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

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

Virtual Meeting – Remote Participation
Wednesday, December 17, 2025 and Thursday, December 18, 2025
9:00 am – 5:00 pm, eastern time (ET)

8:15 am, ET:
• Arrival and sign-in

8:45 am, ET:
• Teams meeting login for both December 17, 2025 and December 18, 2025: https://teams.microsoft.com/l/meetup-join/19%3ameeting_OTdjY2U2NmItOTM2MS00NTUyLWJiMWItMzMxNzdlYmM1NDhi%40thread.v2/0?context=%7b%22Tid%22%3a%22fbdcedc1-70a9-414b-bfa5-c3063fc3395e%22%2c%22Oid%22%3a%22c8215af6-889d-487c-bea2-eb240b7c9a23%22%7d
• Meeting ID: 297 731 536 190 45 • Passcode: Tz7xB3jp
• (888) 588-2610 (Toll-free) • Phone conference ID: 452 323 943#

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-CMSHCPCSLevelII-Coding-Decisions-Narrative-Summary around January 2026 and will be effective April 1, 2026, unless otherwise specified.

This document includes a summary of each HCPCS Level II code application being presented on Wednesday, December 17, 2025, with an overflow date of Thursday, December 18, 2025, if necessary. The same Teams link above will be utilized if the overflow date is necessary. The information provided in each summary reflects claims made by the applicant

and should not be construed as a statement of fact or an endorsement by the federal government.

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Preliminary determinations for the HCPCS Level II Public Meeting on Wednesday, December 17, 2025, with an overflow date of Thursday, December 18, 2025, if necessary.

Agenda Item # 1
myPTM™ - HCP250617B5N9E

Topic/Issue

Request to establish a new HCPCS Level II code to identify myPTM™ personal therapy manager.

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

Summary of Applicant's Submission

Medtronic submitted a request to establish a new HCPCS Level II code to identify myPTM™. The myPTM™ was approved by the Food and Drug Administration (FDA) under a Premarket Approval (PMA) on July 31, 2018. The myPTM™ personal therapy manager is designed to enable personalized, on-demand intrathecal boluses delivered by the SynchroMed™ intrathecal drug delivery system (IDDS) to help alleviate unpredictable pain. This system is prescribed for individuals with intractable chronic pain, including cancer-related pain. Unlike oral pain medications that must be absorbed systemically, SynchroMed™ delivers physician-prescribed doses of medication directly to the intrathecal space at a fraction of an oral medication dose. The myPTM™ personal therapy manager system includes the handset, communicator (when applicable based on model), and myPTM™ app. The device uses an icon-based touch-screen interface and on-screen graphics and audible tones that direct individual interaction. When the activator button on the handset is pressed by the individual, a message is sent by telemetry to the implanted pump for SynchroMed™ III or via the communicator for SynchroMed™ II, which releases a preprogrammed dose of drug. Operationally, Medtronic ships only the component requiring replacement: the programmer (the handset including the myPTM™ app) or the communicator. The programmer and the communicator each have their own unique identifiers. If it cannot be determined which component is not functioning properly, both are replaced. In either scenario, the coding and billing would only be for the programmer component. Therefore, this coding request is specific only to the replacement of the programmer and does not include a separate HCPCS Level II coding request for the communicator or suggested language for the communicator. Given that the average lifespan of an IDDS implant is typically longer than the myPTM™’s reasonable useful life of approximately five years, many individuals will require replacements of the peripheral myPTM™ over the lifetime of the IDDS implant.

CMS Preliminary HCPCS Coding Determination

In the First Biannual 2024 HCPCS Level II Coding Cycle (prior application HCP231221EK8Q5), CMS requested additional time to consider Medtronic’s application. CMS continues to need more time to evaluate this complex issue to determine how this item can be classified under Medicare Part B. In the meantime, coding determinations will be made on an individual claim-by-claim basis by the A/B Medicare Administrative Contractors (MACs).

Preliminary Medicare Benefit Category Determination

No determination.

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

Preliminary Medicare Payment Determination

No determination.

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

Agenda Item # 2
Chemo Mouthpiece™ - HCP250626V4E96

Topic/Issue

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

Applicant's suggested language: XXXXX, “Intra-oral cryotherapy device for patients receiving administration of stomatotoxic chemotherapy / radiation, kit of 6 plus accessories”

Summary of Applicant's Submission

ChemoMouthpiece, LLC, submitted a request to establish a new HCPCS Level II code to identify the Chemo Mouthpiece™. The Chemo Mouthpiece™ received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on January 23, 2024. The Chemo Mouthpiece™ is indicated for use in adults receiving chemotherapy to cool the oral mucosa thus causing vasoconstriction that decreases the flow of chemotherapy, reducing the incidence and severity of chemotherapy-induced oral mucositis. The device is indicated for use in clinical and home settings. The Chemo Mouthpiece™ is a multiple-use item that is supplied in a kit containing six identical devices intended for use by one individual only. Kits are available upon a physician’s prescription and are distributed in the United States by a specialty healthcare service provider. The individuals receiving the Chemo Mouthpiece™ devices are instructed to place them in a freezer six hours prior to the administration of chemotherapy. Ten minutes prior to chemotherapy, the individual is directed to use the device, which will remain in their mouth for the duration of the chemotherapy administration. Each device maintains a temperature of 31.8 degrees to 35.5 degrees Fahrenheit for 30 minutes and the individual is told to switch to another frozen device every 30 minutes for the duration of the chemotherapy infusion. Individuals are instructed to use the device at home (post-administration of chemotherapy) a minimum of two times per day for the following five days to keep the oral cavity cool to reduce the incidence and severity of chemotherapy-induced mucositis. In July 2024, the American Medical Association’s Current Procedural Terminology (CPT®) Editorial Panel established the CPT® Category III code 0881T, “Cryotherapy of the oral cavity using temperature regulated fluid cooling system, including placement of an oral device, monitoring of patient tolerance to treatment, and removal of the oral device.” This code is specific to the Cooral® System, the predicate product to the Chemo Mouthpiece™, which incorporates electronic circuitry and firmware and requires a significant amount of physician work. Multiple certified coders reviewed Chemo Mouthpiece™ and independently determined that the CPT® Category III code 0881T did not adequately describe Chemo Mouthpiece™ as it is a small, portable device suitable for home use by individuals without physician oversight.

CMS Preliminary HCPCS Coding Determination

In the Second Biannual 2024 HCPCS Level II Coding Cycle (prior application HCP240627CH4KV), CMS concluded that for Medicare purposes, if this product were covered, it would be included within the payment for the professional service. CMS maintains that the Chemo Mouthpiece™ is not suitable for coding in HCPCS Level II for Medicare purposes for the above stated reason.

Agenda Item # 3
NEST® BKG Pen Injector - HCP250520RNGME

Topic/Issue

Request to establish a new HCPCS Level II code to identify the NEST® BKC Pen Injector.

Applicant's suggested language: XXXXX, "510K Re-Usable metered controlled=dose auto injection pen with disposable/replacement drug cartridge"

Summary of Applicant's Submission

Signature Rx and BKG Medical Supplies submitted a request to establish a new HCPCS Level II code to describe the NEST® BKC Pen Injector. The NEST® BKG Pen Injector received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on June 18, 2024. The NEST® BKC Pen Injector is a reusable, metered control-dose drug injector pen with disposable and replaceable drug cartridge for use with high demand, high-clinical value medications requiring a subcutaneous injection. The NEST® BKC Pen Injector consists of a pen injector body, a push block, an injection button, a dose display window, a dose adjustment knob, a reservoir and a pen injector cap. The NEST® BKC Pen Injector is available in 3 mL cartridges with sterile, single use detachable and disposable insulin pen needles. The NEST® BKC Pen Injector further helps ensure safer, more accurate self-administration of drugs.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II code A4211, "Supplies for self-administered injections" describes the NEST® BKC Pen Injector. The NEST® BKC Pen Injector is a type of reusable liquid medicine injection device similar to other devices in HCPCS Level II code A4211.

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. We have determined that the NEST® BKG Pen Injector does not meet at least one of the conditions above as follows:

Can withstand repeated use – It was implied in the application that the NEST BKG Pen Injector is intended to be used by a single patient and cannot be rented or used by successive patients.

In addition, it is unclear if the NEST® BKG Pen Injector has an expected life of at least 3 years. The applicant has stated that the injector has a 5-year shelf life. It is unclear if the patient can use the injector for at least 3 years, especially if the injector has been "on the shelf" for over 3 years.

Preliminary Medicare Payment Determination

Items or services described by HCPCS Level II code A4211 are not covered under Medicare Part B.

No Medicare payment. Pricing Indicator = 00

Agenda Item # 4
Tango® Belt - HCP250630UFB2B

Topic/Issue

Request to establish a new HCPCS Level II code to identify the Tango® Belt and the replacement airbag used to recharge the Tango® Belt.

Applicant's suggested language: XXXXX, "Automatic hip airbag deployment belt system, with integrated 3D motion sensor and fall detection analysis"

Summary of Applicant's Submission

Active Protective Technologies submitted a request to establish a new HCPCS Level II code to identify Tango® Belt. Tango® Belt received De Novo classification by the Food and Drug Administration (FDA) on April 9, 2009. Tango® Belt is worn around the waist and uses built-in sensors and algorithms to detect an in-progress serious hip-impacting fall and deploy an airbag. When connected to Wi-Fi, the device can also send notifications to designated caregivers or healthcare providers upon detection of a fall or impact. The Tango® Belt is designed to be used alongside standard care to help protect adults at risk of serious hip injuries from falls, by reducing the chance of hip fractures or dislocations. In addition to the new HCPCS II code to identify the Tango® Belt, we are also seeking a separate HCPCS II code to describe the replacement airbag used to recharge the Tango® Belt once an airbag has been deployed.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II code E0700, "Safety equipment, device or accessory, any type" describes Tango® Belt and the replacement airbag.

The Tango® Belt uses built-in sensors and algorithms to deploy an airbag around both hips just before a fall impact, serving as an intervention to help prevent hip fractures. The Tango® Belt is similar to other devices in the HCPCS Level II code E0700.

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 Tango® Belt does not meet three conditions as follows:

> **Cannot withstand repeated use** – The Tango® Belt cannot be rented or used by successive patients once the airbag has been deployed.
>
> **Does not have an expected life of at least 3 years** – The Tango® Belt cannot be used for 3 years once the airbag has been deployed.
>
> **Is not primarily and customarily used to serve a medical purpose -** While the device is intended to prevent injury during falls, it does not treat a medical condition. Section 110.1 of the Medicare Benefit Policy Manual (Pub. 100-2) does not classify precautionary-type equipment as DME.

Preliminary Medicare Payment Determination

Items or services described by HCPCS Level II code E0700 are not covered under Medicare Part B.

No Medicare payment. Pricing Indicator = 00

Agenda Item # 5
FOOTSNUGGS™ - HCP250213VY7UN

Topic/Issue

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

Applicant's suggested language: XXXXX, “Top of foot pad foot orthotics”

Summary of Applicant's Submission

DHC Marketing Group LLC submitted a request to establish a new HCPCS Level II code to identify FOOTSNUGGS™. FOOTSNUGGS™ are exempt from the premarket notification procedures by the Food and Drug Administration (FDA). FOOTSNUGGS™ are orthotic top-of-foot pads referred by physicians, podiatrists, and foot care specialists for the intended use by individuals with foot problems, such as diabetic neuropathy, runner’s toe, toe and toenail amputations, bone loss, skin grafting, bunionectomies, etc. FOOTSNUGGS™ are worn on top of the foot, usually under the sock, over the metatarsal region, and/or metatarsal region and above, to prevent the individual's foot from sliding forward, backward, or side-to-side in their footwear. They provide a custom and stable fit and assist in treatment before and after foot surgeries.

CMS Preliminary HCPCS Coding Determination

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

FOOTSNUGGS™ are flexible, cushion like, pads for the top of the foot to prevent the foot from sliding within footwear and provide custom stability for individuals with various foot conditions. FOOTSNUGGS™ are similar to other products in HCPCS Level II code A9270.

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 Top of Foot Pad Orthotics does not meet four conditions as follows:

Cannot withstand repeated use – The Top of Foot Pad Orthotics is a one-time use pad that can be disposed once used.

Does not have an expected life of at least 3 years - Once the foot pad is used it is disposable and does not last 3 years.

Not primarily and customarily used to serve a medical purpose – The Top of Foot Pad Orthotics is a pad that prevents pain and provides comfort and prevention for foot related issues. It does not provide treatment for a medical condition.

Is useful to an individual in the absence of an illness or injury – The Top of Foot Pad Orthotics can be used in absence of an illness or injury for comfort or prevent injuries to the foot.

Preliminary Medicare Payment Determination

Items or services described by HCPCS Level II code A9270 are not covered under Medicare Part B.

No Medicare payment. Pricing Indicator = 00

Agenda Item # 6
Q-Collar - HCP250627DAXAC

Topic/Issue

Request to establish a new HCPCS Level II code to identify Q-Collar.

The applicant did not submit any suggested language.

Summary of Applicant's Submission

Q30 Innovations LLC submitted a request to establish a new HCPCS Level II code to identify Q-Collar. Q-Collar received De Novo classification by the Food and Drug Administration (FDA) on February 26, 2021. The Q-Collar is a non-invasive device intended to be worn around the neck of athletes. The Q-Collar is recommended for individuals age 13 years and older during sports activities to protect the brain from effects associated with repetitive sub-concussive head impacts. The Q-Collar applies gentle compression to the internal jugular vein, which increases blood volume in the brain's venous vessels. This increased blood volume creates a protective cushioning effect that reduces brain movement within the skull during head impacts. Importantly, the Q-Collar is specifically engineered to avoid applying excessive pressure that could restrict arterial blood flow and oxygen delivery to the brain. Extensive bench testing and nonclinical studies were conducted to demonstrate the safety and effectiveness of the Q-Collar. The Q-Collar can be worn for up to 4 hours at a time and should be replaced after 2 years of active use or upon the product's expiration date listed on the package, whichever comes first. The Q-Collar does not require a prescription. The Q-Collar is available in 8 different sizes to accommodate neck circumferences ranging from 11 inches to 18 inches. Each Q-Collar package includes a Q-Collar device, travel case, fit check tool, and owners guide.

CMS Preliminary HCPCS Coding Determination

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

The Q-Collar increases blood volume in the brain's venous vessels, which creates a protective cushioning effect that reduces brain movement within the skull during head impact. The Q-Collar is an optional preventative device available for athletes.

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 Q-Collar does not meet three of these conditions as follows:

> **Can withstand repeated use** – According to the application, the Q-Collar is intended to be used by a single patient. Therefore, it cannot be refurbished, rented, and used by successive patients.
>
> **Is primarily and customarily used to serve a medical purpose** – Although the application describes the Q-Collar as a non-invasive device intended to be worn around the neck of athletes during sports activities to aid in the protection of the brain from effects associated with repetitive sub-concussive head impacts, it does not treat a medical condition. Section 110.1 of the Medicare Benefit Policy Manual (Pub. 100-2) does not classify precautionary-type equipment as DME.
>
> **Generally is not useful to an individual in the absence of an illness or injury** - CMS considers the Q-Collar to be a recreational item that may be used by people without medical conditions. Also, the Medicare Benefit Policy Manual (Pub. 100-2) specifically identifies physical fitness equipment as equipment that is not DME.

Preliminary Medicare Payment Determination

Items or services described by HCPCS Level II code A9270 are not covered under Medicare Part B.

No Medicare payment. Pricing Indicator = 00

Agenda Item # 7
ivWatch Model 400 - HCP250529WCEY2

Topic/Issue

Request to establish a new HCPCS Level II code to identify ivWatch Model 400.

Applicant's suggested language: XXXXX, “Peripheral IV Monitoring Sensor”

Summary of Applicant's Submission

ivWatch, LLC submitted a request to establish a new HCPCS Level II code to identify ivWatch Model 400. ivWatch Model 400 received clearance from the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on February 13, 2015. The ivWatch Model 400 is indicated for the detection of subcutaneous infiltrations and extravasations of 10 cc or less of optically clear and iron sucrose infusates. The ivWatch is intended as an adjunctive device to the clinical evaluation in the healthcare setting of children and adults with peripherally inserted intravenous catheters (PIVs). The ivWatch Model 400 uses visible and near-infrared light to measure changes in the optical properties of the tissue near a PIV insertion site. Measured changes between the emitted and reflected signals are processed by the ivWatch signal processing algorithm to determine if an infiltration event may have occurred. If changes consistent with infusate pooling in the subcutaneous tissue are detected, the device's monitor emits audible and visual alerts to prompt the clinician to inspect the site for a potential infiltration event.

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 ivWatch Model 400.

The ivWatch Model 400 measures changes in the optical properties of tissue near a PIV insertion site to detect infusate pooling in the subcutaneous tissue and emits both audible and visual alerts. The ivWatch Model 400 is similar to other devices in the HCPCS Level II code A9279.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS Benefit Category.

This is an item used by clinicians in the hospital while providing infusion therapy.

Preliminary Medicare Payment Determination

Items or services described by HCPCS Level II code A9279 are not covered under Medicare Part B.

No Medicare payment. Pricing Indicator = 00

Agenda Item # 8
Wellsense VŪ™ Pressure Visualization Monitor - HCP250630F2T0W

Topic/Issue

Request to establish a new HCPCS Level II code to identify Wellsense VŪ™ Pressure Visualization Monitor.

Applicant's suggested language: XXXXX, “Pressure monitoring system, real-time, non-therapeutic, includes sensor mat and bedside display to support and validate patient repositioning decisions”

Summary of Applicant's Submission

Wellsense Inc. submitted a request to establish a new HCPCS Level II code to identify Wellsense VŪ™ Pressure Visualization Monitor. Wellsense VŪ™ Pressure Visualization Monitor is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). Wellsense VŪ™ Pressure Visualization Monitor is intended for use by individuals at risk of pressure injuries in inpatient and long-term care settings. The system is currently deployed in 18 hospitals across the United States. The Wellsense VŪ™ system, nursing teams have successfully identified and offloaded high-pressure areas, contributing to measurable reductions in pressure injury rates. This represents a critical advancement, as pressure injuries account for 27 percent of all hospital-acquired conditions (HACs) and approximately 45 percent of HACs-related deaths.

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 Wellsense VŪ™ Pressure Visualization Monitor.

The Wellsense VŪ™ Pressure Visualization Monitor is a non-therapeutic pressure monitoring system consisting of a sensor mat and a bedside display. The system visually maps the interface pressure between an individual and their support surface. The Wellsense VŪ™ Pressure Visualization Monitor is similar to other devices in the HCPCS Level II code A9279.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS Benefit Category. For inpatient use.

Preliminary Medicare Payment Determination

Items or services described by HCPCS Level II code A9279 are not covered under Medicare Part B.

No Medicare payment. Pricing Indicator = 00

Agenda Item # 9
Interossei Keyboard Layout - HCP250630QED9W

Topic/Issue

Request to establish a new HCPCS Level II code to identify Interossei keyboard layout.

The applicant did not submit any suggested language.

Summary of Applicant's Submission

Interossei submitted a request to establish a new HCPCS Level II code to identify Interossei keyboard layout. The Interossei keyboard layout is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). This item is a battery-powered device intended for medical purposes that is used to transmit or receive information. It is used by individuals unable to use normal communication methods because of physical impairment.

CMS Preliminary HCPCS Coding Determination

CMS has not identified a program operating need for Medicare or other insurers to establish a new HCPCS Level II code to describe the Interossei keyboard layout. The Interossei keyboard layout can be used in the absence of illness and injury, and it is "designed to improve typing comfort and efficiency" and "aims to reduce strain on the fingers and wrists." The device is primarily used for ergonomic purposes.

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 Interossei keyboard layout does not meet two conditions as follows:

> **Not primarily and customarily used to serve a medical purpose** – The Interossei keyboard layout is primarily and customarily used as a computer keyboard.
>
> **Is useful to an individual in the absence of an illness or injury** – The Interossei keyboard layout can be used in the absence of an illness or injury as a computer keyboard.

In addition, the keyboard is designed to improve typing comfort and reduce strain on fingers and wrists. Personal comfort items are excluded from Medicare coverage by section 1862(a)(6) of the Social Security Act.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Agenda Item # 10
Safe Place Bedding - HCP250331FEH5E

Topic/Issue

Request to establish a new HCPCS Level II code to identify Safe Place Bedding.

Applicant's suggested language: XXXXX, “Permanent enclosed safety bed, 360 degree enclosure headboard, footboard, mattress included, with or without side rails”

Summary of Applicant's Submission

Safe Place Bedding LLC. submitted a request to establish a new HCPCS Level II code to identify Safe Place Bedding. Safe Place Bedding is exempt from the premarket notification procedures of the Food and Drug Administration (FDA). The enclosed permanent safety bed is a permanent bed containing a frame, headboard, footboard, and enclosed space that offers 360 degrees of protection from falling out of bed. The design of this safety bed eliminates the seven zones of entrapment, as defined by federal safety standards. It is intended for individuals who cannot safely monitor themselves at night. Many of these individuals are prone to elopement, either within the home or outside into potentially hazardous environments such as traffic. Others may engage in self-injurious or aggressive behaviors. The enclosed permanent safety bed is designed to create a secure sleeping environment that helps prevent harm and reduces the risk of elopement. It ensures that individuals remain in a safe space throughout the night, significantly minimizing the chances of injury or escape.

CMS Preliminary HCPCS Coding Determination

Establish a new HCPCS Level II code AXXXX, “Permanent enclosed safety bed, 360-degree side enclosures, headboard, footboard, includes mattress, with or without side rails, single patient use only” to describe Safe Place Bedding.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS Benefit Category.

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

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

All five of these conditions must be met for equipment to be classified as DME. Safe Place Bedding does not meet one of the conditions as follows:

Can withstand repeated use – Per the applicant, the Safe Place Bedding would be unable to be rented or used by successive patients. The applicant says this is because the beds are customized to meet specific medical needs of the individual, such as custom access ports for tube feeding, ventilator access, and cardiac monitoring equipment. Per the applicant, reusing a customized bed introduces safety risks. For example, a port that is unnecessary for the next individual could become an entrapment hazard or provide unsafe access for vulnerable individuals. DME is a benefit for rental of equipment and therefore DME items must be able to withstand repeated use by successive patients. The regulation is in accordance with section 1861(s)(6) of the Social Security Act which sets forth the DME benefit including rental of DME, although purchase of DME items is allowed in limited situations such as section 1834(a)(4) of the Social Security Act for custom DME.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Agenda Item # 11
Freespira System – HCP250701BVJED

Topic/Issue

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

Applicant's suggested language: EXXXX, "Capnometry-guided respiration system, including locked therapy software, all components and accessories, prescription-only"

Summary of Applicant's Submission

Freespira, Inc. submitted a request to establish a new HCPCS Level II code to describe the Freespira System. The Freespira System received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on September 3, 2018. The Freespira System is a capnometry-guided respiration device that delivers a 28-day, at-home course of treatment for individuals with post-traumatic stress disorder (PTSD) or panic disorder (PD). The Freespira System is indicated as an adjunctive treatment of symptoms associated with PD or PTSD to be used under the direction of a healthcare professional, together with other pharmacological or non-pharmacological interventions. PD, PTSD, and panic attacks are associated with carbon dioxide (CO_2) hypersensitivity and breathing dysfunctions such as chronically low CO_2. Evidence shows that breathing dysfunction increases underlying risk of panic attacks, post-traumatic flashbacks, and other disabling symptoms. The Freespira System normalizes dysfunctional breathing associated with PTSD and PD through use of a durable medical device loaded with proprietary software that trains individuals to modulate their breathing patterns through audio and visual cues, as well as real-time capnometer measurements of respiratory rate (RR) and end-tidal carbon dioxide levels ($etCO_2$). During twice-daily treatment sessions, individuals participate in a program in which they modify their breathing patterns to achieve a stable RR and modify air intake to move and hold $etCO_2$ values within the normal range. Over the 28-day treatment program, these sessions lead to the individual developing normalized respiratory patterns to improve their PD/PTSD symptoms. The current Freespira System is comprised of durable hardware components including a capnometry sensor and dedicated display with preloaded Freespira software. An updated form of the Freespira device will combine the separate display device and capnometer into a single integrated, durable component. Additional supplies and accessories include two nasal cannulas, five pre-filled CO_2 calibration cartridges, chargers, cables, and a carrying case.

CMS Preliminary HCPCS Coding Determination

Establish a new HCPCS Level II code AXXXX, "Capnometry-guided respiration system, including locked therapy software, all components and accessories, prescription only" to describe the Freespira System.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS Benefit Category.

The application suggests that the Freespira System is similar to the RelieVRx® (from the Second Biannual 2022 HCPCS Level II coding cycle – application HCP220701K2H96) and

that the Freespira System should be classified as DME. The applicant explained that "like the RelieVRx® device, the Freespira System uses a combination of unique hardware and preprogramed software to guide the patient through a defined treatment program to create lasting physiological effects." However, the two devices differ. For the RelieVRx®, a cognitive behavioral therapy device, the medical software and the device on which it is housed are so integral to each other that CMS considers them to be one whole device, not software and a separate device. CMS considers RelieVRx® to be one whole device for a few reasons, including because the software is locked to the device. In addition, the software cannot be used on any personal devices and no other non-medical software can be added to the device. Also, the software relies on the virtual reality/immersive features of the device to deliver the benefit to the individual, and the device in turn has features that drive the effectiveness of the software. In contrast, the Freespira System uses a treatment mechanism called "capnometry-guided respiratory intervention" and uses software on the Freespira device's platform as well as on the individual's personal smartphone once the initial four-week treatment period ends.

CMS determined that the Freespira System therapy is biofeedback therapy. Section 30.1 of chapter 1, part 1 of the Medicare National Coverage Determinations Manual (Pub. 100-3) states that biofeedback therapy provides visual, auditory or other evidence of the status of certain body functions so that a person can exert voluntary control over the functions and thereby alleviate an abnormal bodily condition. Biofeedback therapy often uses electrical devices to transform bodily signals indicative of such functions as heart rate, blood pressure, skin temperature, salivation, peripheral vasomotor activity, and gross muscle tone into a tone or light, the loudness or brightness of which shows the extent of activity in the function being measured. According to the company's website, individuals use a tablet with a dedicated app with a sensor and a small tube to sample and measure their breathing. This provides real-time feedback (auditory and visual cues) to enable individuals to adjust or fine-tune their breathing-both pace and depth of breaths.

According to the application, the Freespira System normalizes the dysfunctional breathing associated with post-traumatic stress disorder and panic disorder through use of a medical device loaded with proprietary software that trains individuals' respiratory systems to modulate their breathing patterns through audio and visual cues, as well as real-time measurements of RR and $etCO_2$. The Medicare national coverage determination states that biofeedback therapy is not covered for treatment of psychosomatic conditions.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Agenda Item # 12
TetraSens Electrode - HCP250413T6K49

Topic/Issue

Request to establish a new HCPCS Level II code to identify TetraSens Electrode.

Applicant's suggested language: XXXXX, “Surface-based, non-grounded EMG sensor for perioperative and critical care neuromuscular monitoring, single-use”

Summary of Applicant's Submission

Senzime submitted a request to establish a new HCPCS Level II code to identify TetraSens Electrode. The TetraSens Electrode is used with Tetragraph Neuromuscular Transmission Monitor (NMT) which received clearance by the Food and Drug Administration (FDA) through a 510(k) regulatory pathway on August 17, 2022. The TetraSens Electrode is a single-use electrode array. Each array includes two stimulating electrodes and two recording electrodes. The TetraSens Electrode is part of NMT, which is indicated for monitoring the relaxation of an individual when neuromuscular blockade is administered perioperatively, in recovery and critical care environments. The TetraSens Electrode is nonsterile, sold separately and available in boxes of twenty electrodes.

CMS Preliminary HCPCS Coding Determination

The TetraSens Electrode is used with the Tetragraph Neuromuscular Transmission Monitor, which is indicated for monitoring the relaxation of an individual when neuromuscular blockade is administered perioperatively, in recovery and critical care environments. Based on FDA 510(k) regulatory pathway TetraSens Electrode is indicated for use in hospital settings. This technology ensures precise anesthesia management perioperatively, in recovery and critical care environments. As such, the TetraSens Electrode is not suitable for inclusion in the HCPCS Level II code set based on setting of use. Typically for Medicare, when the device is utilized in hospital outpatient or inpatient settings, the TetraSens Electrode would be included in the Outpatient Prospective Payment System bundled payment or in the applicable Medicare Severity Diagnosis Related Group under the Inpatient Prospective Payment System.

Agenda Item # 13
Osteogenesis Stimulator for Cervical Application - HCP2506202JGC2

Topic/Issue

Request to establish a new HCPCS Level II code to separately identify osteogenesis stimulator for cervical application.

Applicant's suggested language: EXXXX, “Osteogenesis stimulator, electrical, non-invasive, cervical applications”

Summary of Applicant's Submission

Voyage Medical Solutions submitted a request to establish a new HCPCS Level II code to separately identify osteogenesis stimulator for cervical applications. This request is for one category of osteogenesis stimulators applied to the cervical region of the spine. The osteogenesis stimulators enhance bone healing after fusion surgery by using pulsed electromagnetic field as a nonsurgical treatment to stimulate the body's natural healing process. Currently, existing HCPCS Level II code E0748, “osteogenesis stimulator, electrical, non-invasive, spinal applications” describes both cervical and lumber spine applications. However, the existing code E0748 is predominantly used to identify devices for lumber applications. The osteogenesis stimulators for cervical and lumbar spine are two different devices. While the osteogenesis stimulators have similar effectiveness, they are not interchangeable, hence the need for a separate HCPCS Level II code. When the existing HCPCS Level II code E0748 is used to bill for both lumbar and cervical spine treatments, insurers deny claims as duplicates within a 5-year period.

CMS Preliminary HCPCS Coding Determination

CMS has not identified a program operating need to separately identify osteogenesis stimulators for cervical application. Osteogenesis stimulators are predominantly for lumber applications; however, both cervical and lumbar are part of the spine. Additionally, we were only able to locate one device since 2004, the Cervical-Stim® Model 505L, Cervical Fusion System, that has been approved by the Food and Drug Administration.

CMS determines that instances where an individual would need an osteogenesis stimulator for the cervical area of the spine and an osteogenesis stimulator for the lumbar area of the spine at the same time are rare and denied claims for the second item can be handled through the insurer's claims appeals process.

Agenda Item # 14
Shoulder Flexionater - HCP250630BYKWB

Topic/Issue

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

Applicant's suggested language: EXXXX, "Stationary, non-electric, hydraulically amplified, shoulder stretch assist machine, with or without range of motion adjustment, includes all components and accessories"

Summary of Applicant's Submission

Ermi LLC submitted a request to establish a new HCPCS Level II code to identify Shoulder Flexionater. The Shoulder Flexionater is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). Currently, existing HCPCS Level II code E1841 ("static progressive stretch (SPS)/patient-actuated serial stretch (PASS) shoulder device, with or without range of motion adjustment, including all components and accessories") combines two different shoulder devices: a portable turnbuckle/worm gear splint, and a stationary, non-electric, hydraulically amplified machine. These two devices should be separated into HCPCS Level II codes E1841 and EXXXX. HCPCS Level II code E1841 houses two operationally and functionally distinct stretch assist devices: 1) a portable turnbuckle/worm gear stretch assist splint, and 2) a stationary, non-electric, hydraulically amplified stretch assist machine. The long description language in HCPCS Level II code E1840 ("dynamic adjustable shoulder flexion / abduction / rotation device, includes soft interface material") uniquely describes the dynamic stretch assist splint, whereas the E1841 code does not. SPS and PASS are physical therapy procedures described in the literature (1950s, 2003), not specific devices. There are already established and distinct HCPCS Level II codes for stationary versus portable devices, e.g., stationary gaseous oxygen (E0424), versus portable gaseous oxygen (E0431). Furthermore, there are also existing, distinct and unique HCPCS Level II codes that are established based on different operational modes, as with portable oxygen concentrators (HCPCS Level II codes E1390, E1391, and E1392), versus portable gaseous oxygen (HCPCS Level II code E0431). Since the current HCPCS Level II code E1841 long description does not specify operational or functional features, Ermi requests that HCPCS Level II code E1841 be revised to conform to a "portable, turnbuckle/worm gear shoulder stretch assist splint", and thus establishing a new HCPCS Level II code EXXXX, to be introduced for a "stationary, non-electric, hydraulically amplified shoulder stretch assist machine". The second reason is that research confirms a lack of provider confidence in the use of portable, stretch-assist splints, either turnbuckle/worm gear or dynamically operated, in the treatment of joint contractures, suggesting a "programmatic need" for a better nonoperative alternative to surgery. Under the current HCPCS Level II code E1841 fee schedule, Ermi cannot provide this alternative device to individuals eligible for Medicare.

CMS Preliminary HCPCS Coding Determination

In the Second Biannual 2024 HCPCS Level II Coding Cycle (prior application HCP2407019NJ9Q), CMS concluded that the revised HCPCS Level II code E1841, "Static progressive stretch/patient actualized serial stretch shoulder device, with or without range of

motion adjustment, includes all components and accessories" describes the Shoulder Flexionater.

CMS notes that both static progressive stretch (SPS) and patient-actuated serial stretch (PASS) devices are designed to apply a series of stresses, whether at low or high loads, that are then released either gradually in the case of SPS or rapidly in the case of PASS. These devices function as stretching mechanisms with a shared therapeutic goal, which is to improve range of motion and reduce joint stiffness. Therefore, the existing HCPCS Level II code E1841, "Static progressive stretch/patient actuated serial stretch shoulder device, with or without range of motion adjustment, includes all components and accessories," appropriately describes the Shoulder Flexionater.

Although the applicant asserts that the Shoulder Flexionater is fundamentally different from other devices grouped under HCPCS Level II code E1841, primarily due to its stationary design, both stationary and portable devices, whether categorized as SPS or PASS, operate based on the same therapeutic principle: static progressive stretch delivered through patient-actuated mechanisms. Regardless of whether the device is powered hydraulically, as in the case of the Shoulder Flexionater, or through mechanical means such as a turnbuckle or worm gear, the clinical objective is to restore range of motion through serial stretching, which remains unchanged. Portability or power source alone does not constitute a meaningful functional distinction in this coding context. The Shoulder Flexionater is not functionally different from other PASS devices. It employs the same clinical principles, such as total end range time, serial stretching, and individual control, despite using a different mechanical delivery system.

CMS has received the supplementary documents submitted in response to its Request for Information. While we appreciate the additional materials, we do find that they provide sufficient justification to support a change in coding or to warrant reconsideration at this time. In summary, the study raises important points regarding treatment timing and the underutilization of stretch-assist devices. However, it does not offer direct clinical evidence demonstrating the efficacy or uniqueness of the Shoulder Flexionater. Additionally, the exclusion of the device central to the broader argument from the study data further limits the ability to support a claim for unique coding or clinical superiority under the HCPCS Level II code classification.

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

Preliminary Medicare Payment Determination

The Medicare payment rules and pricing associated with the existing HCPCS Level II code E1841 apply to this product, if covered. Payment for existing HCPCS Level II code E1841 is made on a capped rental basis. Therefore, the monthly capped rental fee schedule amount would be approximately $635.30 on average for months 1 through 3, and approximately $476.47 on average for months 4 through 13, resulting in a total capped payment of $6,670.60 should there be 13 months of continuous use. Fee schedules are updated annually.

The average fee schedule amount is the average of the 2025 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 36

Agenda Item # 15
GEORGE Feedback System Front-Wheel Walker - HCP250617V2AXF

Topic/Issue

Request to establish a new HCPCS Level II code to identify the GEORGE Feedback System Front-Wheeled Walker.

Applicant's suggested language: XXXXX, “Walker, folding, front-wheeled, adjustable or fixed height, with integrated feedback system to provide real-time visual and audible alerts when improper use is detected, including front wheel lift, rearward tipping, or unsafe weight distribution”

Summary of Applicant's Submission

MediTerry Inc. submitted a request to establish a new HCPCS Level II code to describe the GEORGE Feedback System Front-Wheeled Walker (FWW). The GEORGE Feedback System FWW is a class I device, exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The GEORGE Feedback System FWW is a front-wheeled walker with an integrated real-time feedback system designed to detect and alert individuals of unsafe walker usage. The GEORGE Feedback System FWW combines standard walker functionality with a built-in electronic module that detects when the front wheels lift off the ground, which is a key indicator of rearward tipping. This frequently occurs when individuals attempt to use the walker for leverage while rising from a seated position. Upon detection, the system emits real-time visual light-emitting diode and auditory speaker alerts to prompt the individual to reposition and reinforce safe techniques. The integrated feedback system is designed to reinforce proper usage as taught by therapists, especially in settings where supervision is limited. The function of the device is to serve as a real-time safety reminder that reinforces mobility training and encourages the individual to follow safe walker techniques independently. Existing HCPCS Level II codes such as E0143, “Walker, folding, wheeled, adjustable or fixed height” and E0144, “Walker, enclosed, four sided framed, rigid or folding, wheeled with posterior seat” describe the structural components of standard front-wheeled walkers but do not encompass any type of behavioral feedback, safety alerting mechanism, or intelligent misuse detection. The GEORGE device is indicated for individuals with impaired mobility, balance deficits, neurological or cognitive conditions (e.g., Parkinson’s disease, dementia, or stroke), musculoskeletal weakness, or post-operative rehabilitation needs. Its action is to provide passive, real-time behavioral cues when the walker is being used incorrectly, promoting safer use without caregiver intervention. It is packaged fully assembled with the integrated feedback system installed, a rechargeable battery, and printed instructions for use. The device is available in three sizes (pediatric, standard, and bariatric) and two colors (black and blue), with no disposable or single-use components.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II code E0143, “Walker, folding, wheeled, adjustable or fixed height” describes the GEORGE Feedback System Front-Wheeled Walker. Safety features on devices such as alarms, shut off valves, and other features, are not separately coded and are an integral part of the equipment.

Medicare Benefit Category Determination

Durable Medical Equipment.

Medicare Payment Determination

The Medicare payment rules and pricing associated with the existing HCPCS Level II code E0143 apply to this walker, if covered. The current average purchase 2025 fee schedule amount for HCPCS Level II code E0143 is $61.18 in non-rural areas and $101.37 in rural areas.

The average fee schedule amount is the average of the 2025 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 32

Agenda Item # 16
EZRIDE Wheelchair Power Assist Device - HCP250625DPWGB

Topic/Issue

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

The applicant did not submit any suggested language.

Summary of Applicant's Submission

Shield Innovation LLC submitted a request to revise the existing HCPCS Level II code E0986 to describe EZRIDE wheelchair power assist devices. EZRIDE wheelchair power assist devices are exempt from the premarket notification procedures by the Food and Drug Administration (FDA). They are indicated for individuals with upper limb fatigue, shoulder strain, or insufficient strength for self-propulsion. The EZRIDE wheelchair power assistance devices are used to assist individuals with upper body mobility impairments by transforming the most standard manual wheelchairs into powered, joystick-free mobility systems. The device mounts securely and tool-free via a patented front-locking mechanism and provides forward and reverse propulsion through a 350 W brushless motor, controlled via handlebar throttle rather than rim activation. The EZRIDE wheelchair power assist devices incorporate three selectable speed modes, incline climbing capability, and durable solid-state tire that is suitable for varied terrains. The devices are sold as a single packaged unit and requires no structural modifications to the base wheelchair. The devices measures 36″ × 11.5″ × 7″ when unfolded and fold to a compact size for transport.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II code E0986, “Manual wheelchair accessory, power assist system” describes the EZRIDE wheelchair power assist devices. EZRIDE wheelchair power assist device is similar in nature to other devices coded under the HCPCS Level II code E0986.

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

Preliminary Medicare Payment Determination

The Medicare payment rules and pricing associated with HCPCS Level II code E0986 apply to EZRIDE if covered.

The Medicare payment rules and pricing associated with the existing HCPCS Level II code E0986 apply to this product, if covered. Payment for existing HCPCS Level II code E0986 is made on a capped rental basis. Therefore, the monthly capped rental fee schedule amount would be approximately $682.21 on average for months 1 through 3, and approximately $511.66 on average for months 4 through 13, resulting in a total capped payment of $7,163.25 should there be 13 months of continuous use. Fee schedules are updated annually.

The average fee schedule amount is the average of the 2025 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 36

Agenda Item # 17
NEURO HiSWING R+ - HCP25070189RBA

Topic/Issue

Request to establish a new HCPCS Level II code to identify NEURO HiSWING R+.

Applicant's suggested language: LXXXX, “Addition to lower extremity orthosis, ankle system, microprocessor-controlled plantarflexion and dorsiflexion, dynamic stance control, power source included”

Summary of Applicant's Submission

FIOR & GENTZ submitted a request to establish a new HCPCS Level II code to identify NEURO HiSWING R+. NEURO HiSWING R+ is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The NEURO HiSWING R+ is a microprocessor-controlled multifunction ankle joint that allows an individual to align their center of mass over their base of support on slopes and stairs. This ankle joint device includes three different microprocessor-controlled modes that allow the individual to independently align both plantarflexion (PF) and dorsiflexion (DF) to permit safe and symmetrical walking on inclines and declines, independently align both PF and DF of the orthosis’ footplate to permit safe stair ascent and descent, and plantarflex the footplate to allow full foot contact with the ground when sitting. Although the spring resistance remains constant, adjusting the alignment of the orthosis modifies the effective lever arm at the ankle joint. The alignment of the orthosis alters when and how much external torque is generated during the gait cycle. These alignment changes are critical for adapting to terrain, such as slopes and stairs, where the timing of torque must shift to support safe and efficient movement. As a result, the individual will maintain appropriate PF/DF resistance on slopes and stairs and no longer feel excess flexion/extension forces on the knee. The NEURO HiSWING R+ functions differently and offers a significant therapeutic distinction from other orthotic ankle joints because the electronic system ankle joint allows an individual to use a microprocessor that optimizes PF and DF to the underlying grade/slope.

CMS Preliminary HCPCS Coding Determination

Establish a new HCPCS Level II code LXXXX, “Addition to lower extremity orthosis, ankle system, microprocessor-controlled feature plantarflexion and/or dorsiflexion, includes power source” to describe the NEURO HiSWING R+.

Preliminary Medicare Benefit Category Determination

Orthotic (Leg Brace).

Preliminary Medicare Payment Determination

In accordance with Medicare regulations at 42 Code of Federal Regulations (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 comparable items when items with existing fee schedule amounts are determined to be comparable to the new items and services.

To evaluate whether the devices described by this ankle orthotic code are comparable to items with existing codes and fee schedule amounts, we examined their physical, mechanical, and electrical components, along with their function and intended use. We determined that the overall form and function of the ankle system was comparable to the ankle HCPCS Level II code L2220 (“Addition to lower extremity, dorsiflexion and plantar flexion assist/resist, each joint”) and the microprocessor-control feature of the orthotic HCPCS Level II code L2006 (“Knee ankle foot device, any material, single or double upright, swing and stance phase microprocessor control with adjustability, includes all components (e.g., sensors, batteries, charger), any type activation, with or without ankle joint(s), custom fabricated”).

While the microprocessor control feature in the orthotic HCPCS Level II code L2006 controls the hydraulic damper to adjust knee resistance, the relative increase in cost for items represented by HCPCS Level II code L2006 over the cost of items represented by the average of HCPCS Level II codes L2036 (“Knee ankle foot orthosis, full plastic, double upright, with or without free motion knee, with or without free motion ankle, custom fabricated”) and L2038 (“Knee ankle foot orthosis, full plastic, with or without free motion knee, multi-axis ankle, custom fabricated”) provides an appropriate approximation of the value this microprocessor control feature adds to the ankle orthosis. Therefore, the fee schedule amounts for HCPCS Level II code LXXXX would be set by multiplying the average ratio of the 2025 fee schedule amounts for HCPCS Level II codes L2006, L2036 and L2038 (L2006/average of the L2036 and L2038 fees) minus one by the average of the fee schedule amounts for HCPCS Level II code L2220.

Based on this formula, the average of the 2025 fee schedule amounts for HCPCS Level II code LXXXX would be approximately $1,852.87.

The average fee schedule amount is the average of the 2025 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 38

Agenda Item # 18
Multi-Function Ankle Joint Components - HCP2507010PRED

Topic/Issue

Request to establish a new HCPCS Level II code to identify multi-function ankle joint components.

Applicant's suggested language: LXXXX, “Addition to lower extremity orthosis, multi-function ankle component, with independently adjustable ankle angle, dorsiflexion resistance and plantarflexion resistance, dynamic stance control, alignable system, energy storage and return, each joint”

Summary of Applicant's Submission

Hanger Clinic Healthcare Organization submitted a request to establish a new HCPCS Level II code to identify multi-function ankle joint components. These multi-function ankle control joints (MFAs) are exempt from the premarket notification procedures by the Food and Drug Administration (FDA). MFAs are used in lower limb orthoses. These components differ from existing ankle joints in both mechanical operation, and clinical application and function. Current orthotic ankle joint codes do not describe the functions and features of the Becker Orthopedic Triple Action Joints, FIOR & GENTZ’s Neuro Swing 2 and Neuro Swing Carbon Joints, and Ottobock’s Nexgear Tango Joints. MFA joint systems provide, independent adjustability of both dorsiflexion (DF) resistance and plantarflexion (PF) resistance, high-resistance pre-loadable spring systems, capable of resisting forward tibial advancement, energy storage and return-mimicking prosthetic foot biomechanics, and passive resistive ankle-foot orthoses which by virtue of their design are not adjustable, and independently adjustable ankle alignment, allowing the lower limb orthosis adjustment to the individual’s center of mass aligned over the base of support mimicking the alignable system feature in prosthetics. These systems offer significant biomechanical advantages over existing orthotic ankle joint technologies. Traditional ankle joints described by HCPCS Level II code L2220 offer mechanically inter-dependent control where adjustments to one function inherently alter others. For example, increasing DF resistance to aid swing phase clearance may decrease knee stability in early stance. Similarly, attempts to manage PF weakness often disrupt smooth tibial progression through mid-stance phase. This inter-dependence limits effective management of complex, multi-phase gait abnormalities, common among individuals using lower limb orthoses. MFAs solve these problems by de-coupling mechanical functions. Adjusting DF resistance does not affect PF resistance, alignment, or erythrocyte sedimentation rate. This allows clinicians to target specific gait deficits across discrete gait phases without compromise. For instance, optimizing early stance knee control does not interfere with mid-stance tibial progression or terminal stance push-off. HCPCS Level II code L2220 fails to describe independent multi-axis adjustability, energy return, or high-torque dynamic resistance.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II code L2220, “Addition to lower extremity, dorsiflexion and plantar flexion assist/resist, each joint” describes the multi-function ankle joint components.

CMS has reviewed multi-function ankle joint components, such as the Becker Orthopedic Triple Action Joints, FIOR & GENTZ's Neuro Swing 2 and Neuro Swing Carbon Joints, and Ottobock's Nexgear Tango Joints, and agrees that these systems feature a second mechanical axis, which allows for independent adjustment of DF and PF resistance and facilitates control of forward tibial progression. The applicant contends that this dual-axis design improves alignment control and allows separate adjustment of the shank angle, claiming enhanced functionality compared to traditional single-axis joints. However, CMS finds that the functional goals cited such as adjustment of DF/PF resistance and alignment can also be achieved by double-action joints currently coded under HCPCS Level II code L2220 through existing methods, including modifying spring or stop type, altering joint positioning during fabrication, or remolding the orthosis. CMS recognizes that the dual-axis design of MFA joints does allow for more refined adjustments. The use of springs, pins, and other resistance mechanisms remains consistent with current technology described under HCPCS Level II code L2220. Therefore, although MFA components may offer improved ease of use or tuning, they do not deliver distinct clinical outcomes that would justify the establishment of a new HCPCS Level II code. As such, CMS maintains the current classification under HCPCS Level II code L2220, consistent with the second biannual HCPCS Level II coding cycle determination.

Preliminary Medicare Benefit Category Determination

Orthotic (Leg Brace).

Preliminary Medicare Payment Determination

The Medicare payment rules and pricing associated with the existing HCPCS Level II code L2220 apply to the multi-function ankle control joints, if covered. The average 2025 fee schedule amount for HCPCS Level II code L2220 is $104.81.

The average fee schedule amount is the average of the 2025 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 38

Agenda Item # 19
Carbonhand® - HCP250627GH4P4

Topic/Issue

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

Applicant's suggested language: XXXXX, “Powered, cable driven grip assist orthosis, hand, finger, includes microprocessor, pressure sensors, all components and accessories, custom fitted”

Summary of Applicant's Submission

Bioservo AB submitted a request to establish a new HCPCS Level II code to describe Carbonhand®. Carbonhand® is a class I device, exempt from the premarket notification procedures by the Food and Drug Administration (FDA). Carbonhand® is a powered, microprocessor controlled, cable driven hand, finger orthosis that supports individuals with weakened grip and impaired hand strength due to medical conditions such as traumatic brain injury, spinal cord injury, stroke, multiple sclerosis, amyotrophic lateral sclerosis, rheumatic disease, myositis, orthopedic trauma, sarcopenia, and others. Carbonhand® is a multi-component device comprised of: (1) a glove made of flexible and non-flexible areas, including embedded pressure sensors and cables that act as artificial tendons running from the fingertips of the glove to the cuff then through steel Bowden cables to the connector plate that attaches to the power unit, creating an exoskeleton; (2) a power unit that connects to the glove and contains the battery, microprocessor that captures information from the pressure sensors, motors, and the linear actuator that contracts and releases the cable tendons; (3) supplies including arm straps to keep the glove cord attached to the arm, hip and shoulder strap accessories for the power unit, a charger for the power unit, and a padded washing bag to clean the glove and arm straps; and (4) a mobile application to program maximum force, stickiness, responsiveness, sensitivity, and linking for the sensors, and to assist with custom fitting the brace to the individual’s hand anatomy (e.g., finger length and preventing overextension). In its functional state, Carbonhand® is rigid and restricts motion of and provides support to the individual’s weakened hand to facilitate the performance of activities of daily living. For example, if trying to hold a glass of water without Carbonhand®, an individual with reduced grip strength and/or impaired hand function due to an injury or disease, as listed above, would not be able to grip the glass at all. When Carbonhand® is activated, either by the pressure sensors embedded in the glove or through the lock assist function, the motor in the power unit contracts the cables in the glove to support and lock the individual’s finger and hand in position around the glass until the individual is ready to release. In its functional state, the technology uses a multi-point pressure system mapped in the glove.

CMS Preliminary HCPCS Coding Determination

Establish a new HCPCS Level II code LXXXX, “Powered, cable driven grip assist glove, hand, finger, includes microprocessor, pressure sensors, all components and accessories, custom fitted” to describe the Carbonhand®.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS Benefit Category.

Federal regulations at 42 Code of Federal Regulations (CFR) § 410.2 include the definition of a brace for Medicare program purposes. A brace is defined as a rigid or semi-rigid device used for the purpose of supporting a weak or deformed body member or restricting or elimination motion in a diseased or injured part of the body. As explained in the preamble of the final rule that established this definition, the words "rigid" and "semi-rigid" are used to describe the stiffness of the material used to make the device. A brace must be rigid or semi-rigid to properly function (88 FR 77837).

The Carbonhand® is constructed from elastic material and therefore does not meet the Medicare definition of a brace.

Also, 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. Carbonhand® does not meet at least two of these conditions as follows:

> **Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years** - CMS sent a request for supporting documentation relating to the durability of Carbonhand® under expected usage conditions. The study provided by the applicant defines the "complete system" as including gloves (with tendons and textiles), connector carts, electronics, plastics, motors, actuators, and actuator carts, and it repeatedly emphasizes testing these components together for durability and interaction. Laboratory results showed that using Vapor glove carts and TecaPET TF Grey actuator carts significantly improved tendon and actuator durability, suggesting that gloves are essential system components. However, the study lacks long-term environmental and real-world wear testing, leaving uncertainty about whether the device can meet the 3-year DME life expectancy standard. Additionally, based on the information provided in the manual, the Carbonhand® glove has been tested for ADL-simulated usage and is expected to have a lifetime of only two years. Considering that the device consists of both the glove and the microprocessor unit, the Carbonhand® system does not meet the required 3-year life expectancy requirement.
>
> **Is appropriate for use in the home** - The applicant has stated that DME suppliers do not possess the technical expertise needed to customize and adjust the device for individual patients. Instead, it must be supplied and fitted by a certified provider (CPO/O&P supplier, physician, PT, or OT). The CPO ensures the patient is an

appropriate candidate based on their medical condition and customizes the device in several ways, including:

1. Adjusting the default length of cables to match the patient's anatomy, including for conditions requiring protection against overextension.
2. Setting the maximum force, stickiness, sensitivity, and responsiveness of the glove, and establishing individualized profiles based on the patient's physical functioning and daily activities.
3. Determining whether a patient's condition requires linking the sensors to different glove cables.
4. Creating custom molds and fittings for patients with partial digit amputations or other conditions.

The CPO also trains the patient on how to use Carbonhand®.

These CPO-specialized services go beyond those typically associated with the supply or rental of durable medical equipment and further raise questions about the device's ability to withstand repeated use. Therefore, the Carbonhand® does not meet the requirements for classification as a DME item.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Agenda Item # 19
Carbonhand® Replacement Glove - HCP2506275K9GY

Topic/Issue

Request to establish a new HCPCS Level II code to identify the Carbonhand® replacement glove.

Applicant's suggested language: XXXXX, "Powered, cable driven grip assist orthosis, hand, finger, includes pressure sensors, glove replacement only"

Summary of Applicant's Submission

Bioservo AB submitted a request to establish a new HCPCS Level II code to describe a Carbonhand® replacement glove. Carbonhand® is a class I device, exempt from the premarket notification procedures by the Food and Drug Administration (FDA). Carbonhand® is a powered, microprocessor controlled, cable driven hand finger orthosis that supports individuals with weakened grip and impaired hand strength due to medical conditions such as traumatic brain injury, spinal cord injury, stroke, multiple sclerosis, amyotrophic lateral sclerosis, rheumatic disease, myositis, orthopedic trauma, sarcopenia, and others. In its functional state, Carbonhand® is rigid and restricts motion of and provides support to the individual's weakened hand to facilitate the performance of activities of daily living. Carbonhand® is a multi-component device comprised of: (1) a glove made of flexible and non-flexible areas, including embedded pressure sensors and cables that act as artificial tendons running from the fingertips of the glove to the cuff then through steel Bowden cables to the connector plate that attaches to the power unit, creating an exoskeleton; (2) a power unit that connects to the glove and contains the battery, microprocessor that captures information from the pressure sensors, motors, and the linear actuator that contracts and releases the cable tendons; (3) supplies including arm straps to keep the glove cord attached to the arm, hip and shoulder strap accessories for the power unit, a charger for the power unit, and a padded washing bag to clean the glove and arm straps; and (4) a mobile application to program maximum force, stickiness, responsiveness, sensitivity, and linking for the sensors, and to assist with custom fitting the brace to the individual's hand anatomy (e.g., finger length and preventing overextension). The Carbonhand® glove has an expected life of two years and a six-month warranty. It is expected to be supplied to the individual every other year.

CMS Preliminary HCPCS Coding Determination

Establish a new HCPCS Level II code LXXXX, "Powered, cable-driven grip assist glove, hand, finger, includes pressure sensors, glove replacement only" to describe the Carbonhand® replacement glove.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS Benefit Category.

Federal regulations at 42 Code of Federal Regulations (CFR) § 410.2 include the definition of brace for Medicare program purposes. Brace is defined as a rigid or semi-rigid device used for the purpose of supporting a weak or deformed body member or restricting or elimination

motion in a diseased or injured part of the body. As explained in the preamble of the final rule that established this definition, the words rigid and semi-rigid are used to describe the stiffness of the material used to make the device. A brace must be rigid or semi-rigid to properly function (88 FR 77837).

The Carbonhand® is constructed from elastic material and therefore does not meet the Medicare definition of a brace.

Also, 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. Carbonhand® does not meet at least two of these conditions as follows:

> **Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years** - CMS sent a request for supporting documentation relating to the durability of Carbonhand® under expected usage conditions. The study provided by the applicant defines the "complete system" as including gloves (with tendons and textiles), connector carts, electronics, plastics, motors, actuators, and actuator carts, and it repeatedly emphasizes testing these components together for durability and interaction. Laboratory results showed that using Vapor glove carts and TecaPET TF Grey actuator carts significantly improved tendon and actuator durability, suggesting that gloves are essential system components. However, the study lacks long-term environmental and real-world wear testing, leaving uncertainty about whether the device can meet the 3-year DME life expectancy standard. Additionally, based on the information provided in the manual, the Carbonhand® glove has been tested for ADL-simulated usage and is expected to have a lifetime of only two years. Considering that the device consists of both the glove and the microprocessor unit, the Carbonhand® system does not meet the required 3-year life expectancy requirement.
>
> **Is appropriate for use in the home** - The applicant has stated that DME suppliers do not possess the technical expertise needed to customize and adjust the device for individual patients. Instead, it must be supplied and fitted by a certified provider (CPO/O&P supplier, physician, PT, or OT). The CPO ensures the patient is an appropriate candidate based on their medical condition and customizes the device in several ways, including:
>
> 1. Adjusting the default length of cables to match the patient's anatomy, including for conditions requiring protection against overextension.

2. Setting the maximum force, stickiness, sensitivity, and responsiveness of the glove, and establishing individualized profiles based on the patient's physical functioning and daily activities.
3. Determining whether a patient's condition requires linking the sensors to different glove cables.
4. Creating custom molds and fittings for patients with partial digit amputations or other conditions.

The CPO also trains the patient on how to use Carbonhand®.

These CPO-specialized services go beyond those typically associated with the supply or rental of durable medical equipment and further raise questions about the device's ability to withstand repeated use. Therefore, the Carbonhand® does not meet the requirements for classification as a DME item.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Agenda Item # 20
restiffic® - HCP250624MLGY3

Topic/Issue

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

Applicant's suggested language: LXXXX, “A semi rigid foot brace for the treatment of Restless Leg Syndrome”

Summary of Applicant's Submission

medi USA, LP submitted a request to establish a new HCPCS Level II code to identify restiffic®. restiffic® received De Novo classification by the Food and Drug Administration (FDA) on December 18, 2013. restiffic® is a non-powered lower extremity pressure device. restiffic® is indicated for use by individuals with moderate to severe symptoms associated with primary restless legs syndrome (RLS), also known as Willis-Ekbom disease. restiffic® works to support the targeted areas of the abductor hallucis and flexor hallucis brevis muscles and impede and reduce the urge to move the legs. This targeted therapy uses a specially shaped pad with precise durometer specifications to help individuals' legs relax, allowing them to rest and sleep better. Due to the anatomical shape of the foot and positioning of the muscles, restiffic® is specific to either the right or left foot. An application for code verification for restiffic® was submitted to the Medicare Contractor for Pricing, Data Analysis and Coding (PDAC) in 2014 and the restiffic® device was placed within HCPCS Level II code A4465, “Non-elastic binder for extremity.” medi USA disagrees with this determination because the restiffic® device is a semi-rigid brace that acts as an orthosis, supporting and altering the behavior of specific muscles in the foot to enable the body’s management of RLS symptoms without ambulating. Other products that are classified within HCPCS Level II code A4465 are compression style items with no targeted muscle groups or specific diagnoses. These are compressive or compression devices that do not discern between areas compressed or not compressed. Many feature graduated or similar compression not unlike the wound care surgical dressings or the newly created codes under the lymphedema category. restiffic® is distinct because it is targeted therapy, prescription only and specific to RLS treatment. There are two other devices cleared for the treatment of RLS: one is a vibrating pad, and the other is a stimulation device. Both require a power source which is not needed with the restiffic® device.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II code A4465, “Non-elastic binder for extremity” describes the restiffic® device.

restiffic® is a wrap that consists of high-density foam and a D-ring that allows customization of compression and is not semi-rigid; thus, it is similar to other devices in existing HCPCS Level II code A4465.

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS Benefit Category.

The applicant stated that in 2014, the restiffic® device was assigned HCPCS Level II code A4465 as a non-elastic binder for the extremity under the surgical dressing benefit category. However, the applicant disagrees with this code and requests that this item fall within the orthotic benefit category. CMS agrees that this item is not a surgical dressing, since section 100, chapter 15 of the Medicare Benefit Policy Manual (Pub. 100-2) states that surgical dressings are limited to primary and secondary dressings required for the treatment of a wound caused by, or treated by, a surgical procedure that has been performed by a physician or other health care professional. The restiffic® device's purpose is to treat RLS and not to serve as a primary or secondary dressing for wound care purposes. Therefore, it does not fall within the surgical dressing 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 restiffic® does not meet one of these conditions as follows:

> **Can withstand repeated use** – Since the application states that the restiffic® device is a single-patient use item, it cannot be rented, refurbished, and used by successive patients. Therefore, it cannot withstand repeated use.

The restiffic® device does not meet the definition of a brace found in chapter 15, section 130 of the Medicare Benefit Policy Manual (Pub. 100-2). The brace benefit is limited to devices that are sufficiently rigid or semi-rigid to provide support or restrict or eliminate motion in a diseased or injured body part. Although the applicant described the restiffic® device as a semi-rigid brace, we determined that the high-density foam pad and D-ring fastener components of the device are not sufficiently rigid or semi-rigid. High-density foam can offer support, but it is still compressible and not comparable to rigid materials like metal or hard plastic. The restiffic® functions by interfering with pain signals rather than by providing mechanical support or control. However, there is no evidence that it supports a weak body part or restricts movement.

The restiffic® device also does not meet the definition of a prosthetic device. Section 1861(s)(8) of the Social Security Act and chapter 15, section 120 of the Medicare Benefit Policy Manual (Pub. 100-2) define a prosthetic device as an item that replaces all or part of an internal body organ or replaces all or part of the function of a permanently inoperative or malfunctioning internal body organ. The restiffic® device treats the symptoms of restless leg syndrome by applying adjustable, targeted pressure on the abductor hallucis and flexor hallucis brevis muscles in the feet. Acting as a counter stimulant, the continued pressure on these muscles signals the brain to relax them than to contract them. The restiffic® device does not replace all or part of an internal body organ (abductor hallucis and flexor hallucis

brevis muscles) or all or part of the function of one. Therefore, it does not fall within the prosthetic device benefit category.

Preliminary Medicare Payment Determination

Items or services described by HCPCS Level II code A4465 are not covered under Medicare Part B.

No Medicare payment. Pricing Indicator = 00

Agenda Item # 21
Navina™ Smart System - HCP250627N4DGY

Topic/Issue

Request to establish a new HCPCS Level II code to identify Navina™ Smart System.

Applicant's suggested language: XXXXX, "Electronic Transanal Irrigation System, includes electronic pump, water reservoir, tube set (initial and three (3) replacement tube sets), and accessories, without catheter, any type"

Summary of Applicant's Submission

Wellspect Inc. submitted a request to establish a new HCPCS Level II code to identify Navina™ Smart System. Navina™ Smart System is exempt from the premarket notification by the Food and Drug Administration (FDA). Navina™ Smart System includes an electronic control unit, a power adapter, a cable, Navina tube set, three sets of Navina replacement tube sets, Navina™ water container, Navina™ case, Navina™ positioning strap, Navina™ Smart control unit positioning clip, Navina™ grip rings, and Navina™ lanyard. Navina™ Smart System can be used with either balloon catheters or cone catheters. The Navina™ Smart control unit contains connection points for the water container, the rectal catheter. The control unit has six interactive buttons that include a power button and buttons that allow the individual to adjust the amount and flow rate of water instilled, and the amount of air used to inflate and deflate the balloon catheter. The electronic transanal irrigation (TAI) device does not require significant hand strength and coordination. Electronic TAI has an electronic pump and push-button interface, allowing individuals with reduced dexterity to more easily use TAI independently. Electronic TAI devices have built-in safety mechanisms that ensure optimal and safe irrigation during every use, including controls for balloon size, water volume, and flow rate. The device settings can be locked in place, providing an additional layer of safety. The standard clinical practice guidelines indicate that TAI with rectal balloon catheters, including electronic TAI devices, is a recognized standard treatment for individuals with neurogenic bowel dysfunction/non-neurogenic bowel dysfunction, or congenital disorder (e.g., anorectal malformation and Hirschsprung's disease), or injury/disease/syndrome that render anal sphincter(s) impaired or dysfunctional.

CMS Preliminary HCPCS Coding Determination

Establish a new HCPCS Level II code AXXXX, "Electronic transanal irrigation system, includes electronic pump, water reservoir, tubing, and accessories, without catheter, any type" to describe Navina™ Smart System.

Preliminary Medicare Benefit Category Determination

Prosthetic Device.

CMS determined that TAI systems with rectal catheters described by HCPCS Level II code A4459, "Manual transanal irrigation system, includes water reservoir, pump, tubing, and accessories, without catheter, any type," are prosthetic devices, effective April 1, 2025. The Navina™ Smart System benefit category determination is closely related to the manual TAI system determination under HCPCS Level II code A4459, as both share the same

intended use and similar indications for use. The primary difference between these TAI systems lies in their control mechanism: the Navina™ Smart System utilizes an electro-mechanical design dependent on an energy source, while the manual TAI system operates through manual power.

The same benefit category determination established for the manual TAI systems with balloon or cone-based rectal catheters under HCPCS Level II code A4459 during the Second Biannual 2024 HCPCS Level II coding cycle applies to the electronically controlled Navina™ Smart System.

Preliminary Medicare Payment Determination

In accordance with regulations at 42 Code of Federal Regulations (CFR) § 414.238(b), fee schedule amounts for items and services described by new HCPCS Level II codes are established using existing fee schedule amounts for comparable items when items with existing fee schedule amounts are determined to be comparable to the new items and services. Using fee schedule amounts for comparable items to establish fee schedule amounts for new items can involve a number of pricing combinations including, but not limited to: (1) a one to one mapping where the fees for one code are used to establish the fees for a new code, (2) the use of fees for a combination of codes with established fee schedule amounts; (3) the use of fees for one or more codes minus the fees for one or more other codes identifying a missing feature(s) the newer item does not include; or (4) the use of one or more codes plus additional amounts for the costs of an additional feature(s) the newer items has that the older item(s) does not include (84 FR 60733).

The Navina™ Smart System is closely related to the manual TAI system under HCPCS Level II code A4459 but utilizes an electrically controlled pump rather than a manual operated pump. Therefore, the cost of an electrically controlled pump needs to be added to the manual TAI system fee (HCPCS Level II code A4459) to achieve pricing using a combination of comparable items as described under (4) above. The electronic control characteristics of certain types of electric pumps assigned to HCPCS Level II code E0182 used to inflate and control an alternating pressure pad would be comparable to the electrically controlled pumps used in an electric TAI system. Specifically, those pump products assigned under HCPCS Level II code E0182 with adjustable pressure settings that also regulate the flow of air pressure to the different mattress pad cells (see chart below).

	Navina Smart TAI electronic pump	**Electronic pumps with adjustable pressure settings for alternating pressure pads**
Physical Components	• Electric water pump • Control unit (digital)	• Electric air pump • Control unit (digital or manual)
Mechanical Components	• Electric motor driven • Valves controlling water flow • Pressure regulation system	• Electric motor driven • Valves controlling air flow • Pressure cycling mechanism
Electrical Components	• Battery • Pressure sensors and feedback mechanism	• Power cord/battery • Pressure sensors

Function and Intended Use	• To treat Neurogenic bowel dysfunction and fecal incontinence management • For individuals with neurogenic bowel dysfunction, chronic constipation, or fecal incontinence	• To treat wounds and prevent pressure ulcers • For individuals with limited mobility or at risk of pressure ulcers
Additional Aspects and Features	• Reusable pump • Automated pumps • Home-based care • Functional Similarities: similar electronic motor systems and valve mechanisms	• Reusable pump • Automated pumps • Home-based care • Functional Similarities: similar electronic motor systems and valve mechanisms

The median internet retail price for replacement pumps (HCPCS Level II code E0182) served as the basis for establishing the cost of the electronically controlled pump. However, since the Navina™ Smart System has a two-year lifetime compared to the five- year lifetime of HCPCS Level II code E0182 pumps, the median internet retail price for the replacement pumps was reduced to 40 percent to account for this shorter duration. This 40 percent factor was then increased to 80 percent to recognize the electronic control capabilities of the two pumps present in the Navina ™ Smart System control unit. When 80 percent is applied to the median internet retail price of $80.87 for replacement HCPCS Level II code E0182 pumps, the resulting amount for the electronic control characteristics is $64.70.

Due to the difference in lifetime between manual TAI systems described by HCPCS Level II code A4459 and electronic transanal irrigation systems described by HCPCS Level II code AXXXX, an adjustment to the comparable HCPCS Level II code A4459 fees is necessary. The electronic Navina™ Smart System has a lifetime of 400 uses, while the manual Navina™ Classic System under HCPCS Level II code A4459 has a lifetime of 100 uses. This four-fold difference in lifetime (400/100) indicates that the relative value of the electronic system is approximately four times the cost of the manual system described under HCPCS Level II code A4459. Based on this lifetime differential, the average 2025 Medicare fee schedule amount of $157.27 for HCPCS Level II code A4459 multiplied by four yields a 2025 fee of $629.08 for the electronic system.

The preliminary payment determination for the electric TAI system uses the adjusted relative value fee schedule amounts for HCPCS Level II code A4459 ($629.08) and adds the cost of the electric control using the median internet retail price of $64.70 for electric pumps with adjustable pressure settings used to inflate and control an alternating pressure pad for a 2025 fee schedule amount of $693.78 for the electric TAI system (HCPCS Level II code AXXXX).

Pricing Indicator = 38

Agenda Item # 22
Replacement Prosthetic Foot Shell - HCP250701TPBJT

Topic/Issue

Request to establish a new HCPCS Level II code to identify a replacement prosthetic foot shell.

Applicant's suggested language: LXXXX, “All lower extremity prosthesis, foot shell for modular foot/non-SACH, replacement only”

Summary of Applicant's Submission

The American Orthotic & Prosthetic Association Coding and Reimbursement Committee submitted a request to establish a new HCPCS Level II code to identify a replacement prosthetic foot shell. Prosthetic foot shells are exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The foot shell acts as an external protective covering for the internal keel structure of a prosthetic foot and is frequently replaced due to wear and damage over the lifespan of the prosthesis. Replacement is necessary to prevent premature wear and breakdown of the internal mechanical foot structure. The foot shell also serves as an interface to keep the foot stable within standard shoes. In many ways, the foot shell may be viewed as a consumable but necessary component of the prosthetic system. This item should be billed only when provided independently (e.g., as a replacement for a previously delivered foot shell) and should not be billed in conjunction with a prosthetic foot. When a prosthetic foot is delivered with a foot shell, the shell is considered included in the reimbursement for the foot itself and is not separately billable. This is consistent with the longstanding Medicare bundling policy regarding componentry provided as part of a new prosthesis.

CMS Preliminary HCPCS Coding Determination

Establish a new HCPCS Level II code LXXXX, “All lower extremity prosthesis, foot shell for modular foot/non-solid ankle cushion heel (sach) replacement only” to describe replacement foot shells.

Preliminary Medicare Benefit Category Determination

Prosthetic (Artificial Leg).

Preliminary Medicare Payment Determination

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

factors are applied against current pricing in order to approximate the base period price. The annual deflation factors are specified in the Medicare Claims Processing Manual, chapter 23, section 60.3 (Pub. 100-4) and the deflated amounts are then increased by the update factors also listed in these program instructions.

To determine whether foot shells described under HCPCS Level II code LXXXX are comparable to items with existing codes, we carefully reviewed the existing HCPCS Level II codes as part of our payment review and did not find any codes that adequately compare to the foot shells. This item is not comparable to existing codes and for this reason we have determined that the gap-filling methodology is appropriate for establishing fees for this item.

To develop an appropriate Medicare payment amount in accordance with the gap filling procedure, we must identify appropriate commercial pricing for the items. We have found several internet prices for Ottobock and college park foot shells that would be classified under HCPCS Level II code LXXXX. In addition, we added a single unit of the average 2025 fee for HCPCS Level II code L7520 ("Repair prosthetic device, labor component, per 15 minutes") to the retail prices to recognize the labor associated with replacing the foot shell on the prosthetic foot. The median of these prices is $147.97.

After applying the annual deflation and update factors to the median price of $147.97, the 2025 purchase payment amount for HCPCS Level II code LXXXX would be approximately $96.32. Payment would be made on a purchase basis in accordance with section 1834(h)(1)(A) of the Social Security Act. Fee schedules are updated annually.

Pricing Indicator = 38

Agenda Item # 23
Overlay Transtibial and Overlay Transfermoral - HCP241231FYCJQ

Topic/Issue

Request to establish Medicare payment for Overlay Transtibial (TT) and Overlay Transfemoral (TF).

Summary of Applicant's Submission

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

CMS Final HCPCS Coding Determination

In the First Biannual 2025 HCPCS Level II coding cycle, CMS established new HCPCS Level II code L5657, "Addition to lower extremity prosthesis, manual/automated adjustable air, fluid, gel or equal socket insert for limb volume management, any materials" to describe Overlay Transtibial and Overlay Transfemoral, effective October 1, 2025.

Final Medicare Benefit Category Determination

In the First Biannual 2025 HCPCS Level II coding cycle, CMS determined Overlay Transtibial and Overlay Transfemoral are a Prosthetic (Artificial Leg).

Preliminary Medicare Payment Determination

Following our commitment from the First Biannual 2025 HCPCS Level II coding cycle to address this application at a future public meeting, we are now presenting the preliminary payment determination for HCPCS Level II code L5657.

Volume management systems such as the Overlay Transtibial™ and Overlay Transfemoral™ incorporate a pump to adjust for changes in volume and therefore act like an adjustable prosthetic sock. The number of prosthetic socks the overlay replaces varies as the individual's physical condition and other factors change. Therefore these items are not comparable to prosthetic socks since the number of prosthetic socks they replace varies on an ongoing basis during use of these items, allowing individuals to adjust for changes in volume without removing the prosthetic.

In accordance with regulations at 42 Code of Federal Regulations (CFR) § 414.238(c)(1), fee schedule amounts for items and services without a fee schedule pricing history described by new HCPCS Level II codes that are not comparable to items and services with existing fee schedule amounts may be established using supplier price lists, including catalogs and other retail price lists (such as internet retail prices) that provide information on commercial pricing for the item. The current internet retail price for the Overlay Transtibial™ and Overlay Transfemoral™ is $449.50, which includes a 50 percent discount using code Kerri50. After deflating this price to 1986/87 and updating the result by the annual fee schedule covered item updates mandated by section 1834(h)(4) of the Social Security Act, this results in a 2025 fee schedule amount of $300.31.

Pricing Indicator = 38

Agenda Item # 24
Point Digit and Point Digit Mini - HCP241231JNNFX

Topic/Issue

Request to establish Medicare payment for Point Digit and Point Digit Mini prosthetic terminal devices and their associated mounting brackets.

Summary of Applicant's Submission

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

CMS Final HCPCS Coding Determination

In the First Biannual 2025 HCPCS Level II coding cycle, CMS established HCPCS Level II code L6035, “Single prosthetic digit, mechanical, can include metacarpophalangeal (mcp), proximal interphalangeal (pip), and/or distal interphalangeal (dip) joint(s), with or without locking mechanism, can include flexion or extension assist, any material, attachment, initial issue or replacement” to describe Point Digit and Point Digit Mini, effective October 1, 2025.

Final Medicare Benefit Category Determination

In the First Biannual 2025 HCPCS Level II coding cycle, CMS determined Point Digit and Point Digit Mini are a Prosthetic (Artificial Arm).

Preliminary Medicare Payment Determination

Following our commitment from the First Biannual 2025 HCPCS Level II coding cycle to address this application at a future public meeting, we are now presenting the preliminary payment determination for HCPCS Level II code L6035.

In accordance with Medicare regulations at 42 Code of Federal Regulations (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 items represented by HCPCS Level II code L6035 are comparable to HCPCS Level II codes L6708 ("Terminal device, hand, mechanical, voluntary opening, any material, any size") and L6709 ("Terminal device, hand, mechanical, voluntary closing, any material, any size"). Specifically, since the items represented by HCPCS Level II code L6035 are single prosthetic digits while the devices represented by HCPCS Level II codes L6708 and L6709 are terminal devices for an entire prosthetic hand, HCPCS Level II code L6035 is comparable to one-fifth of HCPCS Level II codes L6708 or L6709. Therefore, the preliminary payment determination for L6035 is (1/5) times the average of HCPCS Level II codes L6708 and L6709.

Based on this formula, the average of the 2025 fee schedule amounts for HCPCS Level II code L6035 would be $280.35.

The average fee schedule amount is the average of the 2025 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 38

Agenda Item # 24
Point Pivot and Point Pivot+ - HCP2412317JPKJ

Topic/Issue

Request to establish Medicare payment for Point Pivot and Point Pivot+.

Summary of Applicant's Submission

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

CMS Final HCPCS Coding Determination

In the First Biannual 2025 HCPCS Level II coding cycle, CMS established HCPCS Level II code L6038, "Addition to single prosthetic digit or thumb, mechanical, attachment, multiaxial and/or internal/external rotation/abduction/adduction mechanism, with or without locking feature, any material" to describe Point Pivot and Point Pivot+, effective October 1, 2025.

Final Medicare Benefit Category Determination

In the First Biannual 2025 HCPCS Level II coding cycle, CMS determined Point Pivot and Point Pivot+ are a Prosthesis (Artificial Arm).

Preliminary Medicare Payment Determination

Following our commitment from the First Biannual 2025 HCPCS Level II coding cycle to address this application at a future public meeting, we are now presenting the preliminary payment determination for HCPCS Level II code L6038.

In accordance with Medicare regulations at 42 Code of Federal Regulations (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 multiaxial attachments represented by HCPCS Level II code L6038 are comparable to the multiaxial component of HCPCS Level II code L5978 ("All lower extremity prostheses, foot, multiaxial ankle/foot"). While HCPCS Level II code L5978 is for a lower-limb prosthesis and must be designed to bear a much higher weight, the relative increase in cost for items represented by HCPCS Level II code L5978 over the cost of items represented by HCPCS Level II code L5974 is an appropriate approximation of the value this multiaxial feature (including internal and external rotation, as well as abduction and adduction) adds to the prosthesis. Therefore, the fee schedule amounts for HCPCS Level II code L6038 would be set by multiplying the average ratio of the fee schedule amounts for HCPCS Level II codes L5978 and L5974 (L5978/L5974) minus one by the average of the fee schedule amounts for HCPCS Level II codes L6035 and L6036 (as proposed in applications HCP241231JNNFX, HCP241231KBG09, HCP241231VULPL, and HCP241231UNXL1).

Based on this formula, the average of the 2025 fee schedule amounts for HCPCS Level II code L6036 would be $64.22.

The average fee schedule amount is the average of the 2025 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 38

Agenda Item # 24
Point Partial - HCP241231VULPL

Topic/Issue

Request to establish Medicare payment for Point Partial prosthetic terminal devices and their associated mounting brackets.

Summary of Applicant's Submission

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

CMS Final HCPCS Coding Determination

In the First Biannual 2025 HCPCS Level II coding cycle, CMS established HCPCS Level II code L6035, "Single prosthetic digit, mechanical, can include metacarpophalangeal (mcp), proximal interphalangeal (pip), and/or distal interphalangeal (dip) joint(s), with or without locking mechanism, can include flexion or extension assist, any material, attachment, initial issue or replacement" to describe Point Partial, effective October 1, 2025.

Medicare Benefit Category Determination

In the First Biannual 2025 HCPCS Level II coding cycle, CMS determined Point Partial is a Prosthetic (Artificial Arm).

Preliminary Medicare Payment Determination

Following our commitment from the First Biannual 2025 HCPCS Level II coding cycle to address this application at a future public meeting, we are now presenting the preliminary payment determination for HCPCS Level II code L6035.

In accordance with Medicare regulations at 42 Code of Federal Regulations (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 items represented by HCPCS Level II code L6035 are comparable to HCPCS Level II codes L6708 (“Terminal device, hand, mechanical, voluntary opening, any material, any size”) and L6709 (“Terminal device, hand, mechanical, voluntary closing, any material, any size”). Specifically, since the items represented by HCPCS Level II code L6035 are single prosthetic digits while the devices represented by HCPCS Level II codes L6708 and L6709 are terminal devices for an entire prosthetic hand, HCPCS Level II code L6035 is comparable to one-fifth of HCPCS Level II codes L6708 or L6709. Therefore, the preliminary payment determination for HCPCS Level II code L6035 is (1/5) times the average of HCPCS Level II codes L6708 and L6709.

Based on this formula, the average of the 2025 fee schedule amounts for HCPCS Level II code L6035 would be $280.35.

The average fee schedule amount is the average of the 2025 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 38

Agenda Item # 24
Point Thumb - HCP241231UNXL1

Topic/Issue

Request to establish Medicare payment for Point Thumb prosthetic terminal devices and their associated mounting brackets.

Summary of Applicant's Submission

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

CMS Final HCPCS Coding Determination

In the First Biannual 2025 HCPCS Level II coding cycle, CMS established HCPCS Level II code L6036, "Prosthetic thumb, mechanical, can include metacarpophalangeal (mcp), and interphalangeal (ip), joint(s), with or without locking mechanism, can include flexion or extension assist, any material, attachment, initial issue or replacement" to describe Point Thumb, effective October 1, 2025.

Final Medicare Benefit Category Determination

In the First Biannual 2025 HCPCS Level II coding cycle, CMS determined Point Thumb is a Prosthetic (Artificial Arm).

Preliminary Medicare Payment Determination

Following our commitment from the First Biannual 2025 HCPCS Level II coding cycle to address this application at a future public meeting, we are now presenting the preliminary payment determination for HCPCS Level II code L6036.

In accordance with Medicare regulations at 42 Code of Federal Regulations (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 items represented by HCPCS Level II code L6036 are comparable to HCPCS Level II codes L6708 (“Terminal device, hand, mechanical, voluntary opening, any material, any size”) and L6709 (“Terminal device, hand, mechanical, voluntary closing, any material, any size”). Specifically, since the items represented by HCPCS Level II code L6036 are for a single prosthetic thumb while the devices represented by HCPCS Level II codes L6708 and L6709 are terminal devices for an entire prosthetic hand, HCPCS Level II code L6036 is comparable to one-fifth of HCPCS Level II codes L6708 or L6709. Therefore, the preliminary payment determination for HCPCS Level II code L6036 is to establish the fee schedule amounts using (1/5) times the average of the fee schedule amounts for HCPCS Level II codes L6708 and L6709.

Based on this formula, the average of the 2025 fee schedule amounts for HCPCS Level II code L6036 would be $280.35.

The average fee schedule amount is the average of the 2025 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 38

Agenda Item # 24
Point Endo - HCP241231KBG09

Topic/Issue

Request to establish Medicare payment for Point Endo prosthetic terminal devices and their associated mounting brackets.

Summary of Applicant's Submission

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

CMS Final HCPCS Coding Determination

In the First Biannual 2025 HCPCS Level II coding cycle, CMS established HCPCS Level II code L6035, "Single prosthetic digit, mechanical, can include metacarpophalangeal (mcp), proximal interphalangeal (pip), and/or distal interphalangeal (dip) joint(s), with or without locking mechanism, can include flexion or extension assist, any material, attachment, initial issue or replacement" to describe Point Endo, effective October 1, 2025.

Final Medicare Benefit Category Determination

In the First Biannual 2025 HCPCS Level II coding cycle, CMS determined Point Endo is a Prosthetic (Artificial Arm).

Preliminary Medicare Payment Determination

Following our commitment from the First Biannual 2025 HCPCS Level II coding cycle to address this application at a future public meeting, we are now presenting the preliminary payment determination for HCPCS Level II code L6035.

In accordance with Medicare regulations at 42 Code of Federal Regulations (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 items represented by HCPCS Level II code L6035 are comparable to HCPCS Level II codes L6708 ("Terminal device, hand, mechanical, voluntary opening, any material, any size") and L6709 ("Terminal device, hand, mechanical, voluntary closing, any material, any size"). Specifically, since the items represented by HCPCS Level II code L6035 are single prosthetic digits while the devices represented by HCPCS Level II codes L6708 and L6709 are terminal devices for an entire prosthetic hand, HCPCS Level II code L6035 is comparable to one-fifth of HCPCS Level II codes L6708 or L6709. Therefore, the preliminary payment determination for HCPCS Level II code L6035 is (1/5) times the average of HCPCS Level II codes L6708 and L6709.

Based on this formula, the average of the 2025 fee schedule amounts for HCPCS Level II code L6035 would be $280.35.

The average fee schedule amount is the average of the 2025 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 38

Agenda Item # 25
Partial Hand and Finger Prostheses - HCP240701W4N75

Topic/Issue

Request to establish Medicare payment for partial hand and finger prostheses.

Summary of Applicant's Submission

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

CMS Final Coding Determination

In the Second Biannual 2024 HCPCS Level II coding cycle, CMS established and/or revised the following HCPCS Level II codes, effective April 1, 2025:

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

2. 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, including palm, for use without external power and or passive prosthetic digit/thumb, not including inserts described by l6692"

3. L6029, "Upper extremity addition, test socket/interface, partial hand including fingers"

4. L6030, "Upper extremity addition, external frame, partial hand including fingers"

5. L6031, “Replacement socket/interface, partial hand including fingers, molded to patient model, for use with or without external power”

6. L6032, “Addition to upper extremity prosthesis, partial hand including fingers, ultralight material (titanium, carbon fiber or equal)”

7. L6033, “Addition to upper extremity prosthesis, partial hand including fingers, acrylic material”

8. L6692, “Upper extremity addition, silicone gel insert or equal, with or without locking mechanism, each”

9. L6698, “Addition to upper extremity prosthesis, lock mechanism, excludes socket insert”

Final Medicare Benefit Category Determination

In the Second Biannual 2024 HCPCS Level II coding cycle, CMS determined devices falling under HCPCS Level II codes L6037, L6028 – L6033, L6692, and L6698 are a Prosthetic (Artificial Arm).

Preliminary Medicare Payment Determination

Following our commitment from the Second Biannual 2024 HCPCS Level II coding cycle to address this application at a future public meeting, we are now presenting the preliminary payment determinations for the following HCPCS Level II codes.

For HCPCS Level II code L6037:

In accordance with Medicare regulations at 42 Code of Federal Regulations (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.

Our review has determined that the items described by HCPCS Level II code L6037 are comparable to the items described by HCPCS Level II code L6380 (“Immediate post surgical or early fitting, application of initial rigid dressing, including fitting alignment and suspension of components, and one cast change, wrist disarticulation or below elbow”). Both codes describe items that serve equivalent functions: an immediate post-surgical or early fitting of an initial rigid dressing, including alignment and suspension of components. In addition to their equivalent function, we have concluded that the materials and labor for fabrication and fitting of the transradial/wrist disarticulation and partial hand prostheses are roughly equivalent. Therefore, the preliminary payment determination for HCPCS Level II code L6037 is to establish the fee schedule amounts using existing fee schedule amounts for comparable items described by HCPCS Level II code L6380.

The 2025 fee schedule amount for HCPCS Level II code L6037 would be approximately $1,552.05.

The average fee schedule amount is the average of the 2025 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 38

For HCPCS Level II code L6028:

HCPCS Level II code L6028 is replacing existing HCPCS Level II codes L6000, L6010, and L6020 for partial hands. Our regulations at 42 CFR § 414.236(b) specifies that when the codes for several different items are combined into a single code, the fee schedule amounts for the new code are established using the average (arithmetic mean), weighted by allowed services, of the fee schedule amounts for the formerly separate codes. Based on allowed services for 2024, the average of the weighted average 2025 fee schedule amounts for HCPCS Level II codes L6000, L6010, and L6020 used to set the fee schedule amounts for HCPCS Level II code L6028 would be $1,905.90.

The average fee schedule amount is the average of the 2025 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 38

For HCPCS Level II code L6029:

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.

Our review has determined that the test sockets/interfaces described by HCPCS Level II code L6029 are comparable to the test sockets described by HCPCS Level II code L6680 ("Upper extremity addition, test socket, wrist disarticulation or below elbow"). Both codes describe items that serve the same primary function: acting as test sockets to assess socket compatibility, positioning, and individual comfort before a definitive socket is fabricated. In addition to their equivalent function, we have concluded that the materials and the labor for fabrication and fitting of the transradial/wrist disarticulation and partial hand test socket prostheses are roughly equivalent between these two codes. Therefore, the preliminary payment determination for HCPCS Level II code L6029 is to establish the fee schedule amounts using existing fee schedule amounts for comparable items described by HCPCS Level II code L6680.

The 2025 fee schedule amount for HCPCS Level II code L6029 would be approximately $325.55.

The average fee schedule amount is the average of the 2025 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 38

For HCPCS Level II code L6030:

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 determined that the items described by HCPCS Level II code L6030 ("Upper extremity addition, external frame, partial hand including fingers") are comparable to the items described by HCPCS Level II code L6687 ("Upper extremity addition, frame type socket, below elbow or wrist disarticulation"). For both codes we have concluded that the materials and labor for fabrication and fitting of the transradial/wrist disarticulation and partial hand prostheses are roughly equivalent. In addition, they share a similar function as a stable outer structure that provides a connection point for prosthetic components and protection for the inner components of the prosthesis. Therefore, the preliminary payment determination for HCPCS Level II code L6030 is to establish the fee schedule amounts using existing fee schedule amounts for comparable items described by HCPCS Level II code L6687.

The 2025 fee schedule amount for HCPCS Level II code L6030 would be approximately $736.46.

The average fee schedule amount is the average of the 2025 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 38

For HCPCS Level II code L6031:

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 replacement partial hand socket/interface described by HCPCS Level II code L6031 ("Replacement socket/interface, partial hand including fingers, molded to patient model, for use with or without external power") is comparable to the original or initial partial hand interface described by HCPCS Level II code L6028 ("Partial hand including fingers, flexible or non-flexible interface, endoskeletal system, molded to patient

model, for use without external power, not including inserts described by l6692"). While HCPCS Level II code L6883 ("Replacement socket, below elbow/wrist disarticulation, molded to patient model, for use with or without external power") is for a below elbow/wrist disarticulation prosthesis, the relative decrease in cost for items represented by HCPCS Level II code L6883 over the cost of items represented by HCPCS Level II code L6100 ("Below elbow, molded socket, flexible elbow hinge, triceps pad") is an appropriate approximation of the value the replacement partial hand socket/interface adds to the original or initial partial hand socket HCPCS Level II code L6028. Therefore, the fee schedule amounts for HCPCS Level II code L6031 would be set by multiplying the ratio of the average fee schedule amounts for HCPCS Level II codes L6883 and L6100 (L6883/L6100) by the fee schedule amounts for HCPCS Level II code L6028 (as proposed above and in application HCP24123181XV9).

Based on this formula, the average of the 2025 fee schedule amount for HCPCS Level II code L6031 would be approximately $1,551.40.

The average fee schedule amount is the average of the 2025 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 38

For HCPCS Level II code L6032

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.

Our review has determined that the ultralight material described by HCPCS Level II code L6032 is comparable to the ultralight material described by HCPCS Level II code L7400 ("Addition to upper extremity prosthesis, below elbow/wrist disarticulation, ultralight material (titanium, carbon fiber or equal)"). Both codes describe items that serve the same function: ultralight material componentry made from titanium, carbon fiber, or equivalent is available as an optional feature in prosthesis fabrication. In addition to their equivalent function, we have concluded that the materials and labor for fabrication and fitting of the transradial/wrist disarticulation and partial hand prostheses are roughly equivalent. Therefore, the preliminary payment determination for HCPCS Level II code L6032 is to establish the fee schedule amounts using existing fee schedule amounts for comparable items described by HCPCS Level II code L7400.

The 2025 fee schedule amount for HCPCS Level II code L6032 would be approximately $368.16.

The average fee schedule amount is the average of the 2025 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 38

For HCPCS Level II code L6033:

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 determined that the items described by HCPCS Level II code L6033 ("Addition to upper extremity prosthesis, partial hand including fingers, acrylic material") are comparable to the items described by HCPCS Level II code L7403 ("Addition to upper extremity prosthesis, below elbow/wrist disarticulation, acrylic material"). Both codes describe items that serve the same function: acrylic material componentry is available as an optional feature in prosthesis fabrication. In addition to their equivalent function, we have concluded that the materials and the labor for fabrication and fitting of the transradial/wrist disarticulation and partial hand test socket prostheses are roughly equivalent. Therefore, the preliminary payment determination for HCPCS Level II code L6033 is to establish the fee schedule amounts using existing fee schedule amounts for comparable items described by HCPCS Level II code L7403.

The 2025 fee schedule amount for HCPCS Level II code L6033 would be approximately $442.35.

The average fee schedule amount is the average of the 2025 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 38

For revised HCPCS Level II codes L6692 and L6698:

The payment rules and pricing associated with existing HCPCS Level II codes L6692 and L6698 apply to items described by these codes, if covered. The current average 2025 fee schedule amount for HCPCS Level II code L6692 is $762.70. The current average 2025 fee schedule amount for HCPCS Level II code L6698 is $709.17.

The average fee schedule amount is the average of the 2025 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 38

Agenda Item # 25
Partial Hand and/or Finger Prosthetic Sockets - HCP24123181XV9

Topic/Issue

Request to establish Medicare payment for partial hand and/or finger prosthetic sockets.

Summary of Applicant's Submission

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

CMS Final HCPCS Coding Determination

In the First Biannual 2025 HCPCS Level II coding cycle, CMS established and/or revised the following HCPCS Level II codes, effective October 1, 2025:

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, including palm, for use without external power and/or passive prosthetic digit/thumb, not including inserts described by l6692"

2. 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"

Medicare Benefit Category Determination

In the First Biannual 2025 HCPCS Level II coding cycle, CMS determined devices falling under HCPCS Level II codes L6028 and L6034 are a Prosthetic (Artificial Arm).

Preliminary Medicare Payment Determination

Following our commitment from the First Biannual 2025 HCPCS Level II coding cycle to address this application at a future public meeting, we are now presenting the preliminary payment determinations for the following HCPCS Level II codes.

For HCPCS Level II code L6028:

As described in application HCP240701W4N75, the average fee schedule amount for HCPCS Level II code L6028 would be $1,905.90.

The average fee schedule amount is the average of the 2025 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 38

For new HCPCS Level II code L6034:

In accordance with Medicare regulations at 42 Code of Federal Regulations (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 items represented by HCPCS Level II code L6034 are comparable to the items represented by HCPCS Level II code L6028. Specifically, while HCPCS Level II code L6028 serves as the base code for a hand/finger prosthesis where the amputation requires a larger base, stabilized across the palm, with the potential to attach up to five prosthetic digits, items described by HCPCS Level II code L6034 are smaller, intending to secure a single prosthetic digit to the remaining biological digit. Therefore, the preliminary payment determination for HCPCS Level II code L6034 is to establish the fee schedule amounts using 1/5 the fee schedule amounts for HCPCS Level II code L6028 (as proposed in application HCP240701W4N75).

Based on this formula, the average of the 2025 fee schedule amounts for HCPCS Level II code L6034 would be $381.18.

The average fee schedule amount is the average of the 2025 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 38

Agenda Item # 25
Non-Specific Custom-Made Terminal Device, Partial Digit - HCP241231PN7NF

Topic/Issue

Request to establish Medicare payment for custom made terminal devices used in partial hand and finger prostheses.

Summary of Applicant's Submission

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

CMS Final HCPCS Coding Determination

In the First Biannual 2025 HCPCS Level II coding cycle, CMS established 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 describe custom made complete prosthesis for the digit or thumb, effective October 1, 2025.

Final Medicare Benefit Category Determination

In the First Biannual 2025 HCPCS Level II coding cycle, CMS determined devices falling under HCPCS Level II code L6039 are a Prosthetic (Artificial Arm).

Preliminary Medicare Payment Determination

Following our commitment from the First Biannual 2025 HCPCS Level II coding cycle to address this application at a future public meeting, we are now presenting the preliminary payment determination for HCPCS Level II code L6039.

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

We have concluded that the items represented by HCPCS Level II code L6039 are comparable to the items represented by HCPCS Level II codes L6900 ("Hand restoration (casts, shading and measurements included), partial hand, with glove, thumb or one finger remaining") and L6905 ("Hand restoration (casts, shading and measurements included), partial hand, with glove, multiple fingers remaining"). Although HCPCS Level II codes L6900 and L6905 describe hand restoration prostheses, while HCPCS Level II code L6039 describes a passive prosthetic digit for use with a base socket (specifically for passive partial hand and finger prostheses that are not similar to those described in HCPCS Level II codes L6028 ("Partial hand including fingers, flexible or non-flexible interface, endoskeletal system, molded to patient model, for use without external power, not including inserts described by l6692") or 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")), these are comparable in terms of the broad form and purpose as evidenced by a similar level of time and materials necessary for the custom fabrication of the prosthetic digits/thumbs described by this code. Therefore, the preliminary payment determination for HCPCS Level II code L6039 is to establish the fee schedule amounts using the average of the existing fee schedule amounts for comparable items described by HCPCS Level II codes L6900 and L6905.

Using the average fee schedule amounts for HCPCS Level II codes L6900 and L6905, the average 2025 fee schedule amount for HCPCS Level II code L6039 would be $2,064.97.

The average fee schedule amount is the average of the 2025 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 38

Agenda Item # 26
Garter Belt - IHC2506243APQR

Topic/Issue

Request to establish Medicare payment for the existing HCPCS Level II code A6544, "Gradient compression stocking, garter belt."

Summary of Applicant's Submission

CMS submitted a request to establish a national fee schedule for the existing HCPCS Level II code A6544, "Gradient compression stocking, garter belt." HCPCS Level II code A6544 was removed from local coverage determination 33831 because it is a lymphedema compression treatment item.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

In accordance with Medicare regulations at 42 Code of Federal Regulations (CFR) § 414.1650, the payment amounts for covered lymphedema compression treatment items are established based on the following hierarchy:

1. If payment amounts are available from Medicaid state plans, then the fee schedule is 120 percent of the average of the Medicaid payment amounts.
2. If payment amounts are not available from Medicaid state plans, then the fee schedule is 100 percent of the average of average internet retail prices and payment amounts from TRICARE (Department of Defense).
3. If payment amounts are not available from Medicaid state plans or TRICARE, then the fee schedule is 100 percent of average internet retail prices.

As payment amounts are available from Medicaid state plans, the payment amount for HCPCS Level II code A6544 would be 120 percent of the average of these Medicaid payment amounts. The average of the Medicaid payment amounts is $32.41. Therefore, the preliminary payment determination for HCPCS Level II code A6544 would be $38.90.

Pricing Indicator = 40

Agenda Item # 27
Silicone Band - IHC241223RED3J

Topic/Issue

Request to establish a new HCPCS Level II code to identify silicone band.

Applicant's suggested language: XXXXX, “Accessory to custom gradient compression garment, silicone band, any size”

Summary of Applicant's Submission

CMS submitted a request to establish a new HCPCS Level II code to identify silicone band as accessory for custom lymphedema compression treatment garments. These bands are used for extra support and to help prevent slipping.

CMS Preliminary HCPCS Coding Determination

Establish a new HCPCS Level II code AXXXX, “Accessory to custom gradient compression garment, silicone band, any size” to describe a silicone band.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

In accordance with Medicare regulations at 42 Code of Federal Regulations (CFR) § 414.1650, fee schedule amounts for new HCPCS Level II codes for lymphedema compression treatment items without a fee schedule pricing history are established based on the following hierarchy:

1. If payment amounts are available from Medicaid state plans, then the fee schedule is 120 percent of the average of the Medicaid payment amounts.
2. If payment amounts are not available from Medicaid state plans, then the fee schedule is 100 percent of the average of average internet retail prices and payment amounts from TRICARE (Department of Defense).
3. If payment amounts are not available from Medicaid state plans or TRICARE, then the fee schedule is 100 percent of average internet retail prices.

As payment amounts for silicone top bands are not available from Medicaid state plans or TRICARE, payment for AXXXX would be based on 100 percent of the average internet retail prices, or $20.86.

Pricing Indicator = 40

Agenda Item # 28
Microlyte® PainGuard™ Matrix - HCP250701M7CDH

Topic/Issue

Request to establish a new HCPCS Level II code to identify Microlyte® PainGuard™ Matrix with lidocaine.

Applicant's suggested language: AXXXX, "Microlyte® PainGuard™ Matrix with lidocaine, per sq cm"

Summary of Applicant's Submission

Imbed Biosciences submitted a request to establish a new HCPCS Level II code to identify Microlyte® PainGuard™ Matrix with lidocaine. Microlyte® PainGuard™ Matrix with lidocaine received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on October 17, 2024. Microlyte® PainGuard™ Matrix with lidocaine is a sterile, single use wound covering made of bioresorbable polymers with lidocaine hydrochloride United States Pharmacopeia and a polymeric surface coating that contains ionic and metallic silver. Microlyte® PainGuard™ Matrix with lidocaine acts as a primary wound covering, absorbs wound fluid and forms a soft matrix that conforms to the wound surface and maintains a moist environment. Microlyte® PainGuard™ Matrix with lidocaine is indicated for the management of partial and full thickness wounds including diabetic foot ulcers, venous stasis ulcers, pressure ulcers, ischemic ulcers, surgical wounds, post-surgical incisions, donor sites, debrided partial thickness wounds, traumatic wounds, first degree burns, partial thickness burns, abrasions and lacerations. The product is supplied in the form of sheets and available in various sizes.

CMS Preliminary HCPCS Coding Determination

Establish a new HCPCS Level II code AXXXX, "Microlyte painguard, per square centimeter" to describe Microlyte® Painguard™ Matrix.

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

Agenda Item # 29
Altrazeal® Transforming Powder - HCP250701TV9EM

Topic/Issue

Request to establish a new HCPCS Level II code to identify Altrazeal® Transforming Powder.

Applicant's suggested language: XXXXX, “Extended wear transforming powder wound mgmt system”

Summary of Applicant's Submission

Altrazeal Life Sciences submitted a request to establish a new HCPCS Level II code to identify Altrazeal® Transforming Powder. Altrazeal® Transforming Powder is a class I device, exempt from the premarket notification procedures by the Food and Drug Administration (FDA). Altrazeal® Transforming Powder is a methacrylate-based, extended-wear transforming powder wound management system to manage wound moisture, facilitate gaseous exchange, serve as a barrier against bacterial infiltration, and fill and cover the wound bed for up to 30 days. Upon application to the wound bed and hydration with sterile saline or wound exudate, the powder transforms and aggregates into a conforming, moist, oxygen-permeable three-dimensional matrix that covers and protects the wound for up to 30 days. The matrix is designed to provide an extended wear cover to reduce disruption from dressing changes during the healing process. The matrix may be “topped off” by applying additional powder as needed without removing or disturbing the existing structure, as the added powder seamlessly integrates into the preformed matrix. As the wound heals, the matrix naturally dries and flakes away like a scab. If clinical removal is necessary before healing is complete, the matrix can be lifted off atraumatically. Its adhesion to the wound bed is maintained by a gentle suction effect—similar to a contact lens—generated by negative pressure from vapor transpiration, rather than by chemical or physical integration with tissue.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II code A6262, “Wound filler, dry form, per gram, not otherwise specified” describes Altrazeal® Transforming Powder.

Altrazeal® Transforming Powder is a wound filler that is supplied in dry form. Altrazeal® Transforming Powder is similar to other products in HCPCS Level II code A6262. 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.

Agenda Item # 30
Foundation DRS+ Duo - HCP250630PHTHC

Topic/Issue

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

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

Summary of Applicant's Submission

Bionova Medical, Inc. submitted a request to establish a new HCPCS Level II code to identify Foundation DRS+ Duo. Foundation DRS+ Duo received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on August 21, 2024. Foundation DRS+ Duo is a sterile, single-use dermal regeneration scaffold comprised of chitosan, chondroitin sulfate and hyaluronic acid with a semi-permeable polyurethane backing layer (offered with and without perforations) which provides a flexible covering for the wound surface. This biodegradable matrix can be used on a variety of wound types and/or prior to definitive treatment. Foundation DRS+ Duo is intended for use in the management of wounds, including: partial- and full-thickness wounds, pressure ulcers, venous ulcers, ulcers caused by mixed vascular etiologies, diabetic ulcers, first degree burns, partial thickness burns (superficial second degree burns), donor sites and other bleeding surface wounds, abrasions, trauma wounds (abrasions, lacerations, skin tears), dehisced wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence). It is applied on a wound after the wound bed is prepared with standard debridement methods. Foundation DRS+ Duo is supplied terminally sterile, in a single use package, and in a variety of sizes to accommodate most wounds.

CMS Preliminary HCPCS Coding Determination

Establish a new HCPCS Level II code AXXXX, “Foundation drs+ duo, per square centimeter” to describe Foundation DRS+ Duo.

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

Agenda Item # 30
Foundation DRS+ Solo - HCP2506304R21D

Topic/Issue

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

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

Summary of Applicant's Submission

Bionova Medical, Inc. submitted a request to establish a new HCPCS Level II code to identify Foundation DRS+ Solo. Foundation DRS+ Solo received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on October 31, 2024. It is a sterile, single-use dermal regeneration scaffold comprised of chitosan, chondroitin sulfate and hyaluronic acid.. This biodegradable matrix can be used on a variety of wound types and/or prior to definitive treatment. Foundation DRS+ Solo is intended for use in the management of wounds, including: partial- and full-thickness wounds, pressure ulcers, venous ulcers, ulcers caused by mixed vascular etiologies, diabetic ulcers, first degree burns, partial thickness burns (superficial second degree burns), donor sites and other bleeding surface wounds, abrasions, trauma wounds (abrasions, lacerations, skin tears), dehisced wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence). It is applied on a wound after the wound bed is prepared with standard debridement methods. The product will full resorb and does not have to be removed. Foundation DRS+ Solo is supplied terminally sterile, in a single use package, and in a variety of sizes to accommodate most wounds.

CMS Preliminary HCPCS Coding Determination

Establish a new HCPCS Level II code AXXXX, “Foundation drs+ solo, per square centimeter” to describe Foundation DRS+ Solo.

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

Agenda Item # 31
Suprello™ Synthetic Surgical Wound Matrix - HCP250701WBN0V

Topic/Issue

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

Applicant's suggested language: AXXXX, "Suprello™ Surgical Wound Matrix, per ml"

Summary of Applicant's Submission

Gel4Med, Inc. submitted a request to establish a new HCPCS Level II code to identify Suprello™ Surgical Wound Matrix. Suprello™ received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on October 11, 2023. It is a synthetic, bioresorbable surgical wound matrix supplied in a sterile prefilled syringe with a flexible applicator tip for precise application to partial and full-thickness surgical wounds, including dehisced, or other complex surgical wounds. Its proprietary self-assembling peptides form a 3D porous scaffold upon application that mimics the human extracellular matrix (ECM), supporting cellular infiltration, granulation tissue formation, revascularization, and re-epithelialization. Suprello™ functions as resorbable ECM-like scaffold designed to conform closely to the surgical wound. Suprello™ is indicated for the local management of partial and full-thickness surgical wounds. Suprello™ is fully bioresorbable, gradually integrating into the host tissue and being replaced by native tissue. Suprello is supplied as a single-use, sterile 2 mL pre-filled syringe. Reapplication may be performed as needed, guided by clinical judgment and wound progression, up to 10 gm/day. It is applied topically directly to the surgical wound via a sterile prefilled syringe. Suprello™ is supplied sterile in prefilled syringe (PFS) with a flexible applicator tip for precise application to the wound. Suprello™ is packaged in a dispenser box containing one sterile PFS, one applicator tip, and instructions for use, with a three-year shelf life at room temperature.

CMS Preliminary HCPCS Coding Determination

Revise existing HCPCS Level II code A2037, "G4derm plus, per milliliter" to read "G4derm plus/suprello, per milliliter" as both, G4Derm™ Plus and Suprello™, have the same FDA 510(k) regulatory pathway clearance.

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

Agenda Item # 32
BIOBRANE™ - HCP250630VNA4W

Topic/Issue

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

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

Summary of Applicant's Submission

Smith and Nephew Inc. submitted a request to establish a new HCPCS Level II code to identify BIOBRANE™. BIOBRANE™ received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on December 17, 2024. It is a biosynthetic dressing made from an ultrathin, semi-permeable, perforated silicone membrane that is mechanically bonded to a flexible knitted tri-filament nylon fabric. Denatured porcine dermal collagen has been bonded to the nylon/silicone membrane to provide a flexible and conformable dressing with adherence properties and hydrophilic surface. BIOBRANE™ Dressings are indicated for covering clean partial thickness burn wounds and split thickness donor sites. The dosage (i.e., the quantity and size of product used) will vary based upon burn wound size. BIOBRANE™ will be available in up to four dressing sizes. BIOBRANE™ dressings are individually placed into folded parchment paper which acts as a protective layer inside the sterile barrier. The device is then individually placed into a poly/paper pouch (primary packaging) which provides the sterile barrier.

CMS Preliminary HCPCS Coding Determination

Establish a new HCPCS Level II code AXXXX, “Biobrane, per square centimeter” to describe BIOBRANE™.

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

Agenda Item # 32
BIOBRANE™ Gloves - HCP250630VUJ1U

Topic/Issue

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

Applicant's suggested language: AXXXX, “BIOBRANE™ gloves, each”

Summary of Applicant's Submission

Smith and Nephew Inc. submitted a request to establish a new HCPCS Level II code to identify BIOBRANE™ gloves. BIOBRANE™ gloves received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on December 17, 2024. It is a biosynthetic dressing made from an ultrathin, semi-permeable, perforated silicone membrane that is mechanically bonded to a flexible knitted tri-filament nylon fabric. Denatured porcine dermal collagen has been bonded to the nylon/silicone membrane to provide a flexible and conformable dressing with adherence properties and hydrophilic surface. BIOBRANE™ gloves are indicated for covering clean partial thickness burn wounds of the hands. The dosage (i.e., the quantity and size of product used) will vary based upon burn wound size. BIOBRANE™ gloves will be available in up to four glove sizes. BIOBRANE™ gloves are individually placed into folded parchment paper which acts as a protective layer inside the sterile barrier. The device is then individually placed into a poly/paper pouch (primary packaging) which provides the sterile barrier.

CMS Preliminary HCPCS Coding Determination

Establish a new HCPCS Level II code AXXXX, “Biobrane glove, each” to describe BIOBRANE™ gloves.

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

Agenda Item # 33
NovaShield Wound Matrix - HCP250630THWV2

Topic/Issue

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

Applicant's suggested language: AXXXX, “NovaShield Wound Matrix, per sq cm”

Summary of Applicant's Submission

Summit Products Group submitted a request to establish a new HCPCS Level II code to identify NovaShield Wound Matrix. NovaShield Wound Matrix received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on June 9, 2023. It is a sterile, single-use dermal regeneration scaffold comprised of bovine type-1 collagen, 45S5 bioactive glass and citric acid. NovaShield Wound Matrix 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 sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, partial thickness burns; and skin tears), and 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. NovaShield Wound Matrix is supplied terminally sterile, in a single use package, and in a variety of sizes to accommodate most wounds.

CMS Preliminary HCPCS Coding Determination

Establish a new HCPCS Level II code AXXXX, “Novashield or novogen wound matrix, per square centimeter” to describe NovaShield and NovoGen Wound Matrix. CMS is grouping both under the same HCPCS Level II code as NovaShield is an exclusive private label version of NovoGen Wound Matrix with the same FDA 510(k) regulatory pathway clearance.

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

Agenda Item # 34
Omeza® Complete Matrix - HCP250701YNBTG

Topic/Issue

Revise existing HCPCS Level II code A2014, “Omeza collagen matrix, per 100 mg” to change with re-branded name of Omeza® Complete Matrix.

Applicant's suggested language: A2014, “Omeza Complete Matrix, per 18 cm²”

Summary of Applicant's Submission

Omeza® LLC submitted a request to revise existing HCPCS Level II code A2014, “Omeza collagen matrix, per 100 mg” with re-branded name of Omeza® Complete Matrix (OCM™), in order to assign it to an appropriate payment category under the Hospital Outpatient Prospective Payment System (OPPS). Omeza® Collagen Matrix received clearance by the Food and Drug Administration (FDA) through the 510(k) regulatory pathway on September 1, 2021. OCM™ is the rebranded name of the Omeza® Collagen Matrix. Although OCM™ is currently coded under the HCPCS Level II code A2014 as Omeza® Collagen Matrix, it remains unassigned to any Ambulatory Payment Classification (APC) group. The current descriptor is both chemically inaccurate and operationally misaligned with the product's therapeutic use and billing structure. Calling OCM™ a “collagen” product is not correct. OCM™ does not contain collagen as a discrete structural protein. Rather, OCM™ is an anhydrous, amorphous solid that contains all natural components, including fish and plant-derived mono and polyunsaturated fatty acids (omega 3,6, and 9), tissue-generating signaling molecules, and nutrients (vitamins A, C, D, and E and minerals.) Together they form a bioactive scaffold that promotes wound healing, reduces biofilm, and supports tissue remodeling. Referring to the product as a “collagen matrix” misrepresents its true composition and mechanism of action. In addition, the current billing unit of “per 100 mg” is inappropriate. OCM™ is not a powdered product dispensed by weight; it is a sterile, solid-phase matrix that forms a conformable sheet upon application. Each 1.6 g vial of OCM™ is standardized to cover approximately 18 cm². In the CY 2024 Medicare Hospital OPPS Final Rule CMS stated that OCM™, as an amorphous solid, is not a graft skin substitute product and therefore cannot be assigned to either the high-cost skin or the low-cost skin substitute APCs. This request seeks alignment of HCPCS Level II code A2014 with the name change of OCM™ to match its composition, and a reimbursable APC under OPPS, as OCM™ meets all criteria for skin substitute grafts and is used comparably to other high-cost skin substitute products already reimbursed. OCM™ forms an in situ 18 cm² sheet-like scaffold upon application, supports tissue regeneration, and involves physician work equivalent in type, intensity, and duration to other covered, high-cost grafts.

CMS Preliminary HCPCS Coding Determination

CMS has not identified a program operating need to revise the existing HCPCS Level II code A2014, “Omeza collagen matrix, per 100 mg.” HCPCS is a system for identifying items and certain services. It is not a methodology or system for making coverage or payment determinations, and the existence of a code does not, in itself, determine coverage or non-coverage for an item or service. While these codes are used for billing purposes, decisions regarding the addition, deletion, or revision of HCPCS codes are made independent of the process for making determinations regarding coverage and payment. As such the HCPCS

Level II application process is not an appropriate route to seek an assignment of your product to an appropriate payment category under the Hospital OPPS.

The request for a revision to the language of the current code has not been approved because it does not improve the code descriptor. In the First Biannual 2022 HCPCS Level II Coding Cycle (application HCP210930GLM48), Omeza® Collagen Matrix was described as "an anhydrous acellular collagen matrix comprised of hydrolyzed fish collagen infused with cod liver oil and other plant-derived oils and waxes." This description of Omeza® Collagen Matrix was consistent with the FDA's 510(k) clearance. HCPCS Level II code A2014, "Omeza collagen matrix, per 100 mg" was then established to describe Omeza® Collagen Matrix.

The current application states, "The current descriptor is both chemically inaccurate and operationally misaligned with the product's therapeutic use and billing structure. Calling Omeza® Complete Matrix (OCM™) a 'collagen' product is not correct." As such, CMS recommends discussing the new descriptor of OCM™ with the FDA to ensure that the descriptor is chemically accurate and aligns with product's therapeutic use.

Agenda Item # 35
SilSecure - HCP250416UF7UY

Topic/Issue

Request to revise existing HCPCS Level II code A6258, "Transparent film, sterile, more than 16 sq. in. but less than or equal to 48 sq. in., each dressing" to identify SilSecure.

The applicant did not submit any suggested language.

Summary of Applicant's Submission

SilSecure submitted a request to revise existing HCPCS Level II code A6258 to identify SilSecure. SilSecure is exempt from the premarket notification by the Food and Drug Administration (FDA). SilSecure dressings are described as hypoallergenic, high-quality silicone-based wound care products designed to minimize skin injuries and irritation, reduce the risk of medical adhesive-related skin injuries (MARSI), and promote faster recovery by creating an optimal healing environment. The primary function of these dressings is to provide gentle yet secure adhesion, ensuring pain-free removal and prioritizing comfort, especially for individuals with sensitive skin or frequent dressing changes. SilSecure dressings are intended for wound care across various demographics, particularly for individuals who are prone to skin irritation or require frequent dressing changes. The advanced silicone technology adheres gently to the skin, creating an optimal healing environment while minimizing the risk of MARSI. SilSecure is available in a variety of sizes, including intravenous patches to accommodate differing wound sizes and the needs of individuals. The dressing is applied topically to the affected area. SilSecure is supplied in sterile packaging with multilingual product information to support the needs of diverse populations.

CMS Preliminary HCPCS Coding Determination

We have not identified a program operating need for Medicare or other insurers to revise the existing HCPCS Level II code A6258, "Transparent film, sterile, more than 16 sq. in. but less than or equal to 48 sq. in., each dressing." Existing HCPCS Level II code A6258 accurately describes SilSecure. SilSecure is a transparent, hypoallergenic silicone dressing and is similar to other dressings in existing HCPCS Level II code A6258.

Preliminary Medicare Benefit Category Determination

Surgical Dressing.

Preliminary Medicare Payment Determination

The Medicare payment rules and pricing associated with the existing HCPCS Level II code A6258 apply to the SilSecure dressing, if covered. The average 2025 fee schedule amount for HCPCS Level II code A6258 is $6.05.

The average fee schedule amount is the average of the 2025 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually. Pricing Indicator = 35

Agenda Item # 36
Eakin Wound Pouch (16 Square Inches or Less) - HCP250627L7TTQ

Topic/Issue

Request to revise existing HCPCS Level II code A6154, “Wound pouch, each” to identify various sizes of wound pouches.

Applicant's suggested language: A6154, “Wound pouch, size 16 sq. in. or less, each”

Summary of Applicant's Submission

T. G. Eakin, Limited, submitted a request to revise existing HCPCS Level II code A6154 to identify various sizes of Eakin Wound Pouch, specifically 16 square inches or less. Eakin Wound Pouch is exempt from the premarket notification by the Food and Drug Administration (FDA). Eakin Wound Pouches are flexible pouches designed to offer skin protection and contain drainage from wounds and fistulas. The pouches can be used for both dressing and draining wounds and fistulas. Wounds and fistulas can occur in various sizes and shapes. Eakin Wound Pouches are available in a variety of shapes and larger sizes, unlike previous wound pouches on the market included in HCPCS Level II code A6154. Revising the description for code A6154, “Wound pouch, each” to include the size description would provide individuals with access to larger wound pouches that meet their diverse wound care needs. The Eakin products to be included in the revised code are the Eakin Fistula and Wound Pouches, with and without remote drainage, up to 16 square inches in size.

CMS Preliminary HCPCS Coding Determination

We have not identified a program operating need for Medicare or other insurers to revise the existing HCPCS Level II code A6154, “Wound pouch, each” to describe various sizes of wound pouches. Existing HCPCS Level II code A6154 includes products that vary in size, similar to the Eakin Wound Pouch, which are designed to offer skin protection and contain drainage from wounds and fistulas.

Preliminary Medicare Benefit Category Determination

Surgical Dressing.

Preliminary Medicare Payment Determination

The Medicare payment rules and pricing associated with the existing HCPCS Level II code A6154 apply to the Eakin Wound Pouch, if covered. The average 2025 fee schedule amount for HCPCS Level II code A6154 is $20.06.

The average fee schedule amount is the average of the 2025 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 35

Agenda Item # 36
Eakin Wound Pouch (Greater Than 16 Square Inches to 48 Square Inches)- HCP250627JXAL9

Topic/Issue:

Request to establish a new HCPCS Level II code to identify various sizes of wound pouches.

Applicant's suggested language: AXXXX, "Wound pouch, size more than 16 sq. in., but less than or equal to 48 sq. in., each"

Summary of Applicant's Submission

T. G. Eakin, Limited, submitted a request to establish a new HCPCS Level II code to identify various sizes of Eakin Wound Pouch, specifically greater than 16 square inches but less than or equal to 48 square inches. Eakin Wound Pouch is exempt from the premarket notification by the Food and Drug Administration (FDA). Eakin Wound Pouches are flexible pouches designed to offer skin protection and contain drainage from wounds and fistulas. The pouches can be used for both dressing and draining wounds and fistulas. Eakin Wound Pouches are available in a variety of cutting areas to accommodate the wounds and fistulas of differing sizes and shapes. The Eakin Wound Pouches to be included in the new code have a cutting area of 6.9 in. x 4.3 in. with remote drainage for wounds and fistulas that are larger than 16 square inches in size but less than or equal to 48 square inches in size.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II code A6154, "Wound pouch, each" describes various sizes of wound pouches and includes products similar to the Eakin Wound Pouch, size greater than 16 square inches, but less than or equal to 48 square inches, which are designed to offer skin protection and contain drainage from wounds and fistulas.

Preliminary Medicare Benefit Category Determination

Surgical Dressing.

Preliminary Medicare Payment Determination

The Medicare payment rules and pricing associated with the existing HCPCS Level II code A6154 apply to the Eakin Wound Pouch, if covered. The average 2025 fee schedule amount for HCPCS Level II code A6154 is $20.06.

The average fee schedule amount is the average of the 2025 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 35

Agenda Item # 36
Eakin Wound Pouch (Greater Than 48 Square Inches) - HCP250627FK5Q7

Topic/Issue

Request to establish a new HCPCS Level II code to identify various sizes of wound pouches.

Applicant's suggested language: AXXXX, “Wound pouch, size more than 48 sq. in., each”

Summary of Applicant's Submission

T. G. Eakin, Limited, submitted a request to establish a new HCPCS Level II code to identify various sizes of Eakin Wound Pouch, specifically greater than 48 square inches. Eakin Wound Pouch is exempt from the premarket notification by the Food and Drug Administration (FDA). Eakin Wound Pouches are flexible pouches designed to offer skin protection and contain drainage from wounds and fistulas. The pouches can be used for both dressing and draining wounds and fistulas. Eakin Wound Pouches are available in a variety of cutting areas to accommodate wounds and fistulas of differing sizes and shapes. The Eakin Wound Pouches to be included in the new code have cutting areas of 9.7 in. x 6.3 in. and 11.4 in. x 5.1 in. with remote drainage and with horizontal or vertical access windows for wound assessment without removing the dressing, for wounds and fistulas that are larger than 48 square inches in size.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II code A6154, “Wound pouch, each” describes various sizes of wound pouches and includes products similar to the Eakin Wound Pouch, size greater than 48 square inches, which are designed to offer skin protection and contain drainage from wounds and fistulas.

Preliminary Medicare Benefit Category Determination

Surgical Dressing.

Preliminary Medicare Payment Determination

The Medicare payment rules and pricing associated with the existing HCPCS Level II code A6154 apply to the Eakin Wound Pouch, if covered. The average 2025 fee schedule amount for HCPCS Level II code A6154 is $20.06.

The average fee schedule amount is the average of the 2025 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 35

Agenda Item # 37
FC2 Female Condom® - HCP2502241H0QY

Topic/Issue

Request to revise existing HCPCS Level II code A4268, “Contraceptive supply, condom, female, each" to identify FC2 Female Condom®.

Applicant's suggested language: A4268, “Contraceptive supply, condom, internal”

Summary of Applicant's Submission

Clear Future Inc. submitted a request to revise the existing HCPCS Level II code A4268 to identify FC2 Female Condom®. FC2 Female Condom® was approved by the Food and Drug Administration (FDA) under a premarket approval (PMA) on March 10, 2009. This single-use internal condom is sold in a 12-pack configuration. The FC2 Female Condom® is indicated for preventing pregnancy, and the transmission of sexually transmitted infections, including human immunodeficiency virus and acquired immunodeficiency syndrome. The existing HCPCS Level II code A4268 does not adequately describe this item because the generic name for the product changed from "female condom," to "single-use internal condom" with the FDA reclassification of this product category in 2018. Also, to list it as "each," is inappropriate because the product’s minimum package supply configuration that is legally labeled in FDA-approved packaging is a 12-pack. The long descriptor could then potentially read, "each box of 12."

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II code A4268, “Contraceptive supply, condom, female, each" describes the FC2 Female Condom.

CMS has not identified a program operating need for Medicare or other insurers to revise existing HCPCS Level II code A4268. The HCPCS Level II coding system is a comprehensive, standardized system that classifies similar items or services that are medical in nature into categories for the purpose of efficient claims processing.

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 FC2 Female Condom® device does not meet three of the conditions as follows:

> **Can withstand repeated use –** The application states that the FC2 Female Condom® is intended to be used by a single patient and that it cannot be rented, refurbished, and used by successive patients.
>
> **Has an expected life of at least 3 years –** The application states that the FC2 Female Condom® is a single use item. As the item is disposable, it does not have an expected life of at least 3 years.
>
> **Is primarily and customarily used to serve a medical purpose -** The application states that the FC2 Female Condom® prevents pregnancy and the transmission of sexually transmitted infections, including HIV/AIDs when used as a barrier contraceptive method during acts of sexual intercourse. Section 110.1.B.2 of the Medicare Benefit Policy Manual (Pub. 100-3) states that precautionary-type equipment is considered nonmedical in nature. Therefore, such items do not fall within the DME benefit category.

Preliminary Medicare Payment Determination

Items or services described by HCPCS Level II code A4268 are not covered under Medicare Part B.

No Medicare payment. Pricing Indicator = 00

Agenda Item # 38
Eddie® - HCP250701U7JBJ

Topic/Issue

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

The applicant did not submit any suggested language.

Summary of Applicant's Submission

Giddy Holdings, Inc. submitted a request to establish a new HCPCS Level II code to identify Eddie®. Eddie® is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). Eddie® is an FDA-registered Class II medical device engineered to address erectile dysfunction (ED). It is a U-shaped, reusable device intended for therapeutic use under the direction or recommendation of a healthcare provider following a formal diagnosis of ED, including physicians such as Veterans Administration providers, endocrinologists, and urologists. It is constructed from medical-grade materials, specifically designed to enhance comfort and safety by selectively restricting venous blood outflow, while preserving arterial inflow and avoiding urethral compression, thereby supporting natural ejaculation and minimizing discomfort. The device is indicated for adult males with ED, particularly those who can achieve but not maintain an erection, including veterans (85% of whom with post-traumatic stress disorder, experience ED), and men with diabetes (65.8% ED prevalence). Eddie® is supported by a 2025 clinical trial demonstrating a 95% positive experience rate, 93% improvement in erection quality, and 96% improvement in confidence, with a projected $1.5 trillion in healthcare savings over 10 years by mitigating ED-related comorbidities such as diabetes, cardiovascular disease, and mental health disorders.

CMS Preliminary HCPCS Coding Determination

CMS has not identified a program operating need for Medicare or other insurers to establish a new HCPCS Level II code to describe Eddie®. Over-the-counter ED devices, such as the Eddie®, are not typically paid for by insurance. While the applicant referenced that ED devices may be covered by health savings accounts and/or flexible spending accounts and mentioned that the Veterans Administration has a need for such devices, CMS did not receive any documentation to demonstrate that insurers provide coverage of the Eddie® device, such as publicly-available written policies pertaining to the Eddie® or devices like it, written correspondence from other insurers that the lack of a unique HCPCS Level II code is the reason for claims denials, or documentation that insurers are allowing the Eddie® device to be billed using an existing HCPCS Level II code(s) or miscellaneous 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 Eddie by Giddy device does not meet at least one of the conditions as follows:

> **Can withstand repeated use** – The applicant stated that the Eddie by Giddy device is intended to be used by a single patient and that the device cannot be rented, refurbished, and used by successive patients.

We also note that section 1834(a)(1)(I) of the Social Security Act prohibits coverage under Medicare Part B of vacuum erection systems that include constriction or tension bands.

Preliminary Medicare Payment Determination

No Medicare payment. Pricing Indicator = 00

Agenda Item # 39
Shaped Pads - HCP2506300NH69

Topic/Issue

Request to establish a new HCPCS Level II code to identify shaped pads.

Applicant's suggested language: XXXXX, “Adult-sized disposable incontinence product, shaped pads, above extra large, each”

Summary of Applicant's Submission

TZMO USA, Inc. submitted a request to establish a new HCPCS Level II code to identify shaped pads for incontinence protection. Shaped pads are exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The shaped pads are used to manage moderate to heavy urinary incontinence in individuals who are unable to control bladder function due to medical conditions such as neurological disorders, post-surgical recovery, age-related decline, mobility limitations, or obesity-related functional impairment. The shaped pads are worn externally with reusable underwear or supporting pants.

CMS Preliminary HCPCS Coding Determination

Existing HCPCS Level II code A4520, "Incontinence garment, any type, (e.g., brief, diaper), each" describes the shaped pads. If other insurers deem appropriate, existing HCPCS Level II code T4535, “Disposable liner/shield/guard/pad/undergarment, for incontinence, each” is available for assignment. The shaped pad for incontinence protection is similar to other incontinence products in HCPCS Level II code A4520 and T4535.

Preliminary Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for HCPCS Level II code A4520 apply to the Seni Shaped Pads.

Preliminary Medicare Payment Determination

Items or services described by HCPCS Level II code A4520 are not covered under Medicare Part B.

No Medicare payment. Pricing Indicator = 00

Agenda Item # 40
Tibbe™ Female External Urinary Device - HCP250616JJGPQ

Topic/Issue

Request to establish a new HCPCS Level II code to identify Tibbe™ Female External Urinary Device.

Applicant's suggested language: XXXXX, "two-piece, fully adhered female external urinary catheter, for use with suction or gravity"

Summary of Applicant's Submission

SBE Medical submitted a request to establish a new HCPCS Level II code to identify the Tibbe™ Female External Urinary Device (EUD). The Tibbe™ Female EUD is exempt from the premarket notification procedures by the Food and Drug Administration (FDA). The Tibbe™ Female EUD is an adhesive device that funnels urine into a closed collection system and directs it away from the individual. The Tibbe™ Female EUD is intended for females with intact skin who need support for incontinence management. The Tibbe™ Female EUD can be used with either suction or gravity for drainage. It is a non-sterile**,** single-use**,** and non-invasive device**.** The Tibbe™ Female EUD is a two-piece system that allows for disconnection of the cup for cleaning, intervention, or to provide additional mobility options for the individual.

CMS Preliminary HCPCS Coding Determination

Establish a new HCPCS Level II code AXXXX, "Female external urinary collection cup, with or without ring attachment, per day" to describe Tibbe™ Female EUD.

The Tibbe™ Female EUD is a single use cup-shaped device and as such adding "catheter" to the descriptor would be inaccurate.

Preliminary Medicare Benefit Category Determination

Prosthetic Device.

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 Tibbe™ Female EUD is comparable to HCPCS Level II code A4327, "Female external urinary collection device, meatal cup, each." Like the Tibbe™ Female EUD, a meatal cup is a small cup-shaped device that can be placed over the urethral opening (meatus) to facilitate the collection of urine. The primary difference between the Tibbe™ Female EUD and the devices classified in HCPCS Level II code A4327 is that

devices classified in A4327 are intended to be re-used for one week, while the Tibbe™ Female EUD is only intended for use over the course of one day.

Therefore, the preliminary payment determination for HCPCS Level II code AXXXX is calculated by dividing the payment amount for A4327 by 7. The 2025 average fee schedule amount for HCPCS Level II code AXXXX would be approximately $8.81.

The average fee schedule amount is the average of the 2025 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 37

Agenda Item # 41
Next Generation Sequencing - IHC251030N8UFD

Topic/Issue

Request to establish two new HCPCS Level II modifiers to identify next generation sequencing (NGS) testing.

Applicant's suggested language:

1. X1, "Next Generation Sequencing performed for patients with early-stage cancer (Stage I or Stage II)"

2. X2, "Next Generation Sequencing performed for patients with advanced (Stage III-IV), recurrent, relapsed, refractory, or metastatic cancer"

Summary of Applicant's Submission

CMS submitted a request to establish a two new HCPCS Level II modifiers to differentiate NGS testing performed for early-stage cancers (Stages I and II) from testing performed for advanced (Stages III and IV), recurrent, relapsed, refractory, or metastatic cancers. The National Coverage Determination 90.2 does not cover early-stage cancers. The current International Classification of Diseases (ICD)-10 diagnosis codes do not distinguish between different cancer stages, creating ambiguity in claims submissions. These new modifiers will ensure greater clarity, align claim submission with coverage requirements and support accurate payment. They will provide a standardized mechanism for providers to report clinical context, while enabling payers to consistently apply the appropriate coverage criteria and maintain data integrity for oversight and claims analysis.

CMS Preliminary HCPCS Coding Determination

Establish two new HCPCS Level II modifiers:

1. X1, "Next generation sequencing performed for patients with early-stage cancer (stage i or stage ii)"

2. X2, "Next generation sequencing performed for patients with advanced (stage iii-iv), recurrent, relapsed, refractory, or metastatic cancer"

Agenda Item # 42
Macugen® - IHC2503232KXMT

Topic/Issue

Request to discontinue existing HCPCS Level II code J2503, "Injection, pegaptanib sodium, 0.3 mg."

Summary of Applicant's Submission

An internal request was received to discontinue existing HCPCS Level II code J2503, "Injection, pegatabnib sodium, 0.3 mg," that Macugen® (pegatabnib sodium). On September 17, 2004, the Food and Drug Administration (FDA) approved Macugen® (pegatabnib sodium) under a New Drug Application (NDA) pathway for the treatment of neovascular (wet) age-related macular degeneration. However, the FDA's Orange Book currently lists Macugen® as discontinued from marketing in the United States.[1]

CMS Final HCPCS Coding Determination

CMS published a final determination for the second quarterly HCPCS Level II coding cycle of 2025 on July 7, 2025, to discontinue existing HCPCS Level II code J2503, "Injection, pegaptanib sodium, 0.3 mg", effective October 1, 2025.

Consistent with our usual practice to discontinue a HCPCS Level II code, we welcome information from other insurers who are currently paying for this product.

[1] Product Details for NDA 021756. FDA Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. https://www.accessdata.fda.gov/scripts/cder/ob/search_product.cfm

Agenda Item # 43
Discontinuation of Existing HCPCS Level II Codes - IHC2503232KXMT

CMS has been conducting a comprehensive review of the HCPCS Level II code set for drugs and biological products to ensure the coding system remains current, accurate, and reflects products that are actively available in the United States market. As part of this ongoing maintenance effort, CMS will discontinue HCPCS Level II codes for products that meet specific criteria: those with no active products listed in the Red Book[2] (the pharmaceutical pricing reference), products not found in the Red Book database, products listed as discontinued in the Food and Drug Administration's (FDA's) Orange Book[3], products not sold in the United States, or products that have been discontinued by manufacturers. This systematic review helps maintain the integrity of the HCPCS Level II coding system, ensures accurate billing and reimbursement for Medicare and other insurers, reduces administrative burden on healthcare providers, and eliminates outdated codes that no longer serve a functional purpose in healthcare billing and documentation. By removing inactive or unavailable product codes, CMS supports more efficient healthcare operations while maintaining accurate records of covered drugs and biological products for beneficiaries.

CMS intends to continue this review in subsequent HCPCS Level II quarterly cycles to ensure the HCPCS Level II code set remains up-to-date and reflects the current pharmaceutical marketplace.

CMS Final HCPCS Coding Determination

CMS published a final determination for the third quarterly HCPCS Level II coding cycle of 2025 on October 21, 2025, to discontinue 57 existing HCPCS Level II codes, effective January 1, 2026.

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

Consistent with our usual practice to discontinue a HCPCS Level II code, we welcome information from other insurers who are currently paying for these products.

[2] https://www.micromedexsolutions.com/micromedex2/librarian
[3] The FDA's Orange Book, officially entitled, *Approved Drug Products With Therapeutic Equivalence Evaluations,* identifies drug products approved on the basis of safety and effectiveness by the FDA, and is published at the following FDA link: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm.

Agenda Item # 44
HCPCS Level II Codes for Various FDA Approvals under the 505(b)(2) or Biologics License Application (BLA) Pathways and Products "Not Otherwise Classified" - HCP220517FAENJ

Topic/Issue

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

Summary of Applicant's Submission

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

In order to conform with the general approach used for the assignment of products paid under section 1847A of the Social Security Act (the Act) to HCPCS Level II codes as described at the following CMS link: https://www.cms.gov/files/document/frequently-asked-questionssingle-source-drugs-and-biologicals.pdf. CMS is making several code changes, including manufacturer specific codes to identify products approved under separate 505(b)(2) NDA or BLA pathways. Since the products are approved under separate 505(b)(2) NDAs and are not rated as therapeutically equivalent by the FDA in the Orange Book[4], they are single source drugs based on the statutory definition of "single source drug" in section 1847A(c)(6) of the Act. Because these are single source drugs, there is a programmatic need for each product to have a unique billing and payment code.

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

Due to the complexity and nuanced nature of the differences between each product, we encourage providers to rely on the Average Sales Price (ASP) HCPCS-National Drug Code (NDC) crosswalk[5] to identify the correct billing and payment code for each applicable product.

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

CMS Final HCPCS Coding Decision

We established fourteen HCPCS Level II codes within the second quarter (Q4) of 2025, effective October 1, 2025, and thirteen HCPCS Level II codes within the third quarter (Q3) of 2025, effective January 1, 2026, to separately identify products approved by the FDA after October 2003, and not rated as therapeutically equivalent to a reference listed product in an existing code.

We seek comment on these code descriptors.

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

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

Appendix A: Discontinuation of Existing HCPCS Level II Codes

HCPCS Code	Long Descriptor	Trade Name	CMS' Rational
J0190	Injection, biperiden lactate, per 2 mg	Akineton	No active products per Red Book; product discontinued per Orange Book
J0200	Injection, alatrofloxacin mesylate, 100 mg	TROVAN	No active products per Red Book; product discontinued per Orange Book
J0205	Injection, alglucerase, per 10 units	Ceredase	No active products per Red Book
J0215	Injection, alefacept, 0.5 mg	Amevive	No active products per Red Book
J0288	Injection, amphotericin B cholesteryl sulfate complex, 10 mg		No active products per Red Book
J0350	Injection, anistreplase, per 30 units	Eminase	No active products per Red Book
J0365	Injection, aprotonin, 10,000 kiu	Trasylol	No active products per Red Book
J0380	Injection, metaraminol bitartrate, per 10 mg		No active products per Red Book
J0395	Injection, arbutamine hcl, 1 mg	GENESA	No active products per Red Book; product discontinued per Orange Book
J0710	Injection, cephapirin sodium, up to 1 gm		No active products per Red Book; product discontinued per Orange Book
J0715	Injection, ceftizoxime sodium, per 500 mg	CEFIZOX	No active products per Red Book; product discontinued per Orange Book
J0795	Injection, corticorelin ovine triflutate, 1 microgram		No active products per Red Book
J1267	Injection, doripenem, 10 mg	Doribax	No active products per Red Book; product discontinued per Orange Book
J1330	Injection, ergonovine maleate, up to 0.2 mg		No active products per Red Book
J1452	Injection, fomivirsen sodium, intraocular, 1.65 mg	Vitavene	No active products per Red Book; product discontinued per Orange Book

HCPCS Code	Long Descriptor	Trade Name	CMS' Rational
J1457	Injection, gallium nitrate, 1 mg	GANITE	No active products per Red Book; product discontinued per Orange Book
J1562	Injection, immune globulin (vivaglobin), 100 mg	VIVAGLOBIN	No active products per Red Book
J1620	Injection, gonadorelin hydrochloride, per 100 mcg	FACTREL	No active products per Red Book; product discontinued per Orange Book
J1655	Injection, tinzaparin sodium, 1000 iu	INNOHEP	No active products per Red Book; product discontinued per Orange Book
J1710	Injection, hydrocortisone sodium phosphate, up to 50 mg		No active products per Red Book; product discontinued per Orange Book
J1945	Injection, lepirudin, 50 mg		No active products per Red Book
J2504	Injection, pegademase bovine, 25 iu	ADAGEN	No active products per Red Book; product discontinued per Orange Book
J2513	Injection, pentastarch, 10% solution, 100 ml		No active products per Red Book
J2910	Injection, aurothioglucose, up to 50 mg	Solganal	No active products per Red Book
J2940	Injection, somatrem, 1 mg		No active products per Red Book
J2995	Injection, streptokinase, per 250,000 iu		No active products per Red Book
J3280	Injection, thiethylperazine maleate, up to 10 mg	Torecan	No active products per Red Book; product discontinued per Orange Book
J3305	Injection, trimetrexate glucuronate, per 25 mg	NEUTREXIN	No active products per Red Book; product discontinued per Orange Book
J3320	Injection, spectinomycin dihydrochloride, up to 2 gm	Trobicin	No active products per Red Book; product discontinued per Orange Book
J3355	Injection, urofollitropin, 75 iu		No active products per Red Book

HCPCS Code	Long Descriptor	Trade Name	CMS' Rational
J3364	Injection, urokinase, 5000 iu vial	KINLYTIC	No active products per Red Book; product discontinued per Orange Book
J3365	Injection, iv, urokinase, 250,000 i.u. vial	KINLYTIC	No active products per Red Book; product discontinued per Orange Book
J3400	Injection, trifluprom azine hcl, up to 20 mg	VESPRIN	No active products per Red Book; product discontinued per Orange Book
J7309	Methyl aminolevulinate (mal) for topical administration,16.8%, 10 mg	METVIXIA	No active products per Red Book; product discontinued per Orange Book
J7310	Ganciclovir, 4.5 mg, long-acting implant	Vitrasert	No active products per Red Book; product discontinued per Orange Book
J7505	Muromonab-cd3, parenteral, 5 mg	Muromonab-CD3, also known as OKT3	Product discontinued
J7513	Daclizumab, parenteral, 25 mg	Zinbryta	Product discontinued
J8562	Fludarabine phosphate, oral, 10 mg	Oforta	No active products per Red Book
J8650	Nabilone, oral, 1 mg	CESAMET	No active products per Red Book; product discontinued per Orange Book
J9019	Injection, asparaginase (erwinaze), 1,000 iu	Erwinaze	No active products per Red Book
J9020	Injection, asparaginase, 10,000 units, not otherwise specified		No active products per Red Book
J9098	Injection, cytarabine liposome, 10 mg		No active products per Red Book
J9151	Injection, daunorubicin citrate, liposomal formulation, 10 mg	DAUNOXOME	No active products per Red Book; product discontinued per Orange Book
J9165	Injection, diethylstilbestrol diphosphate, 250 mg		No active products per Red Book; product discontinued per Orange Book
J9212	Injection, interferon alfacon-1, recombinant, 1 microgram	Infergen	No active products per Red Book

HCPCS Code	Long Descriptor	Trade Name	CMS' Rational
J9270	Injection, plicamycin, 2.5 mg		No active products per Red Book
Q0174	Thiethylperazine maleate, 10 mg, oral, fda approved prescription anti-emetic, for use as a complete therapeutic substitute for an iv anti-emetic at the time of chemotherapy treatment, not to exceed a 48 hour dosage regimen	TORECAN	No active products per Red Book; product discontinued per Orange Book
Q5109	Injection, infliximab-qbtx, biosimilar, (ixifi), 10 mg	Ixifi	Not sold in the U.S.
J1443	Injection, ferric pyrophosphate citrate solution (triferic), 0.1 mg of iron	triferic	Product discontinued; product discontinued per Orange Book
J1444	Injection, ferric pyrophosphate citrate powder, 0.1 mg of iron		Product discontinued
J1445	Injection, ferric pyrophosphate citrate solution (triferic avnu), 0.1 mg of iron	Triferic Avnu	Product discontinued; product discontinued per Orange Book
Q2017	Injection, teniposide, 50 mg	VUMON	Product discontinued; product discontinued per Orange Book
J3310	Injection, perphenazine, up to 5 mg		Not found in the Red Book
J1572	Injection, immune globulin, (flebogamma/flebogamma dif), intravenous, non-lyophilized (e.g., liquid), 500 mg	Flebogamma 5% DIF	Product discontinued
J0889	Daprodustat, oral, 1 mg, (for esrd on dialysis)	JESDUVROQ	Product discontinued
Q4106	Dermagraft, per square centimeter	DERMAGRAFT®	Product discontinued
J0172	Injection, aducanumab-avwa, 2 mg	Aduhelm	Product discontinued

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

HCPCS Code	Action	Long Descriptor
A9612	Add	Injection, fluorescein, 1 mg
J0163	Add	Injection, epinephrine in sodium chloride (endo), 0.1 mg
J0462	Add	Injection, atropine sulfate, not therapeutically equivalent to j0461, 0.01 mg
J0525	Add	Injection, cefotetan disodium, 10 mg
J0582	Add	Injection, bivalirudin (endo), not therapeutically equivalent to j0583, 1 mg
J0675	Add	Injection, carboprost tromethamine, 0.1 mg
J0759	Add	Injection, clevidipine butyrate, 1 mg
J1370	Add	Injection, esomeprazole sodium, 1 mg
J1807	Add	Injection, ethacrynate sodium, 1 mg
J1809	Add	Injection, fosdenopterin, 0.1 mg
J1834	Add	Injection, isoniazid, 1 mg
J2151	Add	Injection, mannitol, 250 mg
J2291	Add	Injection, nafcillin sodium (baxter), 20 mg
J3290	Add	Injection, tranexamic acid, 5 mg
J0013	Add	Esketamine, nasal spray, 1 mg
J0654	Add	Injection, liothyronine, 1 mcg
J1073	Add	Testosterone pellet, implant, 75 mg
J1837	Add	Injection, posaconazole, 1 mg
J2516	Add	Injection, pentamidine isethionate, 1 mg
J2711	Add	Injection, neostigmine methylsulfate 0.1 mg and glycopyrrolate 0.02 mg
J2596	Add	Injection, vasopressin (long grove), not therapeutically equivalent to j2598, 1 unit
J3290	Add	Injection, tranexamic acid in sodium chloride, 5 mg
J3376	Add	Injection, vancomycin hcl (hikma), not therapeutically equivalent to j3373, 10 mg
J3379	Add	Injection, valproate sodium, 5 mg
J3387	Add	Injection, elivaldogene autotemcel, per treatment
J7528	Add	Mycophenolate mofetil, for suspension, oral, 100 mg

Appendix C: DMEPOS Payment Categories

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

Pricing = 00 Service Not Separately Priced
Items or services described by the HCPCS Level II codes that are either not covered under Medicare Part B or for which payment is bundled into the payment some other Medicare service or procedure.

Pricing = 31 Frequently Serviced Items
Payment is generally made on a monthly rental fee schedule basis for items such as ventilators that require frequent and substantial servicing in order to avoid risk to the patient's health. Payment for E0935 is based on a daily rental fee schedule basis since coverage of this device is limited to 21 days.

Pricing = 32 Inexpensive and Other Routinely Purchased Items
Payment is made on a purchase or rental fee schedule basis. This category includes items that have a purchase price of $150 or less, were purchased 75 percent of the time or more from July 1986 through June 1987, or which are accessories used in conjunction with a nebulizer, aspirator, continuous airway pressure device, or respiratory assist device. The beneficiary has the option to acquire the item on a purchase or monthly rental basis. Total payments for the item cannot exceed the purchase fee schedule amount for the item.

Pricing = 33 Oxygen and Oxygen Equipment
Monthly fee schedule payments are made for furnishing oxygen and oxygen equipment. This monthly payment includes payment for all stationary oxygen equipment, supplies, and accessories and delivery of oxygen contents (stationary and portable). A monthly add-on to this payment is made for portable oxygen equipment only for those beneficiaries who require portable oxygen. The monthly payments for oxygen equipment cap after the 36th monthly payment is made, after which payment for the ongoing delivery of contents continues for gaseous or liquid systems.

Pricing = 34 Supplies Necessary for the Effective Use of DME
Payment is made on a purchase fee schedule basis for supplies necessary for the effective use of DME (e.g., lancets that draw blood for use in blood glucose monitor).

Pricing = 35 Surgical Dressings
Payment is made on a purchase fee schedule basis for surgical dressings.

Pricing = 36 Capped Rental Items
Payment is made on a monthly rental fee schedule basis. The beneficiary takes over ownership of the item after the 13th rental payment is made. The rental fee for capped rental items, other than power wheelchairs, for each of the first 3 months of rental is equal to 10 percent of the purchase fee for the item. The rental fee for months 4 through 13 is equal to 7.5 percent of the purchase fee for the item. The rental fee for power wheelchairs for each of the first 3 months of rental is equal to 15 percent of the purchase fee for the item. The rental fee

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

Pricing = 37 Ostomy, Tracheostomy and Urological Supplies
Payment is made on a purchase fee schedule basis for ostomy, tracheostomy and urological supplies.

Pricing = 38 Orthotics, Prosthetics, Prosthetic Devices, and Vision Services (Prosthetic Lenses)
Payment is made on a purchase fee schedule basis for orthotics, prosthetics, and prosthetic devices & lenses.

Pricing = 39 Parenteral and Enteral Nutrition (PEN)
Payment is made on a purchase fee schedule basis for parenteral and enteral nutrients and supplies. Payment is made on a purchase or rental fee schedule basis for parenteral and enteral equipment. The beneficiary has the option to acquire the item on a purchase or monthly rental basis.

Pricing = 40 Lymphedema Compression Treatment Items
Payment is made on a purchase basis for lymphedema compression treatment items.

Pricing = 45 Customized DME
Payment is made for lump-sum purchase of DME that meets the Medicare regulatory definition of customized DME at 42 CFR 414.224. The payment amount is based on the carrier's individual consideration of the item and judgment of a reasonable payment amount, which, at a minimum, includes a review of the costs of labor and material used in constructing the equipment.

Pricing = 46 Carrier Priced Item
The allowed payment amount for covered items is based on local carrier pricing (e.g., local fee schedule amounts or reasonable charges or other carrier pricing method.