being moistened with sterile water & replaced every 72 hours. For exudating wounds, the devices are utilized dry and replaced upon complete saturation of the device. The proposed maximum dosage/usage is up to 900 cm square per day per user. ECM3™ Extra Cellular Matrix is applied directly to the affected area as a direct contact primary wound covering that is secured into place with a suitable secondary dressing. It is a malleable, absorbent, biodegradable porous matrix topical wound dressing comprised of bovine collagen, supplied terminally sterile, in single use Tyvek®/poly packaging, shelf boxes holding 15 dressings, and are available in a variety of sizes to accommodate most wound sizes.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II codes A6021, "Collagen dressing, sterile, size 16 sq. in. or less, each", A6022, "Collagen dressing, sterile, size more than 16 sq. in. but less than or equal to 48 sq. in., each" and A6023, "Collagen dressing, sterile, size more than 48 sq. in., each" depending on size, describes ECM3™ Extra Cellular Matrix.

ECM3™ Extra Cellular Matrix is a bovine collagen matrix similar to other products in HCPCS Level II codes A6021, A6022 and A6023.

Preliminary Medicare Benefit Category Determination

Surgical Dressings.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code A6021, A6022, and A6023 apply to this product, if covered. The current average 2026 fee schedule

amount for HCPCS Level II code A6021 is \$30.08. The current average 2026 fee schedule amount for HCPCS Level II code A6022 is \$30.08. The current average 2026 fee schedule amount for HCPCS Level II code A6023 is \$272.24.

The average fee schedule amount is the average of the 2026 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 = 35

OxyGeni® - HCP26070164E4R

Topic/Issue

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

Applicant's suggested language: XXXXX, "Portable, durable continuous diffusion of oxygen wound therapy system, including oxygen generator, oxygen diffusion dressing interface, adjustable oxygen flow control and display, excessive pressure or blockage monitoring with visual and audible alarms, power supply, tubing, and necessary supplies"

Summary of Applicant's Submission

VantageView submitted a request to establish a new HCPCS Level II code to identify OxyGeni®. TransCu O2 that was replaced by OxyGeni® in 2020, received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on August 12, 2009. OxyGeni® continuously delivers physiologically relevant amounts of pure, humidified oxygen uniformly across the wound tissue of an acute or chronic wound, a therapy commonly referred to as continuous diffusion of oxygen. It provides pure humidified oxygen to the wound bed at a therapeutic concentration, that is controlled, monitored and can be adjusted to different levels. The portability of the OxyGeni® allows an individual to continue their activities of daily living during treatment. It constantly monitors wound bed pressure to prevent tissue damage from localized pressure injury. The flow rate of oxygen can be varied to control the amount of exudate. OxyGeni® treatment results in significant pain relief; the improved wound perfusion and angiogenesis promote the growth of new blood vessels, which is crucial for tissue repair.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II code E0446, "Topical oxygen delivery system, not otherwise specified, includes all supplies and accessories" describes OxyGeni®.

The OxyGeni® replaced the TransCu O2 that was assigned to HCPCS Level II code E0446. HCPCS Level II code E0446 was established in 2010 to differentiate TransCu O2 from the hyperbaric oxygen products described by HCPCS Level II code A4575, "Topical hyperbaric oxygen chamber, disposable."

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

The current Medicare policy and prior established Medicare benefit category determination for HCPCS Level II code E0446 apply to this item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with existing HCPCS Level II code E0446 apply to this product, if covered. HCPCS Level II code E0446 is all-inclusive and includes all supplies and accessories, such as dressings, related to furnishing the oxygen delivery system. In accordance with the DME Medicare Administrative Contractor local coverage

determinations, Medicare claims for code E0446 are denied as not reasonable and necessary. There are no fee schedules established for this code.

Pricing Indicator = 00

OxySpur® Oxygen Diffusion Dressing - HCP260701Y69UV

Topic/Issue

Request to establish a new HCPCS Level II code to identify OxySpur® oxygen diffusion dressing.

Applicant's suggested language: AXXXX, "Disposable oxygen diffusion dressing (ODD) that is used in as part of a portable continuous diffusion of oxygen therapy system that constantly monitors wound bed pressure and delivers oxygen through the ODD for the treatment of qualifying chronic and ischemic wounds"

Summary of Applicant's Submission

VantageView submitted a request to establish a new HCPCS Level II code to identify OxySpur® oxygen diffusion dressing (ODD). TransCu O2 that was replaced by OxyGeni® in 2020, received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on August 12, 2009. The OxySpur® ODD is used with OxyGeni® device to continuously deliver physiologically relevant amounts of pure, humidified oxygen uniformly across the wound tissue of an acute or chronic wound. It provides oxygen to the wound bed at a therapeutic concentration, that is controlled, monitored and can be adjusted to different levels. The portability of the continuous diffusion of oxygen allows the patient to continue their activities of daily living during treatment. The OxySpur® ODD enables monitoring wound bed pressure to prevent tissue damage from localized pressure injury. Continuous diffusion of oxygen treatment results in significant pain relief, making it beneficial for users. The improved wound perfusion and angiogenesis promote the growth of new blood vessels, which is crucial for tissue repair.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II code E0446, "Topical oxygen delivery system, not otherwise specified, includes all supplies and accessories" describes OxySpur® ODD.

The OxyGeni® replaced the TransCu O2 that was assigned to HCPCS Level II code E0446. HCPCS Level II code E0446 was established to differentiate TransCu O2 from the hyperbaric oxygen products described by HCPCS Level II code A4575, "Topical hyperbaric oxygen chamber, disposable."

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

The current Medicare policy and prior established Medicare benefit category determination for HCPCS Level II code E0446 apply to this item. The OxySpur® dressing is a disposable, single use accessory that is designed for use with the OxyGeni® system.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with existing HCPCS Level II code E0446 apply to this product, if covered. HCPCS Level II code E0446 is all-inclusive and includes all supplies

and accessories, such as dressings, related to furnishing the oxygen delivery system. In accordance with the DME Medicare Administrative Contractor local coverage determinations, Medicare claims for HCPCS Level II code E0446 are denied as not reasonable and necessary. There are no fee schedules established for this HCPCS Level II code.

Pricing Indicator = 00

Groove Pad - HCP260202PQ92B

Topic/Issue

Request to establish a new HCPCS Level II code to identify Groove Pad.

Applicant's suggested language: XXXXX, "Silicone lymphedema pressure pad with integrated channeling and anatomical contouring for localized use, accessory to compression therapy, each"

Summary of Applicant's Submission

American Breast Care submitted a request to establish a new HCPCS Level II code to identify Groove Pad. Groove Pad is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). Groove Pad is silicone-based, open-cell lymphatic pressure-modifying pad intended for use under compression therapy in the management of lymphedema or radiation-related fibrosis. It is used as an accessory to compression garments or bandaging systems to locally modify pressure distribution and assist in the management of swelling fibrotic tissue associated with lymphedema. The pad is comprised of a three-dimensional lattice structure with channeled surfaces intended to influence localized tissue response when used under sustained compression.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II code A6593, "Accessory for gradient compression garment or wrap with adjustable straps, not-otherwise specified" describes Groove Pad.

Groove Pad is intended for use as an accessory under compression garments or bandaging systems in the management of lymphedema-related fibrosis and localized edema. The item does not provide compression independently. Groove Pad is a silicone-based, open-cell lymphatic pressure-modifying pad similar to other products in HCPCS Level II code A6593.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code A6593 apply to this product. Local fee schedule amounts are established by the DME Medicare Administrative Contractors for any covered claims.

Pricing Indicator = 40

Aurie Reusable No-Touch Intermittent Catheter System - HCP260701MP8GG

Topic/Issue

Request to establish three new HCPCS Level II codes to identify Aurie Reusable No-Touch Intermittent Catheter System (or Aurie System) and supplies.

Applicant's suggested language:

1. XXXXX, “No-touch intermittent urinary catheter, reusable with automated washer-disinfector, 100 uses, each.”
2. XXXXX, “Washer-disinfector for reusable catheter, home-use, each.”
3. XXXXX, “Reusable catheter system supplies (detergent, high-level disinfectant, lubricant, filters, and self-disinfectant), per 30 days.”

Summary of Applicant's Submission

CathBuddy, Inc. submitted a request to establish three new HCPCS Level II codes to identify Aurie Reusable No-Touch Intermittent Catheter System (or Aurie System). Aurie Reusable No-Touch Intermittent Catheter System received De Novo classification by the Food and Drug Administration (FDA) on April 30, 2026. The Aurie System is indicated for bladder drainage in adult males requiring intermittent catheterization. Before each use, the catheter must be cleaned, high-level disinfected, and lubricated using the Aurie personal washer-disinfector. The Aurie System is intended for single-user reuse. Although the washer-disinfector and reprocessing supplies do not independently drain urine, FDA labeling requires them to prepare the catheter for both initial and continued reuse; therefore, they must be identified in the coding. The Aurie System includes the following components: a reusable, radio-frequency identification device-tagged, no-touch catheter rated for up to 100 uses; a portable washer-disinfector with an accompanying power supply; and monthly reprocessing supplies. Monthly supplies consist of 20 consumable supply pods per 100-use catheter – each containing detergent, high-level disinfectant, and lubricant, as well as a self-disinfection kit containing a replacement filter and self-disinfectant used to disinfect the washer-disinfector every 14 days. The catheter may be reprocessed prior to each use for up to 100 total uses. The Aurie System is shipped monthly and includes 2 reusable catheters, 40 supply pods, and 2 self-disinfection kits. The initial shipment also includes the washer-disinfector and its charger.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II code A4353, “Intermittent urinary catheter, with insertion supplies” describes the Aurie Reusable No-Touch Intermittent Catheter System.

The Aurie Reusable No-Touch Intermittent Catheter System is the reusable equivalent to 100 catheters. HCPCS Level II code A4353 describes an intermittent catheter and is not specific to disposable or non-disposable intermittent catheters.

Preliminary Medicare Benefit Category Determination

Prosthetic Device.

Based on the information submitted, the catheter performs urinary drainage through insertion into the bladder via the urethra and is intended for prescription use by individuals with urinary retention or other voiding dysfunctions requiring intermittent catheterization. Accordingly, we believe this item falls within the Medicare prosthetic device benefit category applicable to urinary catheters when ordered for an individual with permanent urinary incontinence in accordance with section 120 of chapter 15 of the Medicare Benefit Policy Manual. The product can be used for 100 catheter insertions.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code A4353 apply to this product, if covered. The current 2026 fee schedule amounts for each unit of HCPCS Level II code A4353 range from \$9.97 to \$10.97. Multiplying these fee schedule amounts by 100 results in fee schedule amounts for one reusable catheter ranging from \$997.00 to \$1,097.00. Fee schedules are updated annually.

For Medicare billing, additional individual components must not be separately billed, as doing so is considered unbundling. Therefore, the Aurie washer-disinfector, power supply, and monthly supplies would not be separately billable. Catheters are furnished based on the prescribed number of catheterizations per individual. For example, if the prescription indicates four catheterizations per day for the individual, 120 units of HCPCS Level II code A4353 would be billed per month (30 days). In this example, the supplier alternatively would furnish two reusable Aurie Reusable No-Touch Intermittent Catheters for month one, billing 120 units of HCPCS Level II code A4353. The next month, the supplier would still bill 120 units of HCPCS Level II code A4353 but would only need to furnish one reusable Aurie Reusable No-Touch Intermittent Catheter since the second catheter furnished for use in the previous month would continue to be used for 80 catheterizations in the second month. Suppliers of the reusable catheters would continue billing 120 units of HCPCS Level II code A4353 and would furnish replacements of the reusable catheters as needed for each subsequent month.

Pricing Indicator = 37

Peelaways - HCP260522E39PP

Topic/Issue

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

The applicant did not submit any suggested language.

Summary of Applicant's Submission

Peel Away Labs submitted a request to establish a new HCPCS Level II code to identify Peelaways. Peelaways is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). Peelaways is a multilayer disposable waterproof fitted sheet designed for individuals with incontinence in home care, assisted living, and institutional settings. Peelaways is a fitted sheet constructed of multiple bonded waterproof layers that fits directly over a standard mattress like a conventional fitted sheet. Each layer consists of a soft, breathable top surface laminated to a waterproof barrier. When soiling occurs, the caregiver peels away the soiled top layer to reveal a clean, dry layer beneath. Peelaways is used in conjunction with, or as a replacement for, traditional waterproof mattress covers in cases of urinary or fecal incontinence. A soiled sheet change that would otherwise require lifting, repositioning, and laundering is reduced to a single peel. This dramatically lowers the physical and emotional burden on caregivers, while improving user comfort and dignity by minimizing disruption during vulnerable moments.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II code A9270, "Non-covered item or service" describes Peelaways.

Peelaways is a multilayer disposable waterproof fitted sheet designed for use by individuals with incontinence in home care, assisted living, and institutional settings. Like other items and services classified under HCPCS Level II code A9270, Peelaways does not fall under an existing Medicare benefit category or is excluded from Medicare coverage by statute and is non-covered for Medicare. We have not identified a processing need for Medicare or other payers for a unique HCPCS Level II code for this item or service. Other payers may use HCPCS Level II code A9270 or other HCPCS Level II codes as they deem appropriate. 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.

Based on the information submitted, Peelaways is a disposable bedding incontinence supply. In accordance with section 280.1 of chapter 1, part 4 of the Medicare National Coverage Determinations Manual, incontinent pads are not durable medical equipment because they are non-reusable supplies and hygienic items. In accordance with section 120 of chapter 15 of the Medicare Benefit Policy Manual, chucks, diapers, rubber sheets, etc., are supplies that are not classified as prosthetic devices. Incontinent pads or sheets like Peelaways also do not fall under any other DMEPOS benefit category: surgical dressings, splints, casts, braces, artificial

legs, arms, or eyes, therapeutic shoes and inserts or lymphedema compression treatment items.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code A9270 apply to this product. Items or services described by HCPCS Level II code A9270 are not covered under Medicare Part B.

No Medicare payment. Pricing Indicator = 00

Strolll Augmented Reality Rehabilitation System – HCP260701ART0Y

Topic/Issue

Request to revise existing HCPCS Level II code E3200, “Gait modulation system, rhythmic auditory stimulation, including restricted therapy software, all components and accessories, prescription only” to remove the terms rhythmic, auditory stimulation, including restricted therapy software, all components and accessories, and add for the treatment of gait deficits, including auditory, visual, or multimodal sensory cueing, including virtual reality.

Applicant's suggested language: E3200, “Gait modulation system for the treatment of gait deficits, including auditory, visual, or multimodal sensory cueing, including virtual reality, each”

Summary of Applicant's Submission

Strolll Inc. submitted a request to revise the existing HCPCS Level II code E3200 to further identify the Strolll Augmented Reality Rehabilitation System. The Strolll Augmented Reality Rehabilitation System is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The system is a prescription-only assisted rehabilitation and therapy program designed to address cognitive, motor, balance, and gait impairments. The software supports rehabilitation by providing motivation to perform physical exercises and helping individuals train and regain neuromotor control. This is delivered through interactive digital content via wearable augmented reality glasses. The Strolll Augmented Reality Rehabilitation System is a combination of immersive virtual reality, visual cueing, and disease-specific rehabilitation, targeting Parkinson's disease and other conditions associated with cognitive and motor dysfunction.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II code A9270, “Non-covered item or service” describes the Strolll Augmented Reality Rehabilitation System.

The Strolll Augmented Reality Rehabilitation System is a prescription-only rehabilitation and therapy program designed to address cognitive, motor, balance, and gait impairments. HCPCS Level II code E3200 describes a gait modulation system that provides rhythmic auditory stimulation. In contrast, the Strolll Augmented Reality Rehabilitation System provides a broader rehabilitation program that includes visual cueing and therapeutic exercises for cognitive and motor rehabilitation, balance, and gait training. Because the software primarily uses visual cueing rather than the auditory stimulation described by HCPCS Level II E3200, the Strolll Augmented Reality Rehabilitation System is not appropriately described by HCPCS Level II code E3200. Therefore, the request to revise HCPCS Level II code E3200 is denied.

Like other items and services classified under HCPCS Level II code A9270, The Strolll Augmented Reality Rehabilitation System does not fall under an existing Medicare benefit category or is excluded from Medicare coverage by statute and is non-covered for Medicare. We have not identified a processing need for Medicare or other payers for a unique HCPCS Level II code for this item or service. Other payers may use HCPCS Level II code A9270 or

other HCPCS Level II codes as they deem appropriate. 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.

Based on the information submitted, the Strolll Augmented Reality Rehabilitation System delivers its therapeutic effect through software that provides visual cueing and rehabilitation exercises using commercially available augmented reality head mounted devices. The therapeutic intervention is performed by the software, while the head mounted device functions as the platform through which the software is displayed. The information submitted does not demonstrate that the head mounted device itself is a dedicated medical device or that it independently serves a therapeutic function. Accordingly, the item is more accurately characterized as therapeutic software operating on commercially available hardware rather than as durable medical equipment, nor would it fall under any other DMEPOS benefit category. Therefore, we do not believe the Strolll Augmented Reality Rehabilitation System falls within an existing Medicare DMEPOS benefit category.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code A9270 apply to this product. Items or services described by HCPCS Level II code A9270 are not covered under Medicare Part B.

No Medicare payment. Pricing Indicator = 00

NeuroCuple® - HCP260623VD9F1

Topic/Issue

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

Applicant's suggested language: XXXXX, “Reusable passive bioelectrical coupling device, non-powered, external use, for non-pharmacologic pain management, each”

Summary of Applicant's Submission

nCAP Medical Inc. submitted a request to establish a new HCPCS Level II code to identify NeuroCuple®. NeuroCuple® is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). NeuroCuple® is a reusable passive bioelectrical coupling device intended for external use in scalable non-pharmacologic pain management without external power. It is a non-powered, external device, designed to provide a non-drug, non-invasive medical device option without delivering electrical stimulation, externally generated energy, pharmaceuticals, or other consumable agents/components. This Class I medical device is intended to support relief of pain and to facilitate mobility and functional improvement as part of non-opioid care pathways. NeuroCuple® may be applied over intact skin, clothing, or bandaging, and is again reusable for extended periods of use. The device is supplied individually, or in kits, containing multiple sizes for varying individual applications.

CMS Preliminary HCPCS Coding Determination

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

NeuroCuple® is an external passive bioelectrical patch designed for non-pharmacologic pain management. It features a three-layer nano-capacitive structure that passively interacts with the body's bioelectrical field to help calm local electrical disturbances. Like other items and services classified under HCPCS Level II code A9270, NeuroCuple® does not fall under an existing Medicare DMEPOS benefit category or is excluded from Medicare coverage by statute and is non-covered for Medicare. We have not identified a claims processing need for Medicare or other payers for a unique HCPCS Level II code for this item or service. Other payers may use HCPCS Level II code A9270 or other HCPCS Level II codes as they deem appropriate. 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.

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

1. Can withstand repeated use.

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

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

Can withstand repeated use. – According to the application, the “NeuroCuple® is a reusable passive external bioelectrical coupling device intended for extended use by an individual patient.” Medical equipment classified as DME must be able to withstand repeated use. This means that medical equipment must be able to be rented, refurbished and used by successive patients.

Has an expected lifetime of at least 3 years. – The applicant stated that the NeuroCuple® “is not labeled with a fixed multi-year service life and is not intended to meet long-term durability criteria (e.g., ≥ 3 years).”

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code A9270 apply to this product. Items or services described by HCPCS Level II code A9270 are not covered under Medicare Part B.

No Medicare payment. Pricing Indicator = 00

ExaStim® Stimulation System - HCP260630J3GVL

Topic/Issue

Request to establish a new HCPCS Level II code to identify ExaStim® Stimulation System.

Applicant's suggested language: XXXXX, “Transcutaneous electrical spine stimulation system, portable, complete system, with programmable multichannel stimulator and programmer capable of independent channel-specific control and delivery of distinct stimulation parameter sets through a multi-channel spinal electrode pad”

Summary of Applicant's Submission

ANEUVO submitted a request to establish a new HCPCS Level II code to identify ExaStim® Stimulation System. ExaStim® Stimulation System received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on March 27, 2026. ExaStim® Stimulation System is a portable, multichannel transcutaneous spinal neuromodulation system that delivers programmable electrical stimulation through multiple independently controlled channels. Each stimulation channel may be independently programmed with unique waveform, amplitude, frequency, pulse width, polarity, channel selection, and firing sequence, enabling the simultaneous delivery of distinct stimulation programs through a proprietary multichannel spinal electrode pad. The ExaStim® Stimulation System consists of a reusable portable multichannel stimulator, programmer, stimulation and return cables, return electrodes, multichannel spinal electrode pad, and related consumables. The ExaStim® Stimulation System is intended for use by qualified healthcare professionals in hospitals, inpatient rehabilitation, and outpatient rehabilitation settings, and may also be prescribed for home use under professional supervision. The ExaStim® Stimulation System is indicated for adults with chronic, non-progressive neurological deficits resulting from incomplete spinal cord injury, when used in conjunction with functional task practice. Prior to treatment, user-specific spinal motor mapping is performed to identify stimulation locations and channel configurations that selectively recruit targeted spinal neural pathways. The prescribing clinician then programs stimulation parameters according to each individual's anatomy, injury profile, and therapeutic objectives. The ExaStim® Stimulation System is delivered transcutaneously through a multichannel spinal electrode pad positioned over the spine.

CMS Preliminary HCPCS Coding Determination

Establish a new HCPCS Level II code EXXXX, “Transcutaneous electrical spine stimulator” to describe ExaStim® Stimulation System.

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

Based on the information submitted, this is an external, prescription electrical stimulation device intended for home use by beneficiaries with chronic incomplete spinal cord injury. This is used to deliver transcutaneous electrical stimulation as prescribed by the treating practitioner to improve upper extremity neurological function. The device is appropriate for use in the home, is primarily and customarily used to serve a medical purpose, generally is not useful in the absence of illness or injury, and is capable of withstanding repeated use for

at least three years. Accordingly, we believe the ExaStim® device falls within the Durable Medical Equipment benefit category under section 1861(n) of the Social Security Act and 42 Code of Federal Regulations (CFR) 414.202.

Preliminary Medicare Payment Determination

In accordance with Medicare regulations at 42 CFR 414.238(b), fee schedule amounts for new HCPCS Level II codes for items and services without a fee schedule pricing history are established using existing fee schedule amounts for 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 ExaStim® stimulator is comparable to HCPCS Level II code E0730 with respect to its physical, mechanical, and electrical components, technology platform, and overall function. Both are portable, external, non-implanted transcutaneous electrical stimulation devices that include a portable stimulator, user controls, cables that connect the stimulator to surface electrodes, and programmable, user-adjustable stimulation. Although the ExaStim® device targets the spinal cord and items classified in HCPCS Level II code E0730 target peripheral sensory nerves, both use the same general transcutaneous electrical stimulation technology. We also note that HCPCS Level II code E0730 does not distinguish between programmable and non-programmable devices. Therefore, the preliminary payment determination for the ExaStim® device is to establish the fee schedule amounts using the existing fee schedule amounts for comparable items described by HCPCS Level II code E0730.

	ExaStim® Device	HCPCS Level II code E0730
Physical Components	• ExaStim programmer • ExaStim® portable stimulator • ExaStim® return electrode cable • ReCure® stimulation cable	• Built-in programmer • Portable stimulator • Lead wires
Mechanical Components	• Portable housing	• Portable housing
Electrical Components	• External (non-implanted) stimulator • Independent channel-specific waveform control (frequency, amplitude, pulse width, polarity, firing sequence) • Non-invasive 16-channel multi-electrode array • Rechargeable portable stimulator with charging cables	• External (non-implanted) stimulator • Channel-specific stimulation parameter control (frequency, amplitude, pulse width, and treatment mode) • Non-invasive 2-channel, 4-electrode array • Battery-powered or rechargeable

Function and Intended Use	• Provides transcutaneous electrical nerve stimulation • Delivers transcutaneous stimulation through electrodes placed over the cervical spine • Used with functional task practice and rehabilitation. • Target of stimulation: Spinal cord and spinal neural pathways through electrodes placed over the cervical spine • Intended to improve hand strength and sensation in adults with incomplete spinal cord injury	• Provides transcutaneous electrical nerve stimulation • Delivers transcutaneous stimulation through electrodes placed over the skin above the targeted peripheral nerves • Target of stimulation: Peripheral sensory nerves through electrodes placed over or near the painful area • Intended to relieve chronic pain in individuals through transcutaneous electrical nerve stimulation
Additional Aspects and Features	• Under clinician supervision • User-adjustable stimulation parameters • Independently programmable multichannel stimulation • Up to 16 stimulation channels	• Under clinician supervision • User-adjustable stimulation parameters • Programmable multi-channel stimulation • Up to 2 stimulation channels

CMS recognizes the new indications through our preliminary valuation to compare the technology to HCPCS Level II code E0730 devices prior to competitive bidding, when devices to treat a range of conditions like insomnia, depression, anxiety, pain, and in this case, the improvement of hand sensation and strength for certain individuals with a chronic, non-progressive neurological deficit resulting from an incomplete spinal cord injury, were not available to suppliers engaging in the competitive bidding program. As such, CMS would establish the fees for HCPCS Level II code EXXXX using fees for HCPCS Level II code E0730 that were not adjusted using information from the DMEPOS Competitive Bidding Program.

Based on this preliminary determination, the average 2026 fee schedule amount for HCPCS Level II code EXXXX would be based on the unadjusted purchase fee schedule amounts for HCPCS Level II code E0730 of approximately \$517.05. As the purchase price used in calculating the fee schedule amounts is greater than \$150 in the base period, payment would be made on a capped rental basis in accordance with our regulations at 42 CFR 414.229. Our preliminary determination is that the capped rental fee schedule amount would be approximately \$51.70 on average for months 1 through 3, and approximately \$38.76 on average for months 4 through 13, resulting in a total capped payment of \$542.70 should there be 13 months of continuous use.

Pricing Indicator = 36

ExaStim® ReCure® Electrode Pad Supplies - HCP260630X6V2R

Topic/Issue

Request to establish a new HCPCS Level II code to identify ExaStim® ReCure® Electrode Pad Supplies.

Applicant's suggested language: XXXXX, "Disposable multichannel spinal electrode pad for use with a compatible external transcutaneous electrical spine stimulation system, with individually addressable electrode contacts permitting channel specific stimulation delivery by the stimulator"

Summary of Applicant's Submission

ANEUVO submitted a request to establish a new HCPCS Level II code to identify ExaStim® ReCure® Electrode Pad Supplies. ExaStim® ReCure® Electrode Pad Supplies are single-user, disposable multi-electrode pads and associated interfaces designed for use with a clinic-based transcutaneous spinal cord stimulation system. The ExaStim® ReCure® Electrode Pad Supplies enable spatially selective, multi-channel delivery of electrical stimulation to spinal cord circuitry, facilitating modulation of spinal networks to restore or improve voluntary motor function in individuals with spinal cord injury. They are specifically designed, configured to deliver spinal cord neuromodulation, including multi-site stimulation along the spinal column. The ExaStim® ReCure® Electrode Pad Supplies are indicated for use in adults with paralysis or motor impairment due to spinal cord injury who are undergoing transcutaneous spinal cord neuromodulation therapy under the supervision of a health care professional. Usage is determined by the number of therapy sessions and the clinical protocol established by the treating professional.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II code A4595, "Electrical stimulator supplies, 2 lead, per month, (e.g., tens, nmes)" describes ExaStim® ReCure® Electrode Pad Supplies.

The ExaStim® ReCure® Electrode Pad Supplies are single-user, disposable electrode pads furnished for use with a reusable transcutaneous electrical stimulation system. These consumable components are applied to the skin to deliver electrical stimulation and are intended to be replaced periodically throughout the course of treatment. As disposable electrical stimulator supplies used with a reusable electrical stimulation device, they are described by existing HCPCS Level II code A4595.

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

Based on the information submitted, the ExaStim® Stimulation System includes a prescription, external transcutaneous electrical stimulation device/equipment intended for home use by beneficiaries with chronic incomplete spinal cord injury. The equipment delivers electrical stimulation through external surface electrodes as prescribed by a treating practitioner to improve upper extremity neurological function. The information submitted supports a determination that the equipment is primarily and customarily used to serve a

medical purpose, generally is not useful in the absence of illness or injury, is capable of withstanding repeated use for at least three years, and is appropriate for use in the home. Accordingly, we believe the ExaStim® device falls within the Durable Medical Equipment benefit category under section 1861(n) of the Social Security Act and 42 Code of Federal Regulations § 414.202.

The ExaStim™ ReCure® electrodes are necessary for the effective use of the ExaStim® Stimulation System. In accordance with Chapter 15, § 110.3 of the Medicare Benefit Policy Manual, payment may be made for replacement of essential accessories such as hoses, tubes, mouthpieces, etc., for necessary DME, if the beneficiary owns or is purchasing the equipment.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code A4595 apply to this product, if covered. The current average 2026 fee schedule amount for HCPCS Level II code A4595 is \$20.44.

The average fee schedule amount is the average of the 2026 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

VEINOPLUS® - HCP260701KX1DN

Topic/Issue

Request to revise existing HCPCS Level II code E0745, “Neuromuscular stimulator, electronic shock unit” to describe VEINOPLUS®.

Applicant’s suggested language: E0745, “Powered neuromuscular electrical stimulator for FDA-cleared neuromuscular and hemodynamic indications, including prevention or retardation of disuse atrophy, increasing local blood circulation, immediate post-surgical stimulation of calf muscles to prevent venous thrombosis, muscle re-education, relaxation of muscle spasm, and maintaining or increasing range of motion”

Summary of Applicant's Submission

DynaPulse Medical LLC submitted a request to revise an existing HCPCS Level II code E0745 to reflect the full Food and Drug Administration (FDA) cleared labeling of powered neuromuscular electrical stimulation devices whose therapeutic effects are produced through electrically induced skeletal muscle contraction. VEINOPLUS® received clearance by the FDA through the 510(k) regulatory pathway on January 30, 2008. VEINOPLUS® is handheld battery-powered controller that delivers electrical stimulation through two electrodes placed on the calf to produce rhythmic muscle contractions. VEINOPLUS® is indicated for increasing local blood circulation, immediate post-surgical stimulation of calf muscles to prevent venous thrombosis, prevention or retardation of disuse atrophy, muscle re-education, relaxation of muscle spasm, and maintaining or increasing range of motion. VEINOPLUS® electrically contracts the calf muscles to replicate the physiologic calf muscle pump. This single mechanism activates skeletal muscle while increasing venous return and local blood circulation, producing all six FDA-cleared therapeutic effects. HCPCS Level II code E0745 correctly identifies the technology as a powered neuromuscular electrical stimulator but does not fully describe VEINOPLUS® because the descriptor does not reflect the complete FDA-cleared labeling.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II code E0745, “Neuromuscular stimulator, electronic shock unit” as previously assigned to VEINOPLUS®, describes VEINOPLUS®.

VEINOPLUS® delivers electrical stimulation through two electrodes placed on the calf to produce rhythmic muscle contractions. Including all clinical indications for VEINOPLUS® in the HCPCS Level II code descriptor will not improve the code descriptor. In general, clinical indications are not typically added to HCPCS Level II code descriptors because these codes are designed to identify and describe items or services and not the clinical circumstances under which they are used.

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

The current Medicare policy and prior established Medicare benefit category determination for HCPCS Level II code E0745 apply to this item. Based on the information submitted, this

item is a prescription, portable neuromuscular electrical stimulation device intended for home use. The device delivers transcutaneous electrical stimulation through surface electrodes to produce skeletal muscle contraction for its FDA-cleared indications and is primarily and customarily used to serve a medical purpose, generally is not useful in the absence of illness or injury, is capable of withstanding repeated use for at least three years, and is appropriate for use in the home. Therefore, we believe this device falls within the Durable Medical Equipment benefit category.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code E0745 apply to this product, if covered. Payment for existing HCPCS Level II code E0745 is made on a capped rental basis. Therefore, the 2026 monthly capped rental fee schedule amount would be approximately \$120.02 on average for months 1 through 3, and approximately \$90.02 on average for months 4 through 13, resulting in a total capped payment of \$1,260.26 should there be 13 months of continuous use.

The average fee schedule amount is the average of the 2026 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

VEINOPLUS® - HCP2607010W6YY

Topic/Issue

Request to revise existing HCPCS Level II code E0680, “Non-pneumatic compression controller with sequential calibrated gradient pressure” to distinguish VEINOPLUS®’ non-pneumatic technologies that achieve the same therapeutic hemodynamic output through mechanisms other than external compression.

Applicant’s suggested language: E0680, “Non-pneumatic compression controller with sequential calibrated gradient venous return”

Summary of Applicant's Submission

DynaPulse Medical LLC submitted a request to revise existing HCPCS Level II code E0680 to recognize non-pneumatic technologies that achieve the same therapeutic hemodynamic output through mechanisms other than external compression. VEINOPLUS® received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on January 30, 2008. VEINOPLUS® is indicated for increasing local blood circulation, immediate post-surgical stimulation of calf muscles to prevent venous thrombosis, prevention or retardation of muscle disuse atrophy, muscle re-education, maintaining or increasing range of motion, and relaxation of muscle spasm. Treatment consists of externally applied electrical stimulation delivered through two reusable electrodes during a preset 60-minute session. The device is intended for self-administered home or clinical use and is supplied as a reusable handheld stimulator with lead wires and reusable electrodes. Its primary therapeutic purpose is increasing local blood circulation and venous return. Electrically induced calf muscle contraction is the delivery mechanism; and restoration of lower-extremity hemodynamics is the therapeutic effect. By activating the physiologic calf muscle pump, VEINOPLUS® generates sequential, calibrated gradient venous return through internal muscle compression, reproducing the normal mechanism of venous return during ambulation. Clinical studies demonstrate significant increases in venous velocity, venous volume flow, and arterial inflow, together with improvements in chronic venous insufficiency symptoms, reductions in postoperative and recurrent deep vein thrombosis, and accelerated venous recanalization. VEINOPLUS® satisfies every element of the proposed revised HCPCS Level II code E0680 descriptor and its FDA-cleared indications, mechanism of action, and clinical evidence support classification within the revised HCPCS Level II code E0680 descriptor rather than continued classification under HCPCS Level II code E0745.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II code E0745, “Neuromuscular stimulator, electronic shock unit” as previously assigned for VEINOPLUS®, describes VEINOPLUS®.

VEINOPLUS® delivers electrical stimulation through two electrodes placed on the calf to produce rhythmic muscle contractions. The products described under the existing HCPCS Level II code E0680 are indicated for the treatment of lymphedema. In contrast, VEINOPLUS® is a device that is utilized for indications other than lymphedema.

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

The current Medicare policy and prior established Medicare benefit category determination for HCPCS Level II code E0745 apply to this item. Based on the information submitted, this item is a prescription, portable neuromuscular electrical stimulation device intended for home use. The device delivers transcutaneous electrical stimulation through surface electrodes to produce skeletal muscle contraction for its FDA-cleared indications and is primarily and customarily used to serve a medical purpose, generally is not useful in the absence of illness or injury, is capable of withstanding repeated use for at least three years, and is appropriate for use in the home. Therefore, we believe this device falls within the Durable Medical Equipment benefit category.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code E0745 apply to this product, if covered. Payment for existing HCPCS Level II code E0745 is made on a capped rental basis. Therefore, the 2026 monthly capped rental fee schedule amount would be approximately \$120.02 on average for months 1 through 3, and approximately \$90.02 on average for months 4 through 13, resulting in a total capped payment of \$1,260.26 should there be 13 months of continuous use.

The average fee schedule amount is the average of the 2026 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

Encora X1™ - HCP260701RQQ96

Topic/Issue

Request to establish a new HCPCS Level II code to identify Encora X1™.

Applicant's suggested language: XXXXX, “External upper limb tremor stimulator of the peripheral nerves of the wrist, closed-loop mechanical stimulation”

Summary of Applicant's Submission

Encora, Inc. submitted a request to establish a new HCPCS Level II code to identify Encora X1™. Encora X1™ received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on February 5, 2026. The Encora X1™ consists of a base stimulator, a charging station, and a wristband. The Encora X1™ is noninvasive, prescription, wrist-worn device that delivers personalized, closed-loop therapeutic stimulation to the median, radial, and ulnar peripheral nerve distributions. It is indicated to aid in the relief of hand tremors in adults with essential tremor. The Encora X1™ delivers its stimulation by mechanical means through integrated linear resonant actuators.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II code E0734, “External upper limb tremor stimulator of the peripheral nerves of the wrist” describes Encora X1™ and existing HCPCS Level II code A4542, “Supplies and accessories for external upper limb tremor stimulator of the peripheral nerves of the wrist” describes the supplies necessary for Encora X1™.

The Encora X1™ is a noninvasive, wrist-worn device that delivers personalized mechanical stimulation to the peripheral nerves of the wrist. Cala Trio™ and its current successor, Cala kIQ™, target the same wrist nerve pathways as the Encora X1™ and are indicated for the temporary relief of hand tremors in adults with essential tremor. Both systems share the same basic item design: a durable controller that provides power, sensing, control, and treatment parameters, paired with a replaceable wristband that serves as an accessory necessary to deliver therapy. The actuators within the wristband for Encora X1™ conduct and deliver similar therapy as the electrodes within Cala kIQ™.

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

The current Medicare policy and prior established Medicare benefit category determination for HCPCS Level II codes E0734 and A4542 apply to this item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code E0734 apply to the Encora X1™, if covered. The current average 2026 capped rental fee schedule amount for HCPCS Level II code E0734 would be approximately \$448.33 for months 1 through 3 and approximately \$336.25 for months 4 through 13, for a total of \$4,707.49 after 13 months of continuous use. The average fee schedule amount is the average of the 2026 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

The payment rules and pricing associated with the existing HCPCS Level II code A4542 apply to the supplies necessary for the use of the Encora X1™, if covered. The current average 2026 fee schedule amount for HCPCS Level II code A4542 is \$526.85. The average fee schedule amount is the average of the 2026 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

RT300 FES Cycle Ergometer – HCP2606284CPXA

Topic/Issue

Request to establish a new HCPCS Level II code to identify RT300 FES Cycle Ergometer.

Applicant's suggested language: XXXXX, "Closed-loop functional electrical stimulation (FES) neuromuscular rehabilitation system; motor-assisted therapeutic limb mobilization device with real-time angle-synchronized multi-channel stimulation"

Summary of Applicant's Submission

Restorative Therapies, Inc. submitted a request to establish a new HCPCS Level II code to identify RT300 FES Cycle Ergometer. RT300 FES Cycle Ergometer received clearance by the Food and drug Administration (FDA) through the 510(k) regulatory pathway on July 11, 2017. RT300 FES Cycle Ergometer is a closed-loop functional electrical stimulator and neuromuscular electrical stimulation powered therapeutic rehabilitation system. The RT300 FES Cycle Ergometer integrates a multi-channel stimulator – supporting up to 12 simultaneous channels with a pulse width of up to 3,000 microseconds – with a motor-assisted therapeutic limb mobilization unit controlled by proprietary tablet-based software. Indicated for individuals ages 4 and above with neuromuscular impairment due to neurological conditions or injury, the RT300 FES Cycle Ergometer is a prescription-only device intended exclusively for rehabilitation. Its therapeutic applications include the relaxation of muscle spasms; prevention or retardation of disuse atrophy; increasing local blood circulation; maintaining or increasing range of motion; and muscle re-education. The closed-loop integration of sensor feedback, stimulation control, and motor-assisted movement represents a distinct and superior therapeutic mechanism.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II code A9270, "Non-covered item or service," describes the RT300 FES Cycle Ergometer.

The RT300 FES Cycle Ergometer is intended for general rehabilitation, including relaxation of muscle spasms, prevention or retardation of disuse atrophy, increasing local blood circulation, maintaining or increasing range of motion, and muscle re-education. These indications are rehabilitative in nature and are directed toward preserving neuromuscular and musculoskeletal function and preventing or mitigating secondary consequences associated with neurological impairment, reduced mobility, and muscle disuse. The RT300 FES Cycle Ergometer facilitates active cycling through electrically evoked muscle contractions and passive cycling through power provided by the ergometer motor.

Like other items and services classified under HCPCS Level II code A9270, the RT300 FES Cycle Ergometer does not fall under an existing Medicare benefit category or is excluded from Medicare coverage by statute and is non-covered for Medicare. We have not identified a claims processing need for Medicare or other payers for a unique HCPCS Level II code for this item or service. Other payers may use HCPCS Level II code A9270 or other HCPCS Level II codes as they deem appropriate. 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 DMEPOS benefit category.

In accordance with regulations at 42 CFR 414.240(b)(1), under the procedures for making benefit category determinations for new durable medical equipment, prosthetic devices, orthotics and prosthetics, surgical dressings, and therapeutic shoes and inserts, CMS first performs an analysis to determine if the item or service is statutorily excluded from coverage under Medicare under section 1862 of the Social Security Act (the Act). Section 1862(a)(1)(A) of the Act excludes items and services from Medicare coverage that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Based on the indications for use for this device, we do not believe the RT300 FES Cycle Ergometer provides direct treatment of muscle atrophy.

In addition, the ergometer part of the system is useful in the absence of illness or injury as exercise equipment.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code A9270 apply to this product. Items or services described by HCPCS Level II code A9270 are not covered under Medicare Part B.

No Medicare payment. Pricing Indicator = 00

MIRARI® Cold Plasma System - HCP260630NFYW5

Topic/Issue

Request to establish a new HCPCS Level II code to identify ® Cold Plasma System.

Applicant's suggested language: XXXXX, “Portable radiofrequency energy therapy system, rechargeable, with reusable generator/driver unit, including all accessories”

Summary of Applicant's Submission

General Vibronics, Inc. submitted a request to establish a new HCPCS Level II code to identify the MIRARI® Cold Plasma System. The MIRARI® Cold Plasma System received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on November 21, 2024. MIRARI® Cold Plasma System provides heating to elevate tissue temperature for selected medical conditions, including temporary relief of pain, muscle spasms, and increase local circulation. The MIRARI® Cold Plasma System is a portable, handheld device that emits radiofrequency energy at 80 kilohertz, supplied as a complete box set. The box set includes the Driver Unit (reusable), Pain Array medium (single-user), Fleece Pouch medium (single-user), MIRARI® Magnetic Connector Cable (reusable), MIRARI® USB-C Wall Charger (reusable), MIRARI® USB-C Charge Cable (reusable). To use the system, the skin is prepared so that it is clean and dry. The Plasma Array is connected to the magnetic connector cable and placed into the insulating fleece pouch. The encased Plasma Array is then positioned directly over the treatment area and secured. The operator powers on the MIRARI® Driver Unit, selects the appropriate treatment protocol, and presses start to begin the session. Treatment sessions typically last 15 minutes, after which the device automatically stops when the preset treatment duration has been reached. Following treatment, the Plasma Array is removed, disposable pouch components are discarded as applicable, and reusable components are cleaned according to the instructions for use.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II code A9270, “Non-covered item or service” describes MIRARI® Cold Plasma System.

The MIRARI® Cold Plasma System is a portable, handheld device that emits radiofrequency energy to heat and elevate tissue temperature for medical and aesthetic benefits. Like other items and services classified under HCPCS Level II code A9270, the MIRARI® Cold Plasma System does not fall under an existing Medicare benefit category or is excluded from Medicare coverage by statute and is non-covered for Medicare. We have not identified a claims processing need for Medicare or other payers for a unique HCPCS Level II code for this item or service. Other payers may use HCPCS Level II code A9270 or other HCPCS Level II codes as they deem appropriate. 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.

Based on the information submitted, the MIRARI® Cold Plasma System is a portable radiofrequency heating device intended to elevate tissue temperature for the temporary relief of pain, muscle spasms, and increased local circulation. The application states that the device is not useful in the absence of illness or injury.

However, publicly available manufacturer and authorized distributor materials describe the MIRARI® Cold Plasma System as appropriate for a broad range of medical, dermatologic, and aesthetic applications, including skin rejuvenation, beauty care, post aesthetic procedure recovery, and reduction in the appearance of cellulite, in addition to pain management. These materials demonstrate that the device is promoted for uses that may be performed in the absence of illness or injury and are not limited to the treatment of medical conditions.

Accordingly, the available information does not demonstrate that the MIRARI® Cold Plasma System is primarily and customarily used to serve a medical purpose or that it is not generally useful to an individual in the absence of illness or injury, as required under section 1861(n) of the Social Security Act and 42 Code of Federal Regulations § 414.202. Therefore, we do not believe the MIRARI® Cold Plasma System falls within the Medicare durable medical equipment benefit category. We have also determined that the MIRARI® Cold Plasma System does not fall under any other DMEPOS benefit category.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code A9270 apply to this product. Items or services described by HCPCS Level II code A9270 are not covered under Medicare Part B.

No Medicare payment. Pricing Indicator = 00

MIRARI® Fleece Pouch, Medium - HCP260630CEWL9

Topic/Issue

Request to establish a new HCPCS Level II code to identify MIRARI® Fleece Pouch, medium.

Applicant's suggested language: XXXXX, "Replacement fleece pouch for portable radiofrequency energy therapy system, medium, each"

Summary of Applicant's Submission

General Vibronics, Inc. submitted a request to establish a new HCPCS Level II code to identify MIRARI® Fleece Pouch, medium. The MIRARI® Cold Plasma System received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on November 21, 2024. MIRARI® Fleece Pouch, medium is single-use, disposable insulating textile interface designed for use with the MIRARI® Cold Plasma System, supporting approximately 80 treatment sessions per unit. The MIRARI® Fleece Pouch, medium houses the MIRARI® Pain Array, medium during treatment, supporting safe and hygienic application of the system's 80 kilohertz radiofrequency therapy to the treatment site. During use, the MIRARI® Pain Array, medium is inserted into the Fleece Pouch with the connector end remaining accessible for attachment to the magnetic connector cable. The pouch-encased array is then positioned over clean, dry skin for a typical treatment session of approximately 10-15 minutes. The MIRARI® Fleece Pouch, medium is available in a 30-unit package.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II code A9270, "Non-covered item or service" describes MIRARI® Fleece Pouch, medium.

MIRARI® Fleece Pouch, medium is single-use, disposable insulating textile interface used with the MIRARI® Cold Plasma System. Like other items and services classified under HCPCS Level II code A9270, the MIRARI® Fleece Pouch, medium does not fall under an existing Medicare benefit category or is excluded from Medicare coverage by statute and is non-covered for Medicare. We have not identified a claims processing need for Medicare or other payers for a unique HCPCS Level II code for this item or service. Other payers may use HCPCS Level II code A9270 or other HCPCS Level II codes as they deem appropriate. 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.

Based on the information submitted, the MIRARI® Cold Plasma System is a portable radiofrequency heating device intended to elevate tissue temperature for the temporary relief of pain, muscle spasms, and increased local circulation. The application states that the device is not useful in the absence of illness or injury.

However, publicly available manufacturer and authorized distributor materials describe the MIRARI® Cold Plasma System as appropriate for a broad range of medical, dermatologic, and aesthetic applications, including skin rejuvenation, beauty care, post aesthetic procedure recovery, and reduction in the appearance of cellulite, in addition to pain management. These materials demonstrate that the device is promoted for uses that may be performed in the absence of illness or injury and are not limited to the treatment of medical conditions.

Accordingly, the available information does not demonstrate that the MIRARI® Cold Plasma System is primarily and customarily used to serve a medical purpose or that it is not generally useful to an individual in the absence of illness or injury, as required under section 1861(n) of the Social Security Act and 42 Code of Federal Regulations § 414.202. Therefore, we do not believe the MIRARI® Cold Plasma System falls within the Medicare durable medical equipment benefit category. We have also determined that the MIRARI® Cold Plasma System does not fall under any other DMEPOS benefit category.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code A9270 apply to this product. Items or services described by HCPCS Level II code A9270 are not covered under Medicare Part B.

No Medicare payment. Pricing Indicator = 00

MIRARI® Pain Array, Medium - HCP26063075A4D

Topic/Issue

Request to establish a new HCPCS Level II code to identify MIRARI® Pain Array, medium.

Applicant's suggested language: XXXXX, "Replacement treatment array for portable radiofrequency energy therapy system, medium, each"

Summary of Applicant's Submission

General Vibronics, Inc. submitted a request to establish a new HCPCS Level II code to identify MIRARI® Pain Array, medium. MIRARI® Pain Array, medium is a single-use replacement treatment array designed for use with the MIRARI® Cold Plasma System, supporting approximately 80 treatment sessions per unit. As the skin contacting component, it couples the system's 80 kilohertz radiofrequency energy from the reusable driver platform to the treatment site, serving as the replacement interface through which the MIRARI® Cold Plasma System delivers coordinated capacitive/dielectric heating and resistive/Joule heating energy to the user. During use, the array is connected to the magnetic connector cable, placed in the insulating pouch, and positioned over clean, dry skin. A typical treatment session lasts approximately 10-15 minutes. The MIRARI® Pain Array, medium is available as consumable component in a 30-unit package.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II code A9270, "Non-covered item or service" describes MIRARI® Pain Array, medium.

The MIRARI® Pain Array, medium is a single-use replacement treatment array used with the MIRARI® Cold Plasma System. Like other items and services classified under HCPCS Level II code A9270, the MIRARI® Pain Array, medium does not fall under an existing Medicare benefit category or is excluded from Medicare coverage by statute and is non-covered for Medicare. We have not identified a claims processing need for Medicare or other payers for a unique HCPCS Level II code for this item or service. Other payers may use HCPCS Level II code A9270 or other HCPCS Level II codes as they deem appropriate. 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.

Based on the information submitted, the MIRARI® Cold Plasma System is a portable radiofrequency heating device intended to elevate tissue temperature for the temporary relief of pain, muscle spasms, and increased local circulation. The application states that the device is not useful in the absence of illness or injury.

However, publicly available manufacturer and authorized distributor materials describe the MIRARI® Cold Plasma System as appropriate for a broad range of medical, dermatologic, and aesthetic applications, including skin rejuvenation, beauty care, post aesthetic procedure

recovery, and reduction in the appearance of cellulite, in addition to pain management. These materials demonstrate that the device is promoted for uses that may be performed in the absence of illness or injury and are not limited to the treatment of medical conditions.

Accordingly, the available information does not demonstrate that the MIRARI® Cold Plasma System is primarily and customarily used to serve a medical purpose or that it is not generally useful to an individual in the absence of illness or injury, as required under section 1861(n) of the Social Security Act and 42 Code of Federal Regulations § 414.202. Therefore, we do not believe the MIRARI® Cold Plasma System falls within the Medicare durable medical equipment benefit category. We have also determined that the MIRARI® Cold Plasma System does not fall under any other DMEPOS benefit category.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code A9270 apply to this product. Items or services described by HCPCS Level II code A9270 are not covered under Medicare Part B.

No Medicare payment. Pricing Indicator = 00

Jewel® Patch Wearable Cardioverter Defibrillator (WCD) - HCP26070159P9V

Topic/Issue

Request to revise existing HCPCS Level II code K0606, “Automatic external defibrillator, with integrated electrocardiogram analysis, garment type”, to remove the phrase “garment type”, and add the word “wearable” to describe the Jewel® Patch Wearable Cardioverter Defibrillator (WCD).

Applicant's suggested language: K0606, “Automatic external defibrillator, with integrated electrocardiogram analysis, wearable”

Summary of Applicant's Submission

Element Science, Inc. submitted a request to revise the existing HCPCS Level II code K0606 to further describe the Jewel® Patch WCD. The Jewel® Patch WCD was approved by the Food and Drug Administration (FDA) under the premarket approval application (PMA) regulatory pathway on April 30, 2025. The Jewel® Patch WCD is a wearable automated external defibrillator that monitors and treats an individual for ventricular arrhythmias. It is intended to be worn by individuals at risk of sudden cardiac arrest. Like other WCDs reported with HCPCS Level II code K0606, the Jewel® Patch WCD is designed to monitor an individual's heart rhythm continuously and deliver an electric shock if a life-threatening arrhythmia, such as ventricular fibrillation, or ventricular tachycardia is detected. The Jewel® Patch WCD relies on an adhesive, patch-based form factor rather than the legacy, vest-like form factor. All these WCDs have consistent FDA recognition, medically necessary function, mechanism of action, and clinical benefit.

CMS Preliminary HCPCS Coding Determination

1. Revise existing HCPCS Level II code K0606, “Automatic external defibrillator, with integrated electrocardiogram analysis, garment type”, to instead read, “Automatic external defibrillator, with integrated electrocardiogram analysis, wearable, includes all necessary supplies and accessories,” to describe Jewel® Patch WCD.
2. Revise existing HCPCS Level II code E0617, “External defibrillator with integrated electrocardiogram analysis”, to instead read, “External defibrillator with integrated electrocardiogram analysis, includes all necessary supplies and accessories”

The revised HCPCS Level II code K0606 describes the Jewel® Patch WCD's automatic external defibrillator and patch unit supply kit. The addition of “includes all supplies and accessories” to the code descriptors for HCPCS Level II codes K0606 and E0617 clarifies that no separate payment is made for defibrillator replacement accessories during the capped rental payment period. As such, for Medicare, HCPCS Level II codes K0607, K0608, and K0609 will be made invalid for Medicare.

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

The current Medicare policy and prior established Medicare benefit category determination for HCPCS Level II code K0606 apply to this item.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with existing HCPCS Level II code K0606 apply to this product, if covered. The 2026 average capped rental fee schedule amount for HCPCS Level II code K0606 is approximately \$3,588.90 for months 1 through 3 and approximately \$2,691.68 for months 4 through 13, for a total of \$37,683.50 after 13 months of continuous use. Fee schedules are updated annually.

Automatic external defibrillator equipment billed under HCPCS Level II codes K0606 and E0617 is paid for on a monthly rental basis under the capped rental payment methodology. Under section 110.3 of the Medicare Benefit Policy Manual (Pub. 100-02), payment may be made for the replacement of essential accessories such as hoses, tubes, mouthpieces, etc., for necessary DME, only if the beneficiary owns or is purchasing the equipment. Medicare claims data indicate that over 90 percent of beneficiaries rent automatic external defibrillators billed under HCPCS Level II code K0606 for 5 or fewer months of continuous use and therefore never take ownership of the capped rental equipment. Rental payments for HCPCS Level II codes K0606 and E0617 constitute payment for all items related to the rental of automatic external defibrillators, including all supplies and accessories.

Claims data show that more than 99 percent of external defibrillators billed under HCPCS Level II code K0606 are never rented for the full 13-month capped rental period, and therefore ownership is rarely transferred to the beneficiary. Claims data also show that no claims are being paid for HCPCS Level II codes K0607, K0608, or K0609 in those rare cases where beneficiaries do rent the device for 13 months. Furthermore, no claims are being paid for replacement of accessories for automatic external defibrillators described by HCPCS Level II code E0617 under code A9999 or E1399. Since individuals do not own or purchase equipment described by HCPCS Level II codes K0606 and E0617, separate payment for replacement supplies and accessories is not allowed per the policy at section 110.3 of the Medicare Benefit Policy Manual. Accordingly, we are proposing to make replacement accessory HCPCS Level II codes K0607, K0608 and K0609 invalid for Medicare use, as no claims are being paid for replacement of these accessories following rare cases where a beneficiary may use the equipment for more than 13 months and separate payment for accessories for DME that is not owned by the beneficiary is not allowed. In those rare cases where automatic external defibrillators described by HCPCS Level II codes K0606 and E0617 are rented for more than 13 months and title to the equipment is transferred to the beneficiary, HCPCS Level II code A9999 is available for use in submitting claims for replacement of accessories for automatic external defibrillators owned by the beneficiary.

Additionally, automatic external defibrillator devices described by HCPCS Level II codes K0606 and E0617 are classified by the Food and Drug Administration as Class III and must be billed with the KF modifier. Accordingly, CMS is removing the non-KF fees for HCPCS Level II code E0617 from the DMEPOS fee schedule file effective April 1, 2026.

Pricing Indicator = 36

Jewel® Patch Wearable Cardioverter Defibrillator (WCD) Patch Unit - HCP260701HDJYE

Topic/Issue

Request to establish a new HCPCS Level II code to identify Jewel® Patch Wearable Cardioverter Defibrillator (WCD) Patch Unit.

Applicant's suggested language: XXXXX, "Supply and accessory kit for wearable cardioverter defibrillator, including adhesive electrode patches and non-rechargeable battery unit, each"

Summary of Applicant's Submission

Element Science, Inc. submitted a request to establish a new HCPCS Level II code to identify Jewel® Patch WCD Patch Unit. The Jewel® Patch WCD Patch Unit was approved by the Food and Drug Administration (FDA) under the premarket approval application (PMA) regulatory pathway on April 30, 2025. The Jewel® Patch WCD Patch Unit is the necessary supplies for the use of the Jewel® Patch WCD. The Jewel® Patch WCD is a wearable automated external defibrillator worn by individuals at risk of sudden cardiac arrest (SCA). The Jewel® Patch WCD is designed to monitor an individual's heart rhythm continuously and deliver an electric shock if a life-threatening arrhythmia, such as ventricular fibrillation, or ventricular tachycardia is detected. The Jewel® Patch WCD adheres to the individual's body with adhesive electrode patches, one patch for the upper torso, and another patch for the lower torso. By adhering directly to the individual's body and incorporating a water-resistant design, the Jewel® Patch WCD is designed to drive better compliance by an individual at risk of SCA, including allowing wear during showering and other activities. The Jewel® Patch WCD's Patch Unit supplies are provided in a single Patch Unit kit, that includes an upper adhesive electrode patch, a lower adhesive electrode patch, with a battery unit, connection cable, and skin preparation supplies to assist with the removal of the prior adhesive electrode patches and allow application of the new adhesive electrode patches. The lower adhesive electrode patch incorporates an integrated, non-rechargeable battery unit that powers the Jewel® Patch WCD during wear. These supplies are designed to be worn for up to 8 days, then replaced. The Jewel® Patch WCD's durable monitoring and defibrillator unit is attached to each new battery unit during replacement of the lower adhesive electrode patch.

CMS Preliminary HCPCS Coding Determination

1. Revise existing HCPCS Level II code K0606, "Automatic external defibrillator, with integrated electrocardiogram analysis, garment type", to instead read, "Automatic external defibrillator, with integrated electrocardiogram analysis, wearable, includes all necessary supplies and accessories," to describe Jewel® Patch WCD Patch Unit.
2. Revise existing HCPCS Level II code E0617, "External defibrillator with integrated electrocardiogram analysis", to instead read, "External defibrillator with integrated electrocardiogram analysis, includes all necessary supplies and accessories"

The revised HCPCS Level II code K0606 describes the Jewel® Patch WCD's automatic external defibrillator and patch unit supply kit. The addition of "includes all supplies and accessories" to the code descriptors for HCPCS Level II codes K0606 and E0617 clarifies

that no separate payment is made for defibrillator replacement accessories during the capped rental payment period. As such, for Medicare, HCPCS Level II codes K0607, K0608, and K0609 are invalid for Medicare use and will no longer be payable codes.

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

The current Medicare policy and prior established Medicare benefit category determination for HCPCS Level II code K0606 apply to this item.

Preliminary Medicare Payment Determination

As described in the Preliminary Medicare Payment Determination for application HCP26070159P9V, under section 110.3 of the Medicare Benefit Policy Manual (Pub. 100-02), payment may be made for the replacement of essential accessories such as hoses, tubes, mouthpieces, etc., for necessary DME, only if the beneficiary owns or is purchasing the equipment. Rental payments for HCPCS Level II codes K0606 and E0617 constitute payment for all items related to the rental of automatic external defibrillators, including all supplies and accessories.

The payment rules and pricing associated with existing HCPCS Level II code K0606 apply to this product, if covered. The 2026 average capped rental fee schedule amount for HCPCS Level II code K0606 is approximately \$3,588.90 for months 1 through 3 and approximately \$2,691.68 for months 4 through 13, for a total of \$37,683.50 after 13 months of continuous use. Fee schedules are updated annually.

Pricing Indicator = 36

Orpyx® System (Receiver) - HCP2607011JMW

Topic/Issue

Request to establish a new HCPCS Level II code to identify the Orpyx System receiver.

Applicant's suggested language: XXXXX, "External lower limb pressure overload alert system, receiver"

Summary of Applicant's Submission

Orpyx® Medical Technologies Inc. submitted a request to establish a new HCPCS Level II code to identify the Orpyx® System receiver. The Orpyx® System is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The Orpyx® System is a prescription-only powered limb overload warning system that provides real-time alerts for immediate user-directed pressure offloading. A pressure-sensing footbed detects plantar pressure magnitude and duration and sends real-time pressure data to the user-facing receiver. The receiver provides real-time audio, visual, and/or haptic alerts of localized pressure overload. The receiver displays a real-time pressure foot map so the user can identify the affected area and shift weight, reposition, pause activity, check footwear, or remove a foreign object from the footwear until the pressure situation is resolved. The Orpyx® System is intended to act as an adjunct to standard foot care, not a replacement. It is designed for use during activities of daily living (ADLs) by individuals with impaired protective sensation who may not perceive elevated, sustained localized plantar pressure during ADLs. In users with intact protective sensation, discomfort or pain prompts spontaneous pressure relief through weight shifting, repositioning, walking, resting, or footwear adjustment. In users with peripheral neuropathy or loss of protective sensation, that feedback is reduced or absent, allowing active pressure bouts to persist unnoticed. External pressure exceeding local capillary perfusion pressure of 32-35 mmHg may compromise microcirculatory blood flow when sustained, contributing to tissue hypoxia, ischemia, inflammation, and soft-tissue injury. By providing real-time user alerts for dangerous plantar pressure overload, the Orpyx® System can enable users to take immediate action to relieve pressure overload and mitigate the risk of pressure-related injury. The receiver is locked and dedicated solely for Orpyx® System use and is designed for repeated use with an expected useful life of at least three years. The Orpyx® System is supplied as an integrated package that includes the receiver, charger, footbed(s) for one or both feet as prescribed, necessary accessories, and user-facing materials.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II code A9279, "Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified" describes the Orpyx® System.

The information submitted supports describing the receiver and pressure-sensing footbed under a single HCPCS Level II code rather than establishing separate codes for each component. The footbed captures plantar pressure information and transmits the information to the receiver, which analyzes the information to identify pressure bouts and provides audio, visual, and/or haptic alerts, as well as a pressure map, to facilitate immediate user-directed pressure offloading. The applicant states that the footbed functions only within the Orpyx®

System and has no practical stand-alone use, while the receiver is dedicated for use with the footbed and likewise has no practical stand-alone use outside the system. Thus, the two components perform complementary and interdependent functions within the same integrated monitoring system.

CMS agrees that HCPCS Level II code A5514 is no longer appropriate for the current Orpyx® System. The previously submitted Orpyx SI Sensory Insole incorporated the sensing technology into a custom-carved, multiple-density therapeutic shoe insert. The current footbed has been redesigned such that its medical function is no longer dependent on custom diabetic insert fabrication, shape, contour, or materials. Instead, its function is derived from the embedded pressure-sensing technology and associated electronics. As a result, the characteristics that supported use of HCPCS Level II code A5514 for the previously submitted product are no longer present in the current configuration.

HCPCS Level II code A9279 describes the current Orpyx® System because the code encompasses a monitoring feature or device that may be stand-alone or integrated, of any type, and includes all accessories, components, and electronics. These elements are consistent with the configuration and function described in the applications. The footbed contains the pressure sensors, battery, processing circuitry, and communication electronics necessary to capture plantar pressure information, while the receiver processes that information to identify pressure bouts and generate patient alerts. Therefore, the monitoring function is not performed by the receiver or footbed in isolation; rather, it results from the integrated operation of the system's sensing, processing, communication, and alerting components.

The applicant stated that HCPCS Level II code A9279 is not appropriate because the current system provides real-time alerts directly to the user rather than remote monitoring information to a treating practitioner. However, the descriptor for HCPCS Level II code A9279 does not specify that monitoring must be remote, require transmission of information to a treating practitioner, or otherwise limit how the monitored information is communicated or used. Rather, the descriptor applies to a monitoring feature or device "of any type." The Orpyx® System evaluates plantar pressure information and generates an alert when the monitored pressure meets specified magnitude and duration thresholds. The real-time alert is therefore an output of the system's monitoring function and does not distinguish the system from the scope of HCPCS Level II code A9279.

HCPCS Level II code A9279 also expressly includes all accessories, components, and electronics. The footbed performs the pressure-sensing function necessary for the integrated system and has no practical stand-alone use outside the Orpyx® System. Given that the footbed functions as an integral component of the monitoring system described by HCPCS Level II code A9279, its replacement frequency does not, based on the information submitted, establish the need for a separate HCPCS Level II code.

Overall, although HCPCS Level II code A5514 no longer describes the redesigned footbed, the current Orpyx® System remains an integrated monitoring device consisting of sensing, processing, communication, and alerting components. These characteristics are encompassed by existing HCPCS Level II code A9279, including its express inclusion of integrated monitoring devices and their associated accessories, components, and electronics. Therefore, based on the information submitted, separate HCPCS Level II codes for the receiver and pressure-sensing footbed are not warranted.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

Based on the information submitted, the Orpyx® System is a wearable pressure-sensing device intended to monitor plantar pressure and provide sensory feedback to alert the user to sustained pressure associated with the risk of foot ulceration. The device is a monitoring device/app and is not used for treatment purposes or to replace all or part of an internal body organ. Therefore, we do not believe this item falls under the Medicare benefit categories for durable medical equipment or prosthetic devices. We also do not believe it falls under any other DMEPOS benefit category.

Preliminary Medicare Payment Determination

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

No Medicare payment. Pricing Indicator = 00

Orpyx® System (Footbed) - HCP260701XQV1V

Topic/Issue

Request to establish a new HCPCS Level II code to identify the Orpyx® System footbed.

Applicant's suggested language: XXXXX, "External lower limb pressure overload alert system, pressure-sensing footbed, each"

Summary of Applicant's Submission

Orpyx® Medical Technologies Inc. submitted a request to establish a new HCPCS Level II code to identify the Orpyx® System footbed. The Orpyx® System is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The Orpyx® System is a prescription-only powered limb overload warning system that provides real-time alerts for immediate user-directed pressure offloading. The pressure-sensing footbed detects plantar pressure magnitude and duration and sends real-time pressure data to the user-facing receiver. The receiver provides real-time audio, visual, and/or haptic user alerts of localized pressure overload. The receiver displays a real-time pressure foot map so the user can identify the affected area and shift weight, reposition, pause activity, check footwear, or remove a foreign object from the footwear until the pressure situation is resolved. The Orpyx® System is intended to act as an adjunct to standard foot care, not a replacement. It is designed for use during activities of daily living (ADLs) by individuals with impaired protective sensation who may not perceive elevated, sustained localized plantar pressure during ADLs. The footbed contains embedded pressure-sensing technology and related electronics, incorporated into a footbed form factor, that is placed inside the user's footwear and captures localized plantar pressure magnitude and duration during ADLs. Unlike the Orpyx® Custom Insole, the Orpyx® System footbed is not intended to function as a shoe insert, orthotic, accommodative insert, or pressure-redistributing insole based on shape, contour, material, or custom fabrication. The footbed is replaced approximately every four months to maintain pressure-sensing performance. It is supplied for one or both feet, as prescribed, as part of the integrated system package.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II code A9279, "Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified" describes the Orpyx® System.

The Orpyx® System footbed is designed for use during ADLs by individuals with impaired protective sensation who may not perceive elevated, sustained localized plantar pressure during ADLs. The Orpyx® System is similar to other products in HCPCS Level II code A9279.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

Based on the information submitted, the Orpyx® System is a wearable pressure-sensing device intended to monitor plantar pressure and provide sensory feedback to alert the user to

sustained pressure associated with the risk of foot ulceration. The device is a monitoring device/app and is not used for treatment purposes or to replace all or part of an internal body organ. Therefore, we do not believe this item falls under the Medicare benefit categories for durable medical equipment or prosthetic devices. We also do not believe it falls under any other DMEPOS benefit category.

Preliminary Medicare Payment Determination

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

No Medicare payment. Pricing Indicator = 00

Revise HCPCS Level II Code L6692 - IHC2606303072J

Topic/Issue

Request to revise HCPCS Level II code L6692, “Upper extremity addition, silicone gel insert or equal, with or without locking mechanism, each” to identify custom socket inserts used in partial-hand and finger prostheses.

Applicant's suggested language: L6692, “Upper extremity addition, partial hand and/or finger(s), socket insert, silicone gel, elastomer or equivalent, with or without locking mechanism, each”

Summary of Applicant's Submission

An internal request was received to revise existing HCPCS Level II code L6692, to clarify that it applies to custom socket inserts used in partial-hand and finger prostheses. The proposed revision more accurately reflects current clinical practice, improves coding clarity, and promotes consistent coding without changing the scope or intent of the existing HCPCS Level II code.

CMS Preliminary HCPCS Coding Determination

Revise existing HCPCS Level II code L6692, “Upper extremity addition, silicone gel insert or equal, with or without locking mechanism, each” instead read “Upper extremity addition, partial hand and/or finger(s), socket insert, silicone gel, elastomer or equivalent, with or without locking mechanism, each” to identify custom socket inserts used in partial-hand and finger prostheses.

Body Powered Partial Hand - IHC260528GHAUB

Topic/Issue

Request to establish new HCPCS Level II codes to describe body powered digits, thumbs and an attachment plate for a body powered partial hand design.

Applicant's suggested language:

1. LXXXX, “Single prosthetic digit, body-powered, can include metacarpophalangeal (mcp), proximal interphalangeal (pip), and/or distal interphalangeal (dip) joint(s), any material, attachment, initial issue or replacement”
2. LXXXX, “Prosthetic thumb, body-powered, can include metacarpophalangeal (mcp), interphalangeal (ip) joint(s), any material, attachment, initial issue or replacement”
3. LXXXX, “Addition to single prosthetic digit or thumb, body powered, attachment, multiaxial and/or internal/external rotation/abduction/adduction mechanism, with or without locking feature, any material”

Summary of Applicant's Submission

The contractor for Medicare Pricing, Data Analysis and Coding (PDAC) submitted a request to establish new HCPCS Level II codes to describe body powered digits, thumbs and an attachment plate for a body powered partial hand design. In CMS’ HCPCS Level II Final Coding, Benefit Category and Payment Determinations, First Biannual 2025 Coding Cycle, the summaries for Point Design’s applications (HCP241231JNNFX, HCP241231VULPL, HCP241231UNXL1, HCP2412317JPJ, HCP241231KBG09) state the following regarding the types of partial hand prosthetics digits: “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.” The existing categories of partial hand prosthetics digits in the partial hand HCPCS Level II code set include electrically powered devices, specifically HCPCS Level II code L6715, “Terminal device, multiple articulating digit, includes motor(s), initial issue or replacement” and mechanical devices, specifically HCPCS Level II code L6035, “Single prosthetic digit, mechanical, can include metacarpophalangeal (mcp), proximal interphalangeal (pip), and/or distal interphalangeal (dip) joint(s), with or without locking mechanism, can include flexion or extension assist, any material, attachment, initial issue or replacement” and HCPCS Level II code L6036, “Prosthetic thumb, mechanical, can include metacarpophalangeal (mcp), interphalangeal (ip) joint(s), with or without locking mechanism, can include flexion or extension assist, any material, attachment, initial issue or replacement.” However, there are no existing HCPCS Level II codes which describe a body-powered articulated digit, thumb or attachment plate, so this request is an effort to complete this HCPCS Level II code set category.

CMS Preliminary HCPCS Coding Determination

Establish the following HCPCS Level II codes to describe body powered digits, thumbs and an attachment plate for a body powered partial hand design:

1. LXXX1, “Single-digit terminal device, body-powered, can include metacarpophalangeal (mcp), proximal interphalangeal (pip), and/or distal interphalangeal (dip) joint(s), with or without locking mechanism, can include flexion or extension assist, any material, attachment, initial issue or replacement”
2. LXXX2, “Pollex terminal device, body-powered, with metacarpophalangeal (mcp) and interphalangeal (ip) joint(s), any material, attachment, initial issue or replacement”
3. LXXX3, “Addition to pollex terminal device, body-powered, attachment, multiaxial and/or internal/external rotation/abduction/adduction mechanism, with or without locking feature, any material”

Partial hand prosthetic components fall into three distinct categories: mechanical, body-powered, and externally powered. Existing HCPCS Level II codes describe mechanical and externally powered partial hand prosthetic components. Mechanical devices use a locking or ratcheting mechanism that allows the user to manually position and secure the prosthetic digit. Externally powered devices use electric motors and electronic controls, such as myoelectric signals or switches, to actuate the prosthetic components.

Body-powered partial hand prosthetic components rely on the individual’s residual hand, remaining fingers, or wrist motion to actively operate the prosthesis and do not use locking mechanisms, motors, or batteries. Accordingly, separate HCPCS Level II codes are warranted to distinguish body-powered prosthetic digits, thumbs, and multiaxial attachments from existing mechanical and externally powered partial hand prosthetic components.

Preliminary Medicare Benefit Category Determination

Prosthesis (Artificial Arm).

Preliminary Medicare Payment Determination

In accordance with Medicare regulations at 42 Code of Federal Regulations 414.238(b), fee schedule amounts for new HCPCS Level II codes for items and services without a fee schedule pricing history are established using existing fee schedule amounts for 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 body powered partial hand digits and thumb prostheses are comparable to HCPCS Level II codes L6035 and L6036 with respect to their mechanical actuation mechanism and overall function. Both mechanical and body-powered partial hand prostheses rely on the user's mechanical input to actuate the prosthesis and facilitate grasp and release through mechanical actuation, making them functionally comparable to both voluntary-opening and voluntary-closing terminal devices. Although the method of actuation differs between these categories of devices, each requires the user to generate the necessary force to operate the prosthesis and achieve grasp.

Accordingly, the preliminary payment determination for the body powered partial hand digits and thumb is to establish the fee schedule amounts using the existing fee schedule amounts

for comparable items described by HCPCS Level II codes L6035 and L6036. Because both categories of devices utilize a mechanical actuation mechanism to facilitate active grasp, the same fee schedule amount is appropriate.

We also have concluded that the multiaxial attachment for a body-powered partial hand is comparable to HCPCS Level II code L6038 with respect to its function and design. Similar to the multiaxial attachment described by HCPCS Level II code L6038, a body-powered multiaxial attachment provides additional degrees of motion, including internal and external rotation as well as abduction and adduction, thereby increasing the functional capabilities of the prosthesis. Therefore, the preliminary payment determination for the body-powered multiaxial attachment is to establish the fee schedule amount using the existing fee schedule amounts for the comparable items described by HCPCS Level II code L6038.

Per this preliminary determination, the 2026 fee schedule amounts for new HCPCS Level II codes LXXX1 and LXXX2 would be based on the fee schedule amounts for HCPCS Level II codes L6035 and L6036. Therefore, the current average 2026 fee schedule amount for HCPCS Level II codes LXXX1 and LXXX2 would be \$1,591.25.

Also, per this preliminary determination, the 2026 fee schedule amounts for new HCPCS Level II code LXXX3 would be based on the fee schedule amounts for HCPCS Level II code L6038. Therefore, the current average 2026 fee schedule amount for HCPCS Level II code LXXX3 would be \$364.47.

The average fee schedule amount is the average of the 2026 fee schedule amounts for the codes for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 38

**Discontinue HCPCS Level II Codes for Partial Hand/Finger Prostheses -
HCP260701AMEEW, HCP260701C6VVR, HCP260701DYF46, HCP260701K3RYY,
HCP260701KAWNB, HCP260701PWWPP, HCP260701TCPC6**

Topic/Issue

Request to discontinue the following HCPCS Level II codes:

1. L6028, “Partial hand, finger, and thumb prosthesis without prosthetic digit(s) /thumb, amputation at metacarpal level, including flexible or non-flexible interface, molded to patient model, for use without external power and/or passive prosthetic digit/thumb, not including inserts described by l6692”
2. L6031, “Replacement socket/interface, partial hand including fingers, molded to patient model, for use with or without external power”
3. L6034, “Partial hand, finger, and thumb prosthesis without prosthetic digit(s)/thumb, amputation at distal to metacarpal joint, including flexible or non-flexible interface, molded to patient model, for use without external power and/or passive prosthetic digit/thumb, not including inserts described by l6692”
4. L6035, “Single prosthetic digit, mechanical, can include metacarpophalangeal (mcp), proximal interphalangeal (pip), and/or distal interphalangeal (dip) joint(s), with or without locking mechanism, can include flexion or extension assist, any material, attachment, initial issue or replacement”
5. L6036, “Prosthetic thumb, mechanical, can include metacarpophalangeal (mcp), interphalangeal (ip) joint(s), with or without locking mechanism, can include flexion or extension assist, any material, attachment, initial issue or replacement”
6. L6038, “Addition to single prosthetic digit or thumb, mechanical, attachment, multiaxial and/or internal/external rotation/abduction/adduction mechanism, with or without locking feature, any material”
7. L6039, “Passive prosthetic digit or thumb prosthesis not including hand restoration partial hand, full or partial, custom made, any material, initial or replacement, per single passive prosthetic digit or thumb”

Summary of Applicants’ Submissions

Point Designs and the Upper Limb Prosthetics Society of the American Academy of Orthotists and Prosthetists submitted requests to discontinue existing HCPCS Level II codes L6028, L6031, L6034, L6035, L6036, L6038, and L6039, and to instead allow the partial hand prosthetic devices and items they currently describe be billed under the existing HCPCS Level II code L7499, “Upper extremity prosthesis, not otherwise specified.”

Most individuals who need these devices are injured workers and veterans, not Medicare beneficiaries. The payers who serve these individuals, such as the Department of Veterans Affairs (VA), several state Medicaid programs, and many workers’ compensation payers have decided not to use HCPCS Level II codes L6028, L6031, L6034, L6035, L6036, L6038,

and L6039. The VA has also determined that the Medicare fee schedules for HCPCS Level II codes L6028, L6031, L6034, L6035, L6036, L6038, and L6039 pay less than the cost of the products and the VA has instead set its own payment amounts. These partial hand prosthetic devices and items were billed under HCPCS Level II code L7499 before HCPCS Level II codes L6028, L6031, L6034, L6035, L6036, L6038, and L6039 were established.

A payer may not be able to determine which kind of device an individual received or what work was done based on a claim with HCPCS Level II codes L6028, L6031, L6034, L6035, L6036, L6038, or L6039 for the following reasons:

For HCPCS Level II code L6028:

HCPCS Level II code L6028 describes a partial hand base socket at the metacarpal level, but the descriptor names a “partial hand, finger, and thumb prosthesis” and then defines that item as being “without prosthetic digit(s)/thumb.” The descriptor for HCPCS Level II code L6028 includes different amputation levels and different socket systems such as a wrist-driven body-powered socket, a socket for ratcheting mechanical digit, and a socket for a passive opposition.

For HCPCS Level II code L6031:

HCPCS Level II code L6031 describes a replacement socket for an individual who already has a partial hand prosthesis, but it does not describe a clearly defined original item to replace, nor does it carry an amputation level or device type of its own. HCPCS Level II code L6031 depends on the base codes, specifically HCPCS Level II codes L6028 and L6034, to determine what socket is being replaced. The descriptor for HCPCS Level II code L6031 is too broad; for example, “partial hand including fingers” describes many different presentations, and “with or without external power” fits every kind of device.

For HCPCS Level II code L6034:

HCPCS Level II code L6034 describes the base socket for partial hand amputations distal to the metacarpal as the companion items described by existing HCPCS Level II code L6028. HCPCS Level II code L6034 describes a “partial hand, finger, and thumb prosthesis” but also says the item is “without prosthetic digit(s)/thumb” so the code identifies the socket by the parts it leaves out. The anatomical term, “distal to the metacarpal joint,” does not specify which joint is meant, so the wording in the code descriptor is contradictory and the level itself is undefined. The Medicare payment amount for HCPCS Level II code L6034 was set at one-fifth of the Medicare payment amount for HCPCS Level II code L6028.

For HCPCS Level II code L6035:

The descriptor for HCPCS Level II code L6035 is broad so that many different mechanical prosthetic devices fit it, such as a finger that an individual bends and locks by hand, a finger with a ratchet that holds a grip, and a finger that moves when a nearby joint moves. A payer may not be able to determine which kind of device an individual received based on a claim with HCPCS Level II code L6035.

For HCPCS Level II code L6036:

The descriptor for HCPCS Level II code L6036 is not brand-specific; so many different devices are described by it such as a thumb held in place by friction alone, a thumb with a ratchet that locks in place, and a thumb driven by wrist motion through a cuff all meet the description. HCPCS Level II code L6036 also does not specify a common type of thumb amputation at the base, called the carpometacarpal (CMC) joint, that the other fingers do not have. Instead, HCPCS Level II code L6036 only describes prosthetic thumb devices built for amputations at the metacarpophalangeal and interphalangeal joints farther out on the thumb.

For HCPCS Level II code L6038:

HCPCS Level II code L6038 describes an addition that lets a prosthetic finger or thumb rotate, tilt, or both; but it describes two different kinds of additions at once: one that only rotates, and one that both rotates and tilts side to side. These devices are built differently, cost differently to make, and are used for different amputation levels. HCPCS Level II code L6038 is also intended to be billed together with the separate HCPCS Level II code for the prosthetic finger or thumb, on top of the base socket code. However, the wording used across this group of HCPCS Level II codes is inconsistent about whether a “finger” is already included in the base socket or billed apart from it. Therefore, providers may be unclear whether HCPCS Level II code L6038 can be billed as its own line next to the prosthetic thumb code, or whether a payer can treat it as already paid for inside the base code and deny its claim. Finally, the payment amount for HCPCS Level II code L6038 was not determined by comparing its intended devices to a similar hand or wrist device. The payment amount for HCPCS Level II code L6038 was instead determined by using a ratio built from two prosthetic foot codes, then applying that ratio to the payment amounts of the finger and thumb codes.

For HCPCS Level II code L6039:

In the first biannual 2025 HCPCS Level II coding cycle, Point Designs submitted a request to establish a new HCPCS Level II code to describe a custom passive, non-positional opposition post, terminal device intended for individuals whose residual hand or digit could not fit a manufactured mechanical component. The resulting HCPCS Level II code L6039 does not describe a terminal device but rather a complete prosthesis and is unclear whether the base and addition codes can be billed with it. HCPCS Level II code L6039 does not identify one specific device, gives no amputation level, and groups into a single code many different devices such as a cosmetic silicone fingertip, a full silicone finger, a glove-based device, a 3D-printed digit, and a functional opposition post. HCPCS Level II code L6039 never defines “hand restoration,” so it is difficult to determine a passive digit from an excluded hand restoration. While HCPCS Level II code L6039 excludes cosmetic hand restoration, its Medicare payment determination is based on other existing cosmetic hand restoration codes, specifically HCPCS Level II code L6900, “Hand restoration (casts, shading and measurements included), partial hand, with glove, thumb or one finger remaining” and HCPCS Level II code L6905, “Hand restoration (casts, shading and measurements included), partial hand, with glove, multiple fingers remaining.”

CMS Preliminary HCPCS Coding Determination

CMS appreciates the applicants' comments and suggestions regarding the current HCPCS Level II coding for partial hand prostheses. However, the information submitted does not provide sufficient justification to discontinue existing HCPCS Level II codes L6028, L6031,

L6034, L6035, L6036, L6038, and L6039. Applicants requesting discontinuation of an existing HCPCS Level II code must demonstrate that the current HCPCS Level II code is no longer appropriate. Concerns regarding payment rules, payment amounts, or payer adoption related to payment rules or payment amounts, does not provide a sufficient basis for discontinuing an existing HCPCS Level II code.

In the second biannual 2024 and first biannual 2025 HCPCS Level II coding cycle, CMS established or revised HCPCS Level II codes L6028, L6031, L6034, L6035, L6036, L6038, and L6039. These codes were established because HCPCS Level II code L7499 did not distinguish partial hand prostheses and prosthetic components from other upper extremity prostheses. The establishment of unique HCPCS Level II codes provides greater specificity and consistency in HCPCS Level II coding than continued use of a miscellaneous code, and CMS therefore continues to believe that permanent HCPCS Level II codes remain appropriate for these products.

The purpose of the HCPCS Level II coding system is to establish codes that describe categories of items with similar design and functional characteristics. It is not intended to establish a separate billing code for each individual product or design variation. Consistent with this approach, the codes at issue were established to identify distinct categories of partial hand prostheses and related components based on their design, function, level of amputation, and method of operation. Although individual products may differ in design, materials, component configuration, terminal devices, or method of operation, such variations do not necessarily warrant separate HCPCS Level II codes, and products with similar design and functional characteristics may appropriately be described within an existing code category.

Partial hand prosthetic systems may incorporate various components and configurations depending on the user's functional needs. Mechanical systems include prosthetic devices that do not rely on body-powered or externally powered operation, including manually positioned locking or ratcheting terminal devices as well as static or passive prosthetic devices. Manually positioned devices allow the user to position and maintain a prosthetic component in a selected position, while static or passive devices do not provide active movement and primarily serve cosmetic, protective, stabilizing, or other passive functions. Body-powered systems utilize motion generated by the residual hand, remaining digits, or wrist to operate the prosthesis without an external power source. Externally powered systems utilize electric motors controlled by myoelectric signals or other electronic control mechanisms.

CMS appreciates the applicants' recommendations regarding HCPCS Level II code descriptor language and has incorporated revisions where appropriate to improve clarity and more accurately describe the category of items represented by each code. These revisions are intended to enhance the usability of the descriptors while preserving the original HCPCS Level II coding intent and the established coding framework. As such, CMS is proposing the following revisions to the existing HCPCS Level II codes:

1. Revise existing HCPCS Level II code L6028, "Partial hand, finger, and thumb prosthesis without prosthetic digit(s) /thumb, amputation at metacarpal level, including flexible or non-flexible interface, molded to patient model, for use without external power and/or passive prosthetic digit/thumb, not including inserts described by L6692" to instead read "Partial hand socket, including flexible or non-flexible interface, with or without closure system attached to the socket, excluding terminal device(s), amputation at metacarpal level, molded to patient model, for use with body-

powered or mechanical terminal device, not including separate inserts described by L6692”

The applicant stated that the current descriptor for HCPCS Level II code L6028 does not clearly identify the socket component, relies on exclusions to describe the item, and encompasses multiple socket systems. HCPCS Level II code L6028 was established to identify the partial hand socket component at the metacarpal amputation level. CMS recognizes that the current descriptor may benefit from additional clarification and believes the proposed revision improves clarity while maintaining the original coding intent. The socket serves as the foundational component of the prosthesis regardless of the type of terminal device attached. The proposed revision more clearly identifies the partial hand socket rather than the complete prosthesis, clarifies that the terminal device is separately coded, and maintains the distinction between metacarpal-level sockets described by HCPCS Level II code L6028 and sockets for more distal amputations described by HCPCS Level II code L6034.

2. Revise existing HCPCS Level II code L6031, “Replacement socket/interface, partial hand including fingers, molded to patient model, for use with or without external power” to instead read “Replacement socket, with or without flexible or non-flexible interface, partial hand, molded to patient model, for use with or without external power”

The applicant stated that the current descriptor for HCPCS Level II code L6031 does not clearly identify the replacement socket, does not specify the applicable amputation level or prosthetic system, and is dependent upon the descriptors for the associated base socket codes. HCPCS Level II code L6031 was established to identify the replacement of a custom-fabricated partial hand socket, regardless of the type of terminal device used with the prosthesis. The proposed revision more clearly identifies the replacement partial hand socket and clarifies that the interface may be either flexible or non-flexible.

3. Revise existing HCPCS Level II code L6034, “Partial hand, finger, and thumb prosthesis without prosthetic digit(s)/thumb, amputation at distal to metacarpal joint, including flexible or non-flexible interface, molded to patient model, for use without external power and/or passive prosthetic digit/thumb, not including inserts described by L6692” to instead read “Partial hand socket, including flexible or non-flexible interface, with or without closure system attached to the socket, excluding terminal device(s), amputation distal to the metacarpal joint, molded to patient model, for use with body-powered and mechanical terminal devices, not including separate inserts described by L6692”

The applicant stated that the current descriptor for HCPCS Level II code L6034 does not clearly identify the socket component, relies on exclusions to describe the item, and encompasses multiple socket systems. HCPCS Level II code L6034 was established to identify the partial hand and finger socket component for amputations distal to the metacarpal level. The revised descriptor more clearly distinguishes HCPCS Level II code L6034 from HCPCS Level II code L6028 by specifying the distal-to-metacarpal amputation level, clarifies that the terminal device is separately coded, and maintains the partial hand and finger socket as the item being coded rather than the complete prosthesis.

4. Revise existing HCPCS Level II code L6035, "Single prosthetic digit, mechanical, can include metacarpophalangeal (mcp), proximal interphalangeal (pip), and/or distal interphalangeal (dip) joint(s), with or without locking mechanism, can include flexion or extension assist, any material, attachment, initial issue or replacement" to instead read "Single-digit terminal device, mechanical, can include metacarpophalangeal (mcp), proximal interphalangeal (pip), and/or distal interphalangeal (dip) joint(s), with or without locking mechanism, can include flexion or extension assist, any material, attachment, initial issue or replacement"

The applicant stated that the current descriptor for HCPCS Level II code L6035 encompasses multiple mechanical designs and methods of operation and therefore does not clearly identify a single category of prosthetic components. HCPCS Level II code L6035 was established to identify a mechanical single-digit terminal device used as part of a partial hand prosthetic system, and CMS believes it is appropriate for HCPCS Level II code L6035 to represent that category. Differences in specific mechanical design features, including manually positioned, locking, ratcheting, or linkage-driven mechanisms, do not alter the fundamental characteristics of the prosthetic component and do not warrant separate codes. The proposed revision more clearly identifies the mechanical terminal device rather than a complete prosthesis or an anatomical digit and more accurately reflects the function of the prosthetic component within the partial hand prosthetic system.

5. Revise existing HCPCS Level II code L6036, "Prosthetic thumb, mechanical, can include metacarpophalangeal (mcp), interphalangeal (ip) joint(s), with or without locking mechanism, can include flexion or extension assist, any material, attachment, initial issue or replacement" to instead read "Pollex terminal device, mechanical, with metacarpophalangeal (mcp), interphalangeal (ip) joint(s), with or without joint positional locking mechanism, can include flexion or extension assist, any material, attachment, initial issue or replacement"

The applicant stated that the current descriptor for HCPCS Level II code L6036 encompasses prosthetic thumbs with different mechanisms and methods of operation, does not clearly define the mechanical category, does not use terminal device terminology, references the MCP and IP joints but does not address the CMC joint, and may overlap with HCPCS Level II code L6038. HCPCS Level II code L6036 is intended to describe the mechanical category of prosthetic thumb terminal devices. CMS is revising the descriptor to use the term "pollex," the anatomical term for the thumb, to more specifically identify the anatomical component being replaced, and is adding the term "terminal device" to clarify that HCPCS Level II code L6036 describes the prosthetic thumb component rather than a complete partial hand prosthesis. This revision addresses the applicant's concern regarding the absence of terminal device terminology and provides greater consistency with terminology used elsewhere in the upper extremity prosthetic code set. CMS is also revising "locking mechanism" to "joint positional locking mechanism" to more specifically describe the function of mechanical ratcheting prosthetic devices, in which the user manually positions the prosthetic joint and the ratcheting mechanism locks and maintains the joint in the selected position until it is released or repositioned. Regarding the applicant's comment that HCPCS Level II code L6036 does not address the CMC joint, CMS does not believe it is necessary to add the CMC joint to the HCPCS Level II code L6036 descriptor because products with a CMC joint positioning feature are described by L6038. Maintaining this feature under HCPCS Level II code L6038 provides a clearer distinction between the mechanical prosthetic thumb terminal device

described by HCPCS Level II code L6036 and the additional CMC joint positioning mechanism described by HCPCS Level II code L6038.

6. Revise existing HCPCS Level II code L6038, “Addition to single prosthetic digit or thumb, mechanical, attachment, multiaxial and/or internal/external rotation/abduction/adduction mechanism, with or without locking feature, any material” to instead read “Addition to pollex terminal device, mechanical, attachment, multiaxial and/or internal/external rotation/abduction/adduction mechanism, with or without joint positional locking mechanism, any material”

The applicant stated that the current descriptor for HCPCS Level II code L6038 encompasses different multiaxial attachment mechanisms with distinct design characteristics and clinical applications and therefore does not clearly identify the item furnished and also stated that the descriptor creates ambiguity regarding billing in conjunction with the prosthetic thumb code. HCPCS Level II code L6038 was established to describe an addition to a mechanical ratchet-design terminal device that provides additional positioning capability through a mechanical mechanism at the CMC joint. Although these attachments may differ in design and degrees of motion provided, they perform the same fundamental function by increasing the range of motion and positioning capabilities of the prosthesis, and CMS therefore believes it is appropriate for a single HCPCS Level II code to encompass these multiaxial mechanical attachment mechanisms. Based on products currently available on the market, these multiaxial attachments are specifically designed for use with a prosthetic thumb rather than other prosthetic digits, and CMS is accordingly revising HCPCS Level II code L6038 to remove the reference to a prosthetic digit and to reference the pollex terminal device instead. CMS is also revising "locking feature" to "joint positional locking mechanism" to more specifically describe the mechanical ratcheting design and CMC joint positioning function, in which the prosthetic thumb component is manually positioned at the CMC joint and maintained in the selected position until it is released or repositioned.

7. Revise existing HCPCS Level II code L6039, “Passive prosthetic digit or thumb prosthesis not including hand restoration partial hand, full or partial, custom made, any material, initial or replacement, per single passive prosthetic digit or thumb” to instead read “Full or partial hand passive prosthesis, non-hand restoration, custom made, any material, initial issue or replacement”

The applicant stated that the current descriptor for HCPCS Level II code L6039 describes a complete prosthesis rather than a terminal device, does not clearly distinguish passive prosthetic devices from hand restoration devices, does not identify an amputation level, and encompasses multiple passive device designs within a single code. HCPCS Level II code L6039 was established to describe a custom-fabricated, complete static or passive partial hand prosthesis. Although static or passive prostheses fall within the broader non-powered mechanical category, HCPCS Level II code L6039 separately identifies complete partial hand prostheses that provide static or passive functions without active movement. The proposed revision more clearly identifies the prostheses described by the code, distinguishes them from other partial hand prosthetic systems and components, and explicitly excludes hand restoration prostheses described by separate HCPCS Level II codes, while maintaining the intended scope of HCPCS Level II code L6039.

Walkasins® Lower Extremity Sensory Prosthesis – HCP230630P62DH

Topic/Issue

Request for Medicare payment determination for Walkasins® lower extremity sensory prosthesis.

Summary of Applicant’s Submission

RxFunction, Inc. submitted a request to establish a new HCPCS Level II code to identify Walkasins® lower extremity sensory prosthesis. Walkasins® lower extremity sensory prosthesis is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). Walkasins® lower extremity sensory prosthesis is a non-invasive prosthetic device available by prescription for long-term daily use. Walkasins® replaces a part of the lost function of plantar mechanoreceptors, which are internal to the skin. It detects touch and pressure and is an integral part of the integumentary system. Walkasins® is intended for individuals with sensory peripheral neuropathy (PN), a condition where plantar mechanoreceptors are permanently inoperative or malfunctioned. Sensory PN leads to uncoordinated balance with unsteady gait and interferes with ambulation, daily activities, and increases risk for falls. Walkasins® detects pressure between the foot and the ground during standing and walking, signaling sensory (afferent) plantar pressure information to the brain that is critical for the subconscious non-voluntary and automatic control of balance and gait function. The Walkasins® system consists of two components per leg: receptor sole and haptic module. Haptic modules worn around the lower leg above the ankle receive and analyze the measured pressure information through a real-time algorithm that runs on a microprocessor, continuously calculating a representation of the instantaneous balance point of the body. At relevant times during standing and walking, the algorithm activates vibratory actuators embedded in the Haptic Module, to provide non-invasive tactile sensory cutaneous stimulation to the lower leg. This stimulation creates new sensory balance stimuli that transmit signals along the same afferent pathways previously served by the plantar mechanoreceptors, thereby replacing part of the lost plantar sensation.

CMS Final HCPCS Coding Decision

CMS established HCPCS Level II code L8720, “External lower extremity sensory prosthetic device, cutaneous stimulation of mechanoreceptors proximal to the ankle, per leg” to describe Walkasins®, effective October 1, 2024.

Medicare Benefit Category Determination

In the First Biannual (B1) 2024 HCPCS Level II coding cycle, CMS determined that the Walkasins® lower extremity sensory prosthesis is a Prosthetic Device.

Preliminary Medicare Payment Determination

In accordance with regulations at 42 Code of Federal Regulations (CFR) 414.238(c), fee schedule amounts for items and services described by new HCPCS Level II codes that do not have a fee schedule pricing history and that are not comparable to items and services with existing fee schedule amounts may be established using supplier price lists, including catalogs and other retail price lists (such as internet retail prices) that provide information on

commercial pricing for the item. 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.

We concluded in the Second Biannual (B2), 2024 HCPCS Level II Coding Cycle that no items described by HCPCS Level II codes with existing fee schedule amounts are comparable to the Walkasins® Lower Extremity Sensory Prosthesis and that it is most appropriate to determine the Medicare payment amount in accordance with the “gap filling” procedure outlined in 42 CFR 414.238(c). To develop an appropriate Medicare payment amount in accordance with the regulations at 42 CFR 414.238(c), we must identify appropriate commercial pricing for the underlying items. We emphasize that a Manufacturer Suggested Retail Price (MSRP) is not, by itself, an adequate source of commercial pricing. Only verifiable supplier or commercial pricing may be used (84 FR 60739).

In our B2 2024 preliminary payment determination, we used several invoices sent to us by the applicant for the Walkasins® Lower Extremity Sensory Prosthesis. These invoices were mainly from Department of Veteran Affairs (VA) locations across the country, as well as some invoices from individuals who self-paid for the device. The median invoice price was \$2,485 for each unit (one unit being one Walkasins® Lower Extremity Sensory Prosthesis, per leg).

Since then, the applicant has sent us additional pricing information. The applicant has sent us an additional 38 prices from non-Medicare payers. All but two are from private payers, with the remaining two from self-pay individuals. The data come from documents such as single case agreements, remittance advice, and provider claim summaries. The median of these additional prices is \$5,440 per unit.

In addition to the applicant-submitted pricing, we have also identified a contract between RxFunction, Inc. and the VA, which was awarded on July 5, 2023, for \$25,698 (Contract Number: 36C25023P1522).¹ This contract included five pairs of the Walkasins® Lower Limb Sensory Prosthesis, with each pair consisting of two leg units of the Walkasins® Lower Extremity Sensory Prosthesis and two units of the Walkasins® Receptor Sole, for a total of 10 leg units and 10 receptor soles. The price under this contract for the Walkasins® Lower Extremity Sensory Prosthesis was \$2,265 for each leg unit, and the price of one Walkasins® Receptor Sole was \$220.

This payment determination will incorporate all the non-Medicare payer pricing information identified to date, including the invoices from our B2 2024 preliminary payment determination and the additional pricing sources described above. The median of all this pricing information for the Walkasins® Lower Extremity Sensory Prosthesis is \$4,586.73. As was done in the B2 2024 preliminary payment determination, we will count a right and left leg unit (a pair) from one invoice as one price in the median calculation instead of counting each leg unit separately. For example, the 2023 VA contract included five pairs of the Walkasins® Lower Limb Sensory Prosthesis, with each pair consisting of two leg units. Each leg unit was priced at \$2,265, and since there were five pairs, we counted this \$2,265 price

five times in our median calculation, once for each pair.

In accordance with regulations at 42 CFR 414.238(c), \$4,586.73 is deflated to the 1986 fee schedule base period using the percentage change in the consumer price index for all urban consumers (CPI-U) from the mid-point of the year the prices are in effect to the mid-point of the fee schedule base period. The price is then updated to the current year using the covered item update factors specified in program instructions (Medicare Claims Processing Manual, Chapter 23, Section 60.3). After applying the annual deflation and update factors, the 2026 payment amount for HCPCS Level II code L8720 would be approximately \$2,939.09. It is our understanding that when a Walkasins® Lower Extremity Sensory Prosthesis is furnished it also includes a Walkasins® Receptor Sole. As such, HCPCS Level II code L8720 includes payment for one Walkasins® Receptor Sole, consistent with the pricing sources.

Pricing Indicator = 38

Vibrant® Capsule - HCP260629VB445

Topic/Issue

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

Applicant's suggested language: XXXXX, "Orally ingested capsule programmed to induce intracolonic peristalsis with the Vibrant System"

Summary of Applicant's Submission

Vibrant Gastro, Inc. (Vibrant) submitted a request to establish a new HCPCS Level II code to identify the Vibrant® Capsule for use with the Vibrant System®. Vibrant® Capsule received De Novo classification by the Food and Drug Administration (FDA) on August 26, 2022. The Vibrant® Capsules are orally ingested single-use disposable capsules, programmed to induce intracolonic peristalsis. Through programmed vibratory stimulation, the system mechanically induces the colon's physiologic propulsive activity, serving as a substitute for impaired colonic motor stimulation that causes effective colonic muscular contraction responsible for stool propulsion and evacuation. This evidence was not available or considered during the prior HCPCS Level II code applications: HCP221222CTE53 (Vibrant® Capsule, from 2023), HCP2212200H7AK (Vibrant System®, from 2023), and HCP240628ETVLX (Vibrant System®, from 2024). As a result, CMS' previous coding determinations did not evaluate the Vibrant System® under the framework that stimulates and restores deficient intracolonic peristaltic function. Therefore, the Vibrant System® and the Vibrant® Capsule are more appropriately categorized as a prosthetic, and not as durable medical equipment. The Vibrant System® is comprised of three components: a multi-use activation pod, a disposable drug-free single use capsule, and a companion computer program application so that individuals may track treatment progress and results. The pod is easy to use and operate, requiring only simple training that is provided by the clinician prior to its first use. The Vibrant® Capsule is activated by the pod before it is swallowed. The pod transmits an electromagnetic signal which carries the stimulation parameters. After activation, the Vibrant® Capsule will then execute the adaptive delay mechanism followed by the sequence mechanism. The Vibrant® Capsule is being proposed under the prosthetic benefit category because it is a non-pharmacologic, single-use medical device that provides mechanical colonic motility stimulation to induce adequate physiologic propulsion in individuals with chronic idiopathic constipation. Unlike drugs that modify secretion or absorption, the Vibrant® Capsule functions by delivering programmed mechanical stimulation that induces coordinated propagating colonic muscular contractions, thereby restoring physiologic propulsion of intraluminal contents/induction of adequate colonic peristalsis.

CMS Preliminary HCPCS Coding Determination

Revise existing HCPCS Level II code A9269, "Programable, transient, orally ingested capsule, for use with external programmer, per month" to instead read "Orally ingested, transient programmable vibrational capsule, for gastrointestinal stimulation, each."

Based on the responses submitted in reply to CMS' request for information and the supporting clinical literature describing the device, CMS determined that the Vibrant® Capsule functions by delivering programmed vibrational stimulation to the gastrointestinal tract in individuals with chronic idiopathic constipation. This mechanism distinguishes the

device from other categories of ingestible capsules, including diagnostic imaging capsules, motility sensing capsules, and drug delivery capsules, none of which operate through mechanical vibration or stimulation.

Preliminary Medicare Benefit Category Determination

Prosthetic Device.

The applications for the Vibrant® System (Pod) and Vibrant® Capsule support a preliminary benefit category determination that the Vibrant® Capsule falls within the prosthetic device benefit category and that the Vibrant® Pod serves as an accessory to the prosthetic device. Section 120 of Chapter 15 of the Medicare Benefit Policy Manual states that prosthetic devices replace all or part of an internal body organ or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ. The information submitted indicates that, in patients with chronic idiopathic constipation and slow transit constipation, dysfunction of the interstitial cells of Cajal (ICC) results in impaired neurologic signaling associated with initiation of colonic peristalsis. The ICC function as pacemaker cells of the gastrointestinal tract and normally initiate signaling that leads to peristaltic muscular activity and movement of bowel contents. The Vibrant® Capsule stimulates mechanoreceptors in the intestinal wall to initiate neurologic stimulation that mimics the stimulation normally produced by the ICC cells. In this manner, the Vibrant® Capsule replaces part of the function of the malfunctioning colon by providing the neurologic stimulation that would otherwise initiate the muscular activity necessary for peristalsis and ultimately a bowel movement. The application therefore supports a preliminary determination that the Vibrant® Capsule meets the Medicare benefit category for prosthetic devices and that the Vibrant® Pod, which programs the activation start time for each Capsule prior to ingestion, is an accessory to the prosthetic device.

Preliminary Medicare Payment Determination

In accordance with regulations at 42 Code of Federal Regulations (CFR) 414.238(c), fee schedule amounts for items and services described by new HCPCS Level II codes that do not have a fee schedule pricing history and that are not comparable to items and services with existing fee schedule amounts may be established using supplier price lists, including catalogs and other retail price lists (such as internet retail prices) that provide information on commercial pricing for the item. 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.

We have concluded that Vibrant® Capsule is not comparable to existing HCPCS Level II codes. Therefore, the fee schedule amounts for this item may be established using supplier or commercial price lists.

To develop an appropriate Medicare payment amount in accordance with the regulations at 42 CFR 414.238(c), we must identify appropriate commercial pricing for the underlying

items. We emphasize that a Manufacturer Suggested Retail Price (MSRP) is not, by itself, an adequate source of commercial pricing. Only verifiable supplier or commercial pricing may be used for gap-filling purposes (84 FR 60739). As described below, we have identified two general sources of commercial pricing information: pricing from the Department of Veterans Affairs and pricing at retail pharmacies as published by Goodrx.com; we welcome additional examples of verifiable commercial pricing.

The Department of Veteran Affairs (VA) National Acquisition Center (NAC) Contract Catalog Search Tool (CCST) shows that the VA has a contract for the “Vibrant Disposable Capsules, Oral, 20 count” and the “Vibrant Starter Kit (1 Reusable Pod + 20 Disposable Capsules).” The effective date for this contract is 7/15/2025 to 7/14/2030. The price for the “Vibrant Disposable Capsules, Oral, 20 count” is \$390, and the price for the “Vibrant Starter Kit (1 Reusable Pod + 20 Disposable Capsules)” is \$810.

We have also found pricing on Goodrx.com showing a median price of 20 Vibrant® Capsules for \$665.20, which include 14 prices from 14 pharmacies. The median price of the starter kit on Goodrx.com is \$1,371, which includes 14 prices from 14 pharmacies. The GoodRx prices that we are using are from the 21244 ZIP code in the Baltimore, MD area. We compared pricing across various ZIP codes nationwide in GoodRx for the Vibrant® Capsules and starter kit and found no significant variation in price. Based on this, we believe the median of prices in the 21244 ZIP code is generally representative and appropriate for use in this determination.

In this preliminary payment determination, we will create the lump-sum purchase fee schedule amount that is mandated by Section 1834(h)(1)(A) of the Social Security Act (the Act) for prosthetic devices defined under section 1834(h)(4)(B) of the Act. The amount in this payment determination reflects the price for one use of the Vibrant®, defined as one Vibrant® Capsule together with the corresponding activation and calibration of that Capsule by the Vibrant® Pod. As a result, one unit of HCPCS Level II code A9269 corresponds to one Vibrant® Capsule-plus-Pod-activation, purchased for each time it is used.

To calculate this, we first calculated the median of prices within each payor type and then the median of these medians in order to come up with one overall price that combines the VA and GoodRx pricing information. For the Vibrant® Capsules, we used the median of the VA price of \$390 with the median GoodRx price of \$665.20, which results in an overall median price of \$527.60. For the starter kit, we used the VA price of \$810 with the median GoodRx price of \$1,371, which results in an overall median price of \$1,090.50.

Next, we subtract the cost of the capsules from the starter kit by subtracting the overall median price of the 20 capsules (\$527.60) from the overall median price of the starter kit (\$1,090.50), resulting in \$562.90. This is the price for everything in the Vibrant® starter kit except the 20 capsules (hereafter referred to as the Pod).

Then, we calculate the monthly Pod price. To do so we divide the Pod price (\$562.90) by the five-year reasonable useful lifetime under 42 CFR 414.210(f)(1) (60 months), which results in a monthly pod price of \$9.38.

After this, we calculate the price per Pod use. We divide the monthly Pod price (\$9.38) by 20, assuming a dose of 20 capsules per month and therefore 20 pod uses (that is, 20 activations and time calibrations) per month. This results in a price per Pod use of \$0.47.

We then calculate the price per Vibrant® Capsule. We divide the overall median price of \$527.60 for 20 Vibrant® Capsules by 20, resulting in a per capsule price of \$26.38.

Next, we take the \$26.38 price per Vibrant® Capsule and add this to the Pod price per use (\$.47), resulting in \$26.85. This is the amount we will gap-fill.

In accordance with regulations at 42 CFR 414.238(c), \$26.85 is deflated to the 1986 fee schedule base period using the percentage change in the consumer price index for all urban consumers (CPI-U) from the mid-point of the year the prices are in effect to the mid-point of the fee schedule base period. The price is then updated to the current year using the covered item update factors specified in program instructions (Medicare Claims Processing Manual, Chapter 23, Section 60.3).

After applying the annual deflation and update factors, the 2026 payment amount for HCPCS Level II code A9269 would be approximately \$17.17. Fee schedules are updated annually.

Pricing Indicator = 38

Vibrant System® - HCP260629LKFYH

Topic/Issue

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

Applicant's suggested language: XXXXX, “Orally ingestible mechanical stimulation system for restoration of impaired colonic propulsive function”

Summary of Applicant's Submission

Vibrant Gastro, Inc. (Vibrant) submitted a request to establish a new HCPCS Level II code to identify the Vibrant System® as an external programmable system for restoration of impaired colonic propulsive function through orally ingestible mechanical stimulation, programmed to induce intracolonic peristalsis. Vibrant System® received De Novo classification by the Food and Drug Administration (FDA) on August 26, 2022. The Vibrant System®’s pod functions as the activation and programming component of the Vibrant System®, transmitting the prescribed operating parameters required from the pod to the Vibrant® Capsule to perform its intended activation cycle of vibrations that mechanically produce peristaltic function in a malfunctioning colon. Through programmed vibratory stimulation, the system mechanically induces the colon's physiologic propulsive activity, serving as a substitute for impaired colonic motor stimulation that causes effective colonic muscular contraction responsible for stool propulsion and evacuation. This evidence was not available or considered during the prior HCPCS Level II code applications: HCP221222CTE53 (Vibrant® Capsule, from 2023), HCP2212200H7AK (Vibrant System®, from 2023), and HCP240628ETVLX (Vibrant System®, from 2024). As a result, CMS’ previous coding determinations did not evaluate the Vibrant System® under the framework that stimulates and restores deficient intracolonic peristaltic function. Therefore, the Vibrant System® and the Vibrant® Capsule are more appropriately categorized as a prosthetic, and not as durable medical equipment (DME). The Vibrant System® includes an orally administered, drug-free Vibrant® Capsule prescribed for outpatient use to treat chronic idiopathic constipation in individuals who have not responded to at least one month of recommended laxative therapy. The pod verifies activation, and then communicates activation information, including time of activation, to the Vibrant® Capsule for dose adherence tracking, utilized by healthcare practitioners and individuals for clinical outcomes. Because this is the only FDA-cleared Class II device product that has the ability to stimulate and restore deficient intracolonic peristaltic neuromuscular stimulation replacing that function of the deficient malfunctioning colon, this should also provide further rationale for it to be categorized as a prosthetic, and not as DME.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II code A9268, “Programmer for transient, orally ingested capsule” as previously assigned, describes Vibrant System®.

The Vibrant® System includes a reusable pod, charging adapter, and single-use Vibrant® Capsules. The pod is used to activate and calibrate the Vibrant® Capsule before ingesting. The Vibrant® Capsule delivers the preprogrammed physical vibrations at timed intervals before passing naturally through the digestive tract. The suggested HCPCS Level II code language for the Vibrant® System does not improve the existing HCPCS Level II code descriptor.

Preliminary Medicare Benefit Category Determination

No separate DMEPOS Benefit Category.

During HCPCS Level II B1 2023 coding cycle, CMS issued final Medicare Benefit Category Determinations stating that the Vibrant System® (a base unit or Pod and a naive capsule) and the Vibrant® Capsule did not fall within a Medicare (Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) benefit category.

As described in response to application HCP260629VB445 for the Vibrant® Capsule, for Medicare purposes, the Vibrant System® will be treated as a single prosthetic device. Therefore, the programmer does not have a separate benefit category.

Preliminary Medicare Payment Determination

As described in response to application HCP260629VB445 for the Vibrant® Capsule, for Medicare purposes, the Vibrant System® will be paid through HCPCS Level II code A9269 as a single purchase for the Vibrant® Capsule and any accessories necessary for its use. Therefore, HCPCS Level II code A9268 will be made not valid for Medicare.

No Medicare payment. Pricing Indicator = 00

Dermagraft® - HCP2606307AQ3D

Topic/Issue

Request to reinstate HCPCS Level II code Q4106 to identify Dermagraft®.

Applicant's suggested language: Q4106, "Dermagraft, per square centimeter"

Summary of Applicant's Submission

Organogenesis submitted a request to reinstate HCPCS Level II Q4106 code to identify Dermagraft®. Dermagraft® received clearance by the Food and Drug Administration (FDA) through the premarket approval pathway (PMA) on September 28, 2001. Dermagraft® is a cryopreserved human fibroblast-derived dermal substitute that is composed of fibroblasts, extracellular matrix, and a bioabsorbable scaffold. It is indicated for treatment of full-thickness diabetic foot ulcers greater than six weeks duration, which extend through the dermis, but without tendon, muscle, joint capsule, or bone exposure. It is administered by placing Dermagraft® directly on the prepared wound bed. Dermagraft® is supplied frozen in a clear bag containing one piece of approximately 2 inches x 3 inches for a single-use application.

CMS Preliminary HCPCS Coding Determination

Reinstate HCPCS Level II code Q4106, "Dermagraft, per square centimeter (add-on, list separately in addition to primary procedure)" to identify Dermagraft®.

Activate™ Plus+ Matrix - HCP260629P43HE

Topic/Issue

Request to establish a new HCPCS Level II code to identify Activate™ Plus+ Matrix.

Applicant's suggested language: QXXXX, “Activate Plus+ Matrix, per CM²”

Summary of Applicant's Submission

Sequence LifeScience Inc. submitted a request to establish a new HCPCS Level II code to identify Activate™ Plus+ Matrix. Activate™ Plus+ Matrix is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 Code of Federal Regulations (CFR) part 1271 when intended for use as a “barrier or protective cover for acute and chronic wounds.” Activate™ Plus+ Matrix consists of four layers of placental membrane, including the amnion, intermediate layer, chorion, and a second layer of amnion. The product is minimally manipulated human placental membrane derived from donated placental tissues that retain the structural and functional characteristics of the tissues. The final product is dehydrated, packaged in different sized sheets and terminally sterilized by irradiation. Activate™ Plus+ Matrix is for single use and is composed of extracellular matrix proteins and serves as a natural, biological barrier or wound cover for chronic full-thickness ulcers and other wounds where a biological barrier or cover is required.

CMS Preliminary HCPCS Coding Determination

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, Activate™ Plus+ Matrix, “when intended for use as a ‘barrier or protective cover for acute and chronic wounds,’ appears to meet the criteria for regulation solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271.” As a result of our review of the TRG’s feedback, CMS has decided to:

Establish a new HCPCS Level II code QXXXX, “Activate plus+ matrix, per square centimeter (add-on, list separately in addition to primary procedure)”

This coding determination applies to the Activate™ Plus+ Matrix product described in the application and accompanying FDA TRG letter dated March 26, 2026, when intended for use as a “barrier or protective cover for acute and chronic wounds.”

AdvoGraft TLS™ - HCP260701F4MPC

Topic/Issue

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

Applicant's suggested language: XXXXX, “AdvoGraft TLS, per square centimeter”

Summary of Applicant's Submission

Surgenex submitted a request to establish a new HCPCS Level II code to identify AdvoGraft TLS™. AdvoGraft TLS™ is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 Code of Federal Regulations (CFR) part 1271 when intended for use as a “barrier” and “to provide protective coverage from the surrounding environment for acute and chronic wounds.” AdvoGraft TLS™ is a dehydrated, triple-layer human amniotic membrane allograft derived from donated human placental tissue. The triple-layer construction adds thickness and durability for robust coverage. Cryopreservation, refrigeration, or rehydration is not required before use. AdvoGraft TLS™ is intended for use as a barrier and to provide protective coverage from the surrounding environment for acute and chronic wounds, including diabetic foot ulcers, venous leg ulcers, pressure injuries, post-surgical wound dehiscence, traumatic skin loss, and dermal defects. AdvoGraft TLS™ is supplied in various sizes.

CMS Preliminary HCPCS Coding Determination

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, AdvoGraft TLS™, “when intended for use as a ‘barrier’ and ‘to provide protective coverage from the surrounding environment for acute and chronic wounds,’ appears to meet the criteria for regulation solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271.” As a result of our review of the TRG’s feedback, CMS has decided to:

Establish a new HCPCS Level II code QXXXX, “Advograft tls, per square centimeter (add-on, list separately in addition to primary procedure)”

This coding determination applies to the AdvoGraft TLS™ product described in the application and accompanying FDA TRG letter dated April 13, 2026, when intended for use as a “barrier” and “to provide protective coverage from the surrounding environment for acute and chronic wounds.”

Akesoe TL - HCP260604DH74T

Topic/Issue

Request to establish a new HCPCS Level II code to identify Akesoe TL.

Applicant's suggested language: XXXXX, “Akesoe TL, per sq cm (add-on, list separately in addition to primary procedure)”

Summary of Applicant's Submission

Akesoe Biologics submitted a request to establish a new HCPCS Level II code to identify Akesoe TL. Akesoe TL is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 Code of Federal Regulations (CFR) part 1271 when intended for use as a “barrier and applied as a covering.” Akesoe TL is a minimally manipulated triple-layer amnion graft that is intended to act as a protective covering for chronic wounds, corneal repair, and eye surgery, used in corneal reconstruction and treatment of ocular surfaces, and oral wounds. Akesoe TL is supplied in various sheet sizes.

CMS Preliminary HCPCS Coding Determination

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, Akesoe TL, “when intended for use as a ‘barrier and applied as a covering,’ appears to meet the criteria for regulation solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271.” As a result of our review of the TRG’s feedback, CMS has decided to:

Establish a new HCPCS Level II code QXXXX, “Akesoe tl, per square centimeter (add-on, list separately in addition to primary procedure)”

This coding determination applies to the Akesoe TL product described in the application and accompanying FDA TRG letter dated May 11, 2026, when intended for use as a “barrier and applied as a covering.”

Akesoe DL - HCP2606046Y4T7

Topic/Issue

Request to establish a new HCPCS Level II code to identify Akesoe DL.

Applicant's suggested language: XXXXX, “Akesoe DL, per sq cm (add-on, list separately in addition to primary procedure)”

Summary of Applicant's Submission

Akesoe Biologics submitted a request to establish a new HCPCS Level II code to identify Akesoe DL. Akesoe DL is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 Code of Federal Regulations (CFR) part 1271 when intended for use as a “barrier” and a “cover.” Akesoe DL is a minimally manipulated dual-layer amnion graft that is intended to act as a protective covering for chronic wounds, corneal repair, and eye surgery, used in corneal reconstruction and treatment of ocular surfaces, and oral wounds. Akesoe DL is supplied in various sheet sizes.

CMS Preliminary HCPCS Coding Determination

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, Akesoe DL, “when intended for use as a barrier and a cover appears to meet the criteria for regulation solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271.” As a result of our review of the TRG’s feedback, CMS has decided to:

Establish a new HCPCS Level II code QXXXX, “Akesoe dl, per square centimeter (add-on, list separately in addition to primary procedure)”

This coding determination applies to the Akesoe DL product described in the application and accompanying FDA TRG letter dated May 11, 2026, when intended for use as a “barrier” and a “cover.”

Akesoe SL - HCP260604121DE

Topic/Issue

Request to establish a new HCPCS Level II code to identify Akesoe SL.

Applicant's suggested language: XXXXX, “Akesoe SL, per sq cm (add-on, list separately in addition to primary procedure)”

Summary of Applicant's Submission

Akesoe Biologics submitted a request to establish a new HCPCS Level II code to identify Akesoe SL. Akesoe SL is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 Code of Federal Regulations (CFR) part 1271 when intended for use as a “barrier and applied as a covering.” Akesoe SL is a minimally manipulated single-layer amnion graft that is intended to act as a protective covering for chronic wounds, corneal repair, and eye surgery, used in corneal reconstruction and treatment of ocular surfaces, and oral wounds. Akesoe SL is supplied in various sheet sizes.

CMS Preliminary HCPCS Coding Determination

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, Akesoe SL, “when intended for use as a ‘barrier and applied as a covering,’ appears to meet the criteria for regulation solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271.” As a result of our review of the TRG’s feedback, CMS has decided to:

Establish a new HCPCS Level II code Akesoe sl, per square centimeter (add-on, list separately in addition to primary procedure)”

This coding determination applies to the Akesoe SL product described in the application and accompanying FDA TRG letter dated May 11, 2026, when intended for use as a “barrier and applied as a covering.”

ChorioMatrix™ Barrier - HCP260506DWCEC

Topic/Issue

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

Applicant's suggested language: QXXXX, "ChorioMatrix Barrier, per square centimeter"

Summary of Applicant's Submission

IX Biomedical LLC submitted a request to establish a new HCPCS Level II code to identify ChorioMatrix™ Barrier. ChorioMatrix™ Barrier is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 Code of Federal Regulations (CFR) part 1271 when intended for use as a "barrier that protects wounds." ChorioMatrix™ Barrier is a sterile, human amnion-chorion membrane allograft, which is used as a wound cover to protect damaged soft tissue from the environment, in acute and chronic wounds. ChorioMatrix™ Barrier is a single-use product, lyophilized to an acceptable residual moisture level, sterilized, and packaged in a primary film-Tyvek® pouch and a secondary foil/clear chevron pouch. ChorioMatrix™ Barrier is available in multiple sizes.

CMS Preliminary HCPCS Coding Determination

After review of the Food and Drug Administration's (FDA's) Tissue Reference Group (TRG) letter submitted by the applicant, ChorioMatrix™ Barrier, "when intended for use as a 'barrier that protects wounds,' appears to meet the criteria for regulation solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271." As a result of our review of the TRG's feedback, CMS has decided to:

Establish a new HCPCS Level II code QXXXX, "Choriomatrix barrier, per square centimeter (add-on, list separately in addition to primary procedure)"

This coding determination applies to the ChorioMatrix™ Barrier product described in the application and accompanying FDA TRG letter dated April 20, 2026, when intended for use as a "barrier that protects wounds."

IntraLayer™ Patch - HCP260506QB331

Topic/Issue

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

Applicant's suggested language: QXXXX, “IntraLayer Patch, per square centimeter”

Summary of Applicant's Submission

IX Biomedical LLC submitted a request to establish a new HCPCS Level II code to identify IntraLayer™ Patch. IntraLayer™ Patch is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 Code of Federal Regulations (CFR) part 1271 when intended for use as a “barrier that protects wounds.” IntraLayer™ Patch is a sterile, human two-layer amnion membrane allograft, comprised of the amnion layer and the intermediate layer, which is used as a wound cover to protect damaged soft tissue from the environment, in acute and chronic wounds. IntraLayer™ Patch is a single-use product, lyophilized to an acceptable residual moisture level, sterilized, and packaged in a primary film-Tyvek® pouch and a secondary foil/clear chevron pouch. IntraLayer™ Patch is available in multiple sizes.

CMS Preliminary HCPCS Coding Determination

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, IntraLayer™ Patch, “when intended for use as a ‘barrier that protects wounds,’ appears to meet the criteria for regulation solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271.” As a result of our review of the TRG’s feedback, CMS has decided to:

Establish a new HCPCS Level II code QXXXX, “Intralayer patch, per square centimeter (add-on, list separately in addition to primary procedure)”

This coding determination applies to the IntraLayer™ Patch product described in the application and accompanying FDA TRG letter dated April 21, 2026, when intended for use as a “barrier that protects wounds.”

AmniMend™ Patch - HCP2605043T861

Topic/Issue

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

Applicant's suggested language: QXXXX, “AmniMend Patch, per square centimeter”

Summary of Applicant's Submission

IX Biomedical LLC submitted a request to establish a new HCPCS Level II code to identify AmniMend™ Patch. AmniMend™ Patch is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 Code of Federal Regulations (CFR) part 1271 when intended for use as a “barrier that protects wounds.” AmniMend™ Patch is a sterile, human single layer amnion membrane allograft, which is used as a wound cover to protect damaged soft tissue from the environment, in acute and chronic wounds. Following standard wound preparation, AmniMend™ Patch can be applied directly to the wound. AmniMend™ Patch is a single-use product, lyophilized to an acceptable residual moisture level, sterilized, and packaged in a primary film-Tyvek® pouch and a secondary foil/clear chevron pouch. AmniMend™ Patch is available in multiple sizes.

CMS Preliminary HCPCS Coding Determination

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, AmniMend™ Patch, “when intended for use as a ‘barrier that protects wounds,’ appears to meet the criteria for regulation solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271.” As a result of our review of the TRG’s feedback, CMS has decided to:

Establish a new HCPCS Level II code QXXXX, “Amnimend patch, per square centimeter (add-on, list separately in addition to primary procedure)”

This coding determination applies to the AmniMend™ Patch product described in the application and accompanying FDA TRG letter dated April 20, 2026, when intended for use as a “barrier that protects wounds.”

Embodic™ Amnion Patch - HCP260504V7BM3

Topic/Issue

Request to establish a new HCPCS Level II code to identify Embodic™ Amnion Patch.

Applicant's suggested language: QXXXX, “Embodic Amnion Patch, per square centimeter”

Summary of Applicant's Submission

IX Biomedical LLC submitted a request to establish a new HCPCS Level II code to identify Embodic™ Amnion Patch. Embodic™ Amnion Patch is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 Code of Federal Regulations (CFR) part 1271 when intended for use “barrier that protects wounds.” Embodic™ Amnion Patch is a sterile, human dual layer amnion membrane allograft, which is used as a wound cover for acute and chronic wounds to protect damaged soft tissue from the environment. Following standard wound preparation, Embodic™ Amnion Patch can be applied directly to the wound. Embodic™ Amnion Patch is a single-use product, lyophilized to an acceptable residual moisture level, sterilized, and packaged in a primary film-Tyvek® pouch and a secondary foil/clear chevron pouch. Embodic™ Amnion Patch is available in multiple sizes.

CMS Preliminary HCPCS Coding Determination

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, Embodic™ Amnion Patch, “when intended for use as a ‘barrier that protects wounds,’ appears to meet the criteria for regulation solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271.” As a result of our review of the TRG’s feedback, CMS has decided to:

Establish a new HCPCS Level II code QXXXX, “Embodic amnion patch, per square centimeter (add-on, list separately in addition to primary procedure)”

This coding determination applies to the Embodic™ Amnion Patch product described in the application and accompanying FDA TRG letter dated April 21, 2026, when intended for use as a “barrier that protects wounds.”

Renastere AC Membrane - HCP260624LJTGQ

Topic/Issue

Request to establish a new HCPCS Level II code to identify Renastere AC Membrane.

Applicant's suggested language: XXXXX, “Renastere AC Membrane, a human placental membrane”

Summary of Applicant's Submission

Pinnacle Transplant Technologies submitted a request to establish a new HCPCS Level II code to identify Renastere AC Membrane. Renastere AC Membrane is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 Code of Federal Regulations (CFR) part 1271 when intended for use as a “wound covering and to act as a barrier to protect the wound.” Renastere AC Membrane, a full thickness amnion chorion layer membrane derived from donated human placenta. Renastere AC Membrane is intended for use as a wound covering and acts as a barrier for full and partial-thickness, chronic and acute wounds. Renastere AC Membrane is applied directly to the wound. Renastere AC Membrane is provided sterile and for single use only, with a shelf life of up to 5 years. Renastere AC Membrane is available in multiple sizes.

CMS Preliminary HCPCS Coding Determination

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, Renastere AC Membrane, “when intended for use as a wound covering and to act as a barrier to protect the wound, appears to meet the criteria for regulation solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271.” As a result of our review of the TRG’s feedback, CMS has decided to:

Establish a new HCPCS Level II code QXXXX, “Renastere ac membrane, per square centimeter (add-on, list separately in addition to primary procedure)”

This coding determination applies to the Renastere AC Membrane product described in the application and accompanying FDA TRG letter dated August 8, 2025, when intended for use as a “wound covering and to act as a barrier to protect the wound.”

Renastere Membrane - HCP260624QP3DP

Topic/Issue

Request to establish a new HCPCS Level II code to identify Renastere Membrane.

Applicant's suggested language: XXXXX, “Renastere Membrane, a human placental membrane”

Summary of Applicant's Submission

Pinnacle Transplant Technologies submitted a request to establish a new HCPCS Level II code to identify Renastere Membrane. Renastere Membrane is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 Code of Federal Regulations (CFR) part 1271 when intended for use as a “wound covering and to act as a barrier to protect the wound.” Renastere Membrane is an amniotic layer membrane derived from donated human placenta. Renastere Membrane serves as a barrier and protective wound covering for acute and chronic wounds. Renastere Membrane is restricted to use by a licensed healthcare professional.

CMS Preliminary HCPCS Coding Determination

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, Renastere Membrane, “when intended for use as a wound covering and to act as a barrier to protect the wound, appears to meet the criteria for regulation solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271.” As a result of our review of the TRG’s feedback, CMS has decided to:

Establish a new HCPCS Level II code QXXXX, “Renastere membrane, per square centimeter (add-on, list separately in addition to primary procedure)”

This coding determination applies to the Renastere Membrane product described in the application and accompanying FDA TRG letter dated August 8, 2025, when intended for use as a “wound covering and to act as a barrier to protect the wound.”

Membrane Wrap-Amniotic Hydro™ - HCP260608KN098

Topic/Issue

Request to establish a new HCPCS Level II code to identify Membrane Wrap-Amniotic Hydro™.

The applicant did not submit any suggested language.

Summary of Applicant's Submission

BLS Labs submitted a request to establish a new HCPCS Level II code to identify Membrane Wrap-Amniotic Hydro™. Membrane Wrap-Amniotic Hydro™ is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 Code of Federal Regulations (CFR) part 1271 when intended for use as a “supportive barrier and provides protective coverage from the surrounding environment to acute and chronic wounds.” Membrane Wrap-Amniotic Hydro™ is a human amniotic membrane allograft intended for use in the management of acute and chronic wounds. The primary function of Membrane Wrap-Amniotic Hydro™ is to serve as a supportive barrier and provide protective coverage from the surrounding environment for acute and chronic wounds. The route of administration is topical. Following the appropriate preparation of the wound site, the amniotic allograft is applied directly to the wound surface by a licensed healthcare provider and secured using a fixation method of the provider's choice. Reapplication is determined by the clinician based on the condition of the wound. Membrane Wrap-Amniotic Hydro™ is packaged in a dual-pouch system designed to ensure sterility and facilitate aseptic presentation in clinical settings. The inner pouch is sterile and functions as a moisture barrier. The outer pouch is a peelable pouch that allows for aseptic transfer onto the sterile field and includes a transparent side for visualization of the contents before use. The product is supplied in varying sizes to accommodate different wound dimensions, with dosing determined on a per square centimeter basis.

CMS Preliminary HCPCS Coding Determination

After review of the Food and Drug Administration's (FDA's) Tissue Reference Group (TRG) letter submitted by the applicant, Membrane Wrap-Amniotic Hydro™, “when intended for use ‘as a supportive barrier and provides protective coverage from the surrounding environment to acute and chronic wounds,’ appears to meet the criteria for regulation solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271.” As a result of our review of the TRG's feedback, CMS has decided to:

Establish a new HCPCS Level II code QXXXX, “Membrane wrap-amniotic hydro, per square centimeter (add-on, list separately in addition to primary procedure)”

This coding determination applies to the Membrane Wrap-Amniotic Hydro™ product described in the application and accompanying FDA TRG letter dated February 5, 2026, when intended for use as a “supportive barrier and provides protective coverage from the surrounding environment to acute and chronic wounds.”

SkinTE - HCP2603312XV08

Topic/Issue

Request to discontinue existing HCPCS Level II code Q4200, “Skin te, per square centimeter (add-on, list separately in addition to primary procedure)” as the SkinTE is no longer manufactured.

Summary of Applicant's Submission

PolarityBio submitted a request to discontinue existing HCPCS Level II code Q4200, “Skin TE, per square centimeter.” PolarityTE (now PolarityBio) has not marketed or manufactured the product for commercial use since May 2021. As the product is no longer available, there is no need for product-specific code for this human cell, tissue, or cellular or tissue-based product. SkinTE was intended to be used for the treatment of acute burns requiring excision or grafting and chronic wounds. It was composed of viable skin cells and an organized extracellular matrix, with no additional cell or tissue source from another human (allogeneic) or animal (xenogeneic). Following application to a wound bed, the product functioned to regenerate full-thickness functional skin across the entire surface. The dosage of SkinTE corresponded to the surface area of the wound being treated in square centimeters. The product was administered by physicians for homologous uses of the skin and integumentary system. SkinTE was supplied as a viscous tissue product via syringe.

CMS Preliminary HCPCS Coding Determination

Discontinue existing HCPCS Level II code Q4200, “Skin te, per square centimeter (add-on, list separately in addition to primary procedure).”

Hylen AA™ - HCP260628UABB3

Topic/Issue

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

Applicant's suggested language: QXXXX, “Hylen AA, per square centimeter”

Summary of Applicant's Submission

Pinnacle Transplant Technologies submitted a request to establish a new HCPCS Level II code to identify Hylen AA™. Hylen AA™ is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 Code of Federal Regulations (CFR) part 1271 when intended for use as a “protective barrier for wounds.” Hylen AA™ is a sterile, human dual-layer amnion-amnion membrane allograft, which is used as a wound cover to protect the wound from the environment. Following standard wound preparation, Hylen AA™ can be applied directly to the wound. Hylen AA™ is a single-use product, packaged in a primary film-Tyvek® pouch and a secondary film-Tyvek® pouch. Hylen AA™ is available in multiple sizes.

CMS Preliminary HCPCS Coding Determination

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, Hylen AA™, “when intended for use as a ‘protective barrier for wounds,’ appears to meet the criteria for regulation solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271.” As a result of our review of the TRG’s feedback, CMS has decided to:

Establish a new HCPCS Level II code QXXXX, “Hylen aa, per square centimeter (add-on, list separately in addition to primary procedure)”

This coding determination applies to the Hylen AA™ product described in the application and accompanying FDA TRG letter dated March 26, 2026, when intended for use as a “protective barrier for wounds.”

Hylen ACA™ - HCP2606289R0C1

Topic/Issue

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

Applicant's suggested language: QXXXX, “Hylen ACA, per square centimeter”

Summary of Applicant's Submission

Pinnacle Transplant Technologies submitted a request to establish a new HCPCS Level II code to identify Hylen ACA™. Hylen ACA™ is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 Code of Federal Regulations (CFR) part 1271 when intended for use as a “protective barrier for wounds.” Hylen ACA™ is a sterile, human tri-layer amnion-chorion-amnion membrane allograft, which is used as a wound cover to protect the wound from the environment. Following standard wound preparation, Hylen ACA™ can be applied directly to the wound. Hylen ACA™ is a single-use product, packaged in a primary film-Tyvek® pouch and a secondary film-Tyvek® pouch. Hylen ACA™ is available in multiple sizes.

CMS Preliminary HCPCS Coding Determination

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, Hylen ACA™, “when intended for use as a ‘protective barrier for wounds,’ appears to meet the criteria for regulation solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271.” As a result of our review of the TRG’s feedback, CMS has decided to:

Establish a new HCPCS Level II code QXXXX, “Hylen aca, per square centimeter (add-on, list separately in addition to primary procedure)”

This coding determination applies to the Hylen ACA™ product described in the application and accompanying FDA TRG letter dated March 26, 2026, when intended for use as a “protective barrier for wounds.”

DermaBind CH Air™, DermaBind CHN Air™, DermaBind CH+ Air™, and DermaBind CHX Air™- HCP2604157NU7G

Topic/Issue

Request to establish a new HCPCS Level II code to identify DermaBind CH Air™, DermaBind CHN Air™, DermaBind CH+ Air™, and DermaBind CHX Air™.

Applicant's suggested language: QXXXX, “DermaBind CH Air, DermaBind CHN Air, DermaBind CH+ Air, DermaBind CHX Air, per sq cm”

Summary of Applicant's Submission

HealthTech Wound Care submitted a request to establish a new HCPCS Level II code to identify DermaBind CH Air™, DermaBind CHN Air™, DermaBind CH+ Air™, and DermaBind CHX Air™. DermaBind CH Air™, DermaBind CHN Air™, DermaBind CH+ Air™, and DermaBind CHX Air™ are regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 Code of Federal Regulations (CFR) part 1271 when intended for use “as a wound covering” and “to protect those wounds from the environment.” DermaBind CH Air™, DermaBind CHN Air™, DermaBind CH+ Air™, and DermaBind CHX Air™ are dehydrated human chorion membranes comprised of an extracellular matrix that is rich in collagen, fibrin, and elastin fibers native to the tissue. DermaBind CH Air™ is the base chorionic membrane with no modifications. DermaBind CHN Air™ has an orientation notch, and DermaBind CH+ Air™ and DermaBind CHX Air™ are pre-folded for use on convex and concave wounds, respectively. DermaBind CH Air™, DermaBind CHN Air™, DermaBind CH+ Air™, and DermaBind CHX Air™ are designed for application directly to acute and chronic wounds, are flexible, and are conforming covers that adhere to complex anatomies. The membranes are intended for use as a wound covering by providing protection for the wound from the external environment and maintaining a moist environment. The allografts are provided in various square-shaped sizes.

CMS Preliminary HCPCS Coding Determination

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, DermaBind CH Air™, DermaBind CHN Air™, DermaBind CH+ Air™, and DermaBind CHX Air™, “when intended for use ‘as a wound covering’ and ‘to protect those wounds from the environment,’ appears to meet the criteria for regulation solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271.” As a result of our review of the TRG’s feedback, CMS has decided to:

Establish a new HCPCS Level II code QXXXX, “Dermabind ch air or dermabind ch+ air or dermabind chn air or dermabind chx air, per square centimeter (add-on, list separately in addition to primary procedure)”

This coding determination applies to the DermaBind CH Air™, DermaBind CHN Air™, DermaBind CH+ Air™, and DermaBind CHX Air™ products described in the application and accompanying FDA TRG letter dated June 10, 2025, when intended for use “as a wound covering” and “to protect those wounds from the environment.”

DermaBind TLN Air™, DermaBind TL+ Air™, and DermaBind TLX Air™ - HCP260415CTJ89

Topic/Issue

Request to establish a new HCPCS Level II code to identify DermaBind TLN Air™, DermaBind TL+ Air™, and DermaBind TLX Air™.

Applicant's suggested language: QXXXX, "DermaBind TLN Air, DermaBind TL+ Air, DermaBind TLX Air, per sq cm"

Summary of Applicant's Submission

HealthTech Wound Care submitted a request to establish a new HCPCS Level II code to identify DermaBind TLN Air™, DermaBind TL+ Air™, and DermaBind TLX Air™. DermaBind TLN Air™, DermaBind TL+ Air™, and DermaBind TLX Air™ are regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 Code of Federal Regulations (CFR) part 1271 when intended for use "as a wound covering" and "to protect those wounds from the environment." DermaBind TLN Air™, DermaBind TL+ Air™, and DermaBind TLX Air™ are dehydrated human full-thickness placental membranes comprised of an extracellular matrix that is rich in collagen, fibrin, and elastin fibers native to the tissue. DermaBind TLN Air™ has an orientation notch, and DermaBind TL+ Air™ and DermaBind TLX Air™ are pre-folded for use on convex and concave wounds, respectively. The allografts are designed for direct application to acute and chronic wounds, are flexible, and are conforming covers that adhere to complex anatomies. These membranes are intended for use as a wound covering and to provide protection for the wound from the external environment while maintaining a moist environment. The allografts are provided in a square shape in various sizes.

CMS Preliminary HCPCS Coding Determination

After review of the Food and Drug Administration's (FDA's) Tissue Reference Group (TRG) letter submitted by the applicant, DermaBind TLN Air™, DermaBind TL+ Air™, and DermaBind TLX Air™, "when intended for use 'as a wound covering' and 'to protect those wounds from the environment,' appears to meet the criteria for regulation solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271." As a result of our review of the TRG's feedback, CMS has decided to:

Establish a new HCPCS Level II code QXXXX, "Dermabind tln air or dermabind tl+ air or dermabind tlx air, per square centimeter (add-on, list separately in addition to primary procedure)"

This coding determination applies to the DermaBind TLN Air™, DermaBind TL+ Air™, and DermaBind TLX Air™ products described in the application and accompanying FDA TRG letter dated June 10, 2025, when intended for use "as a wound covering" and "to protect those wounds from the environment."

DermaBind SLN Air™, DermaBind SL+ Air™, and DermaBind SLX Air™ - HCP2604150WH05

Topic/Issue

Request to establish a new HCPCS Level II code to identify DermaBind SLN Air™, DermaBind SL+ Air™, and DermaBind SLX Air™.

Applicant's suggested language: QXXXX, “DermaBind SLN Air, DermaBind SL+ Air, DermaBind SLX Air, per sq cm.”

Summary of Applicant's Submission

HealthTech Wound Care submitted a request to establish a new HCPCS Level II code to identify DermaBind SLN Air™, DermaBind SL+ Air™, and DermaBind SLX Air™. DermaBind SLN Air™, DermaBind SL+ Air™, and DermaBind SLX Air™ are regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 Code of Federal Regulations (CFR) part 1271 when intended for use “as a wound covering” and “to protect those wounds from the environment.” DermaBind SLN Air™, DermaBind SL+ Air™, and DermaBind SLX Air™ are dehydrated human amnion membranes comprised of an extracellular matrix that is rich in collagen, fibrin, and elastin fibers native to the tissue. DermaBind SLN Air™ has an orientation notch, and DermaBind SL+ Air™ and DermaBind SLX Air™ are pre-folded for use on convex and concave wounds, respectively. DermaBind SLN Air™, DermaBind SL+ Air™, and DermaBind SLX Air™ membranes are designed for application directly to acute and chronic wounds, are flexible, and are conforming covers that adhere to complex anatomies. These membranes are intended for use as wound coverings, protecting the wound from the external environment and maintaining a moist environment. Before applying the allograft, ensure the wound and/or skin is totally clean and free of infection and debrided. Each membrane may be secured to the wound before or after hydration. Allografts can be rehydrated using three methods. Using sterile water, the membrane can be hydrated before wound application or after the product is secured to the wound with the amnion (epithelial) side facing the wound and smoothing the allograft with non-toothed forceps. The allograft can be hydrated passively by wound exudate if applied before hydration to a lightly exuding wound. The grafts are packaged amnion (epithelial) side facing down. The pouch label will identify “amnion side down”, meaning the amnion will face the opaque layer of packaging. To discourage allograft displacement following transplantation, the membranes may be affixed to the site using aseptic technique with a variety of wound closure mechanisms, including absorbable sutures, non-absorbable sutures, non-adhesive wrapping, adhesive wrapping, and/or tissue adhesive appropriate for the procedure type. DermaBind SLN Air™, DermaBind SL+ Air™, and DermaBind SLX Air™ are packaged in a double peel-pouch packaging configuration. The outer pouch is not sterile. The inner pouch that contains the membrane is sterile.

CMS Preliminary HCPCS Coding Determination

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, DermaBind SLN Air™, DermaBind SL+ Air™, and DermaBind SLX Air™, “when intended for use ‘as a wound covering’ and ‘to protect those wounds from the environment,’ appears to meet the criteria for regulation solely under

section 361 of the PHS Act and the regulations in 21 CFR part 1271.” As a result of our review of the TRG’s feedback, CMS has decided to:

Establish a new HCPCS Level II code QXXXX, “Dermabind sln air or dermabind sl+ air or dermabind slx air, per square centimeter (add-on, list separately in addition to primary procedure)”

This coding determination applies to the DermaBind SLN Air™, DermaBind SL+ Air™, and DermaBind SLX Air™ products described in the application and accompanying FDA TRG letter dated June 10, 2025, when intended for use “as a wound covering” and “to protect those wounds from the environment.”

DermaBind DLN Air™, DermaBind DL+ Air™, and DermaBind DLX Air™ - HCP260415KEXYU

Topic/Issue

Request to establish a new HCPCS Level II code to identify DermaBind DLN Air™, DermaBind DL+ Air™, and DermaBind DLX Air™.

Applicant's suggested language: QXXXX, "DermaBind DLN Air, DermaBind DL+ Air, DermaBind DLX Air, per sq cm."

Summary of Applicant's Submission

HealthTech Wound Care submitted a request to establish a new HCPCS Level II code to identify DermaBind DLN Air™, DermaBind DL+ Air™, and DermaBind DLX Air™. DermaBind DLN Air™, DermaBind DL+ Air™, and DermaBind DLX Air™ are regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 Code of Federal Regulations (CFR) part 1271 when intended for use "as a wound covering" and "to protect those wounds from the environment." DermaBind DLN Air™, DermaBind DL+ Air™, and DermaBind DLX Air™ are dehydrated human amnion/chorion membranes comprised of an extracellular matrix that is rich in collagen, fibrin, and elastin fibers native to the tissue. DermaBind DLN Air™ has an orientation notch, and DermaBind DL+ Air™ and DermaBind DLX Air™ are pre-folded for use on convex and concave wounds, respectively. DermaBind DLN Air™, DermaBind DL+ Air™, and DermaBind DLX Air™ membranes are designed for application directly to acute and chronic wounds, are flexible, and are conforming covers that adhere to complex anatomies. These membranes are intended for use as wound coverings, protecting the wound from the external environment and maintaining a moist environment. Before applying the allograft, ensure the wound and/or skin is totally clean and free of infection and debrided. Each membrane may be secured to the wound before or after hydration. Allografts can be rehydrated using three methods. Using sterile water, the membrane can be hydrated before wound application or after the product is secured to the wound with the amnion (epithelial) side facing the wound and smoothing the allograft with non-toothed forceps. The allograft can be hydrated passively by wound exudate if applied before hydration to a lightly exuding wound. The grafts are packaged amnion (epithelial) side facing down. The pouch label will identify "amnion side down", meaning the amnion will face the opaque layer of packaging. To discourage allograft displacement following transplantation, the membranes may be affixed to the site using aseptic technique with a variety of wound closure mechanisms, including absorbable sutures, non-absorbable sutures, non-adhesive wrapping, adhesive wrapping, and/or tissue adhesive appropriate for the procedure type. DermaBind DLN Air™, DermaBind DL+ Air™, and DermaBind DLX Air™ are packaged in a double peel-pouch packaging configuration. The outer pouch is not sterile. The inner pouch that contains the membrane is sterile.

CMS Preliminary HCPCS Coding Determination

After review of the Food and Drug Administration's (FDA's) Tissue Reference Group (TRG) letter submitted by the applicant, DermaBind DLN Air™, DermaBind DL+ Air™, and DermaBind DLX Air™, "when intended for use 'as a wound covering' and 'to protect those wounds from the environment,' appears to meet the criteria for regulation solely under

section 361 of the PHS Act and the regulations in 21 CFR part 1271.” As a result of our review of the TRG’s feedback, CMS has decided to:

Establish a new HCPCS Level II code QXXXX, “Dermabind dln air or dermabind dl+ air or dermabind dlx air, per square centimeter (add-on, list separately in addition to primary procedure)”

This coding determination applies to the DermaBind DLN Air™, DermaBind DL+ Air™, and DermaBind DLX Air™ products described in the application and accompanying FDA TRG letter dated June 10, 2025, when intended for use “as a wound covering” and “to protect those wounds from the environment.”

MendEra - HCP260629R07CN

Topic/Issue

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

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

Summary of Applicant's Submission

Ponya Therapeutics submitted a request to establish a new HCPCS Level II code to identify MendEra. MendEra is regulated as a human cell, tissue, or cellular or tissue-based product (HCT/P) solely under section 361 of the Public Health Service (PHS) Act and 21 Code of Federal Regulations (CFR) part 1271 when intended for use as a “protective covering for acute and chronic wounds.” MendEra is a dehydrated dual-layer human amniotic membrane allograft. MendEra is a prescription-only, sterile allograft derived from donated human placental tissue that is minimally processed. MendEra is intended for homologous use as a protective covering for acute and chronic wounds. The amniotic membrane functions as an extracellular matrix sheet that is applied topically directly to the wound site by a qualified healthcare professional as a wound covering or protective barrier. The product is supplied as a sterile, single-use graft packaged in a dual-pouch sterile barrier system and is available in multiple sizes to accommodate varying wound dimensions.

CMS Preliminary HCPCS Coding Determination

After review of the Food and Drug Administration’s (FDA’s) Tissue Reference Group (TRG) letter submitted by the applicant, MendEra, “when intended for use as a ‘protective covering for acute and chronic wounds,’ appears to meet the criteria for regulation solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271.” As a result of our review of the TRG’s feedback, CMS has decided to:

Establish a new HCPCS Level II code QXXXX, “Mendera, per square centimeter (add-on, list separately in addition to primary procedure)”

This coding determination applies to the MendEra product described in the application and accompanying FDA TRG letter dated May 13, 2026, when intended for use as a “protective covering for acute and chronic wounds.”

Symphony™ and Symphony OPX™ - HCP26062655QMV

Topic/Issue

Request to revise existing HCPCS Level II code A2009, “Symphony, per square centimeter (add-on, list separately in addition to primary procedure)” to add “ovine forestomach matrix bioscaffold with hyaluronic acid” to the code descriptor to identify Symphony™ and Symphony OPX™.

Applicant's suggested language: A2009, “Symphony, ovine forestomach matrix bioscaffold with hyaluronic acid, per square centimeter”

Summary of Applicant's Submission

Aroa Biosurgery Limited submitted a request to revise the existing HCPCS Level II code A2009 to further identify Symphony™ and Symphony OPX™. Symphony OPX™ received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on June 29, 2020. Symphony™ and Symphony OPX™ are extracellular matrix (ECM) bioengineered skin substitutes derived from ovine forestomach tissue and include hyaluronic acid (HA). Symphony™ is a family of product configurations operating under the same FDA 510(k) clearance, with different configurations of Symphony™ operating under distinct Symphony™ brand names (e.g., “Symphony™” for the 3-layer configuration, “Symphony OPX™” for the 2-layer configuration). All Symphony™ family products are composed of the same ovine-derived ECM and the same HA and have the same mechanisms of action, route of administration, coding unit, and reimbursement pathway and are under the same 510(k) clearance. The function of all Symphony™ family product configurations is also identical. All configurations are intended for the treatment of acute and chronic wounds and serve as a temporary bio scaffold for host cell infiltration, migration, proliferation, and tissue remodeling.

CMS Preliminary HCPCS Coding Determination

Revise existing HCPCS Level II code A2009, “Symphony, per square centimeter (add-on, list separately in addition to primary procedure) to instead read “Symphony or symphony opx, per square centimeter (add-on, list separately in addition to primary procedure)” to describe Symphony™ and Symphony OPX™.

BaseMEM® - HCP260628G09G5

Topic/Issue

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

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

Summary of Applicant's Submission

Viscus Biologics LLC submitted a request to establish a new HCPCS level II to identify BaseMEM®. BaseMEM® received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on June 26, 2015. It is an acellular, porcine peritoneal matrix. It is indicated for the management of wounds including partial and full thickness wounds, pressure ulcers, diabetic ulcers, tunneled/ undermined wounds, surgical wounds, trauma wounds, and draining wounds. It provides a robust biological matrix that allows for easier handling during preparation and application of the product. It is supplied in a sterile pouch and is available in multiple sizes. It is applied directly to the wound bed and secured using the provider's choice of fixation.

CMS Preliminary HCPCS Coding Determination

Establish a new HCPCS Level II code AXXXX, “Basemem, per square centimeter (add-on, list separately in addition to primary procedure)” to describe BaseMEM®.

Bonvadis® - HCP260701PN8JF

Topic/Issue

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

Applicant's suggested language: AXXXX, “Bonvadis®, prescription provider-applied semi-viscous, semi-solid topical matrix, per 3 g single-use tube”

Summary of Applicant's Submission

Oneness Biotech Inc. submitted a request to establish a new HCPCS Level II code to identify Bonvadis®. Bonvadis® received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on June 17, 2026. Bonvadis® is a prescription topical wound matrix supplied as a ready-to-use, non-sheet, semi-viscous, semi-solid matrix formulated with an aqueous phase and hydrophobic phase components to form a structured matrix in a single-use 3 g aluminum tube. Bonvadis® is indicated for the management of partial- and full-thickness wounds, diabetic foot ulcers, venous leg ulcers, pressure ulcers, post-surgical wounds, and first- and superficial second-degree burns. It is applied directly to the wound bed by a provider, conforms to irregular wound geometry, and maintains continuous physical contact throughout the application period for the wound management and creates a wound bed conducive to wound healing.

CMS Preliminary HCPCS Coding Determination

Establish a new HCPCS Level II code AXXXX, “Bonvadis, per gram” to describe Bonvadis®.

In accordance with regulatory guidance CMS effectuated for non-sheet form skin substitutes in the Calendar Year 2026 Physician Fee Schedule (PFS) Final Rule, Medicare payment under the PFS for this product will be determined by the Medicare Administrative Contractors.

Catalyze™ - HCP26062670WNU

Topic/Issue

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

Applicant's suggested language: XXXXX, "Catalyze, per mg"

Summary of Applicant's Submission

BioTissue Holdings Inc. submitted a request to establish a new HCPCS Level II code to identify Catalyze™. Catalyze™ received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on June 5, 2026. It is a resorbable particulate device derived from human amniotic membrane and umbilical cord extracellular matrix. Catalyze™ is intended to cover, protect, and provide a moist wound environment. It is indicated for use in the management of chronic and acute wounds such as pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, surgical wounds (donor sites/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, partial-thickness burns, and skin tears) and draining wounds. The device is available in multiple sizes and is designed for single use only by a licensed physician or qualified healthcare professional with relevant clinical expertise. Catalyze™ may be applied either in its dry particulate form as a dressing or rehydrated with 0.9% sterile saline to form a paste, which can facilitate application in anatomically challenging wound locations. Catalyze™ is supplied as a lyophilized, particulate device packaged in a sterile vial within a single peel pouch.

CMS Preliminary HCPCS Coding Determination

Establish a new HCPCS Level II code AXXXX, "Catalyze, per milligram" to describe Catalyze™.

In accordance with regulatory guidance CMS effectuated for non-sheet form skin substitutes in the Calendar Year 2026 Physician Fee Schedule (PFS) Final Rule, Medicare payment under the PFS for this product will be determined by the Medicare Administrative Contractors.

ECMT-100 WMD - HCP260625QBVAL

Topic/Issue

Request to establish a new HCPCS Level II code to identify ECMT-100 WMD.

Applicant's suggested language: XXXXX, "ECMT-100 WMD, per mL"

Summary of Applicant's Submission

ECM Therapeutics, Inc. Submitted a request to establish a new HCPCS Level II code to identify ECMT-100 WMD. ECMT-100 received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on June 18, 2026. WMD ECMT-100 WMD is a sterile, single use, medical device consisting of extracellular matrix derived from porcine dermis used for safe and effective wound treatment. ECMT-100 WMD is primarily composed of collagen and is produced in a flowable colloidal hydrogel formulation in a variety of volumes. ECMT-100 WMD is intended for use in the management of wounds, including partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor site/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds, (abrasions, lacerations, partial thickness burns, skin tears), draining wounds. It is applied on a wound after the wound bed is prepared with standard debridement methods. The product will fully resorb and does not have to be removed.

CMS Preliminary HCPCS Coding Determination

Establish a new HCPCS Level II code AXXXX, "Ecmt-100 wmd, per milliliter" to describe ECMT-100 WMD.

In accordance with regulatory guidance CMS effectuated for non-sheet form skin substitutes in the Calendar Year 2026 Physician Fee Schedule (PFS) Final Rule, Medicare payment under the PFS for this product will be determined by the Medicare Administrative Contractors.

DermaForm™ - HCP2607013BV3X

Topic/Issue

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

Applicant's suggested language: AXXXX, “DermaForm, per mg”

Summary of Applicant's Submission

StimLabs LLC submitted a request to establish a new HCPCS Level II code to identify DermaForm™. DermaForm™ received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on January 22, 2026. DermaForm™ is a wound care device derived from porcine peritoneum, consisting of a collagen scaffold that protects wounds. It is intended to be used for the management of a variety of wounds including partial and full thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunnel/undermined wounds, surgical wounds, trauma wounds, and draining wounds. The device is supplied in particle form, currently in units of 500mg and packaged in sterile double layer packaging. DermaForm™ is for single-use only. DermaForm™ is currently offered in a 500 mg vial and is not available in a sheet format.

CMS Preliminary HCPCS Coding Determination

Establish a new HCPCS Level II code AXXXX, “Dermaform, per milligram” to describe DermaForm™.

In accordance with regulatory guidance CMS effectuated for non-sheet form skin substitutes in the Calendar Year 2026 Physician Fee Schedule (PFS) Final Rule, Medicare payment under the PFS for this product will be determined by the Medicare Administrative Contractors.

Redermo® Wound Matrix and SurCura™ Wound Matrix - HCP260626KGKHX

Topic/Issue

Request to establish a new HCPCS Level II code to identify Redermo® Wound Matrix and SurCura™ Wound Matrix.

Applicant's suggested language: AXXXX, “Redermo Wound Matrix or SurCura Wound Matrix, per square centimeter”

Summary of Applicant's Submission

Kreate Medical Inc. submitted a request to establish a new HCPCS Level II code to identify Redermo® Wound Matrix and SurCura™ Wound Matrix. Redermo® Wound Matrix and SurCura™ Wound Matrix received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on April 16, 2026. The devices are identical sterile, single-use, fully synthetic, absorbable wound matrices supplied in sheet form and composed of poly (lactic-co-glycolic acid), polydioxanone, and poloxamer 188. The products are intended for the management of acute and chronic wounds and function as temporary three-dimensional matrices that support cellular infiltration, vascularization, and tissue formation while gradually degrading through hydrolysis within the wound bed. Unlike traditional wound dressings that are removed and replaced, Redermo® Wound Matrix and SurCura™ Wound Matrix are designed to remain in the wound and be absorbed as healing progresses.

CMS Preliminary HCPCS Coding Determination

Establish a new HCPCS Level II code AXXXX, “Redermo wound matrix or surcura wound matrix, per square centimeter (add-on, list separately in addition to primary procedure)” to describe Redermo® Wound Matrix and SurCura™ Wound Matrix.

Redermax® Antibacterial Wound Matrix and SurCura™ Antibacterial Wound Matrix - HCP2606267CTWX

Topic/Issue

Request to establish a new HCPCS Level II code to identify Redermax® Antibacterial Wound Matrix and SurCura™ Antibacterial Wound Matrix.

Applicant's suggested language: AXXXX, “Redermax Antibacterial Wound Matrix or SurCura Antibacterial Wound Matrix, per square centimeter”

Summary of Applicant's Submission

Kreate Medical Inc. Submitted a request to establish a new HCPCS Level II code to identify Redermax® Antibacterial Wound Matrix or SurCura™ Antibacterial Wound Matrix. Redermax® Antibacterial Wound Matrix and SurCura™ Antibacterial Wound Matrix received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on February 2, 2026. These products are identical sterile, single-use, fully synthetic, absorbable antibacterial wound matrices supplied in sheet form and composed of poly (lactic-co-glycolic acid), polydioxanone, poloxamer 188, and poly (hexamethylene biguanide) hydrochloride (PHMB). The products function as temporary three-dimensional bioabsorbable matrix that support the body's natural healing process while, based on in vitro testing, the incorporated PHMB reduces the growth of bacteria within the wound matrix for up to seven days.

CMS Preliminary HCPCS Coding Determination

Establish a new HCPCS Level II code AXXXX, “Redermax antibacterial wound matrix or surcura antibacterial wound matrix, per square centimeter (add-on, list separately in addition to primary procedure)” to describe Redermax® Antibacterial Wound Matrix and SurCura™ Antibacterial Wound Matrix.

Appendix A: DMEPOS Payment Categories

The Social Security Act separates DMEPOS into different Medicare payment categories, each with its own unique payment rules. The pricing indicator codes in the HCPCS identify which major payment category a HCPCS Level II code falls under. The pricing indicator codes applicable to DMEPOS.

Pricing = 00 Service Not Separately Priced

Items or services described by the HCPCS Level II codes that are either not covered under Medicare Part B or for which payment is bundled into the payment some other Medicare service or procedure.

Pricing = 31 Frequently Serviced Items

Payment is generally made on a monthly rental fee schedule basis for items such as ventilators that require frequent and substantial servicing in order to avoid risk to the patient's health. Payment for E0935 is based on a daily rental fee schedule basis since coverage of this device is limited to 21 days.

Pricing = 32 Inexpensive and Other Routinely Purchased Items

Payment is made on a purchase or rental fee schedule basis. This category includes items that have a purchase price of \$150 or less, were purchased 75 percent of the time or more from July 1986 through June 1987, or which are accessories used in conjunction with a nebulizer, aspirator, continuous airway pressure device, or respiratory assist device. The beneficiary has the option to acquire the item on a purchase or monthly rental basis. Total payments for the item cannot exceed the purchase fee schedule amount for the item.

Pricing = 33 Oxygen and Oxygen Equipment

Monthly fee schedule payments are made for furnishing oxygen and oxygen equipment. This monthly payment includes payment for all stationary oxygen equipment, supplies, and accessories and delivery of oxygen contents (stationary and portable). A monthly add-on to this payment is made for portable oxygen equipment only for those beneficiaries who require portable oxygen. The monthly payments for oxygen equipment cap after the 36th monthly payment is made, after which payment for the ongoing delivery of contents continues for gaseous or liquid systems.

Pricing = 34 Supplies Necessary for the Effective Use of DME

Payment is made on a purchase fee schedule basis for supplies necessary for the effective use of DME (e.g., lancets that draw blood for use in blood glucose monitor).

Pricing = 35 Surgical Dressings

Payment is made on a purchase fee schedule basis for surgical dressings.

Pricing = 36 Capped Rental Items

Payment is made on a monthly rental fee schedule basis. The beneficiary takes over ownership of the item after the 13th rental payment is made. The rental fee for capped rental items, other than power wheelchairs, for each of the first 3 months of rental is equal to 10 percent of the purchase fee for the item. The rental fee for months 4 through 13 is equal to 7.5 percent of the purchase fee for the item. The rental fee for power wheelchairs for each of the first 3 months of rental is equal to 15 percent of the purchase fee for the item. The rental fee

for power wheelchairs for months 4 through 13 is equal to 6 percent of the purchase fee for the item. Complex rehabilitative power wheelchairs can also be purchased in the first month.

Pricing = 37 Ostomy, Tracheostomy and Urological Supplies

Payment is made on a purchase fee schedule basis for ostomy, tracheostomy and urological supplies.

Pricing = 38 Orthotics, Prosthetics, Prosthetic Devices, and Vision Services (Prosthetic Lenses)

Payment is made on a purchase fee schedule basis for orthotics, prosthetics, and prosthetic devices & lenses.

Pricing = 39 Parenteral and Enteral Nutrition (PEN)

Payment is made on a purchase fee schedule basis for parenteral and enteral nutrients and supplies. Payment is made on a purchase or rental fee schedule basis for parenteral and enteral equipment. The beneficiary has the option to acquire the item on a purchase or monthly rental basis.

Pricing = 40 Lymphedema Compression Treatment Items

Payment is made on a purchase basis for lymphedema compression treatment items.

Pricing = 45 Customized DME

Payment is made for lump-sum purchase of DME that meets the Medicare regulatory definition of customized DME at 42 CFR 414.224. The payment amount is based on the carrier's individual consideration of the item and judgment of a reasonable payment amount, which, at a minimum, includes a review of the costs of labor and material used in constructing the equipment.

Pricing = 46 Carrier Priced Item

The allowed payment amount for covered items is based on local carrier pricing (e.g., local fee schedule amounts or reasonable charges or other carrier pricing method).