E07DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Centers for Medicare & Medicaid Services' (CMS') Second Biannual 2024 Healthcare Common Procedure Coding System (HCPCS) Public Meeting Agenda

Zoom Meeting - Remote participation
Friday, November 8, 2024, 9:00 am – 5:00 pm, eastern time (ET)

8:45 am, ET:
• Zoom meeting login:
https://cms.zoomgov.com/j/1602260511?pwd=hoK9eXztvwuVhSHLLReBBaVnlwiuaC.1
• Passcode: 132470; Dial: 833 435 1820 US Toll Free; Webinar ID: 160 226 0511
• Individuals who plan to speak as a primary or 5-minute speaker must register by emailing HCPCS@cms.hhs.gov, by the published deadline. All attendees can access the virtual public meeting through the Zoom link above.

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

Provided for each agenda item is a written overview of the applicant's request, CMS' preliminary coding recommendation, as well as CMS' preliminary benefit category and payment determination, if applicable. Preliminary recommendations are not final or binding upon any payer 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 decisions are not made at the public meeting. CMS' final coding, benefit category, and payment decisions will be published on CMS' HCPCS website at: https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Prior-Years-CMS-HCPCSLevelII-Coding-Decisions-Narrative-Summary around January 2025 and will be effective April 1, 2025, unless otherwise specified.

This agenda includes a summary of each HCPCS Level II code application being presented on Friday, November 8, 2024. 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 decisions for the HCPCS Virtual Public Meeting on Friday, November 8, 2024.

Agenda Item # 1
Physiotrace Smart - HCP240606J8EVA

Topic/Issue

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

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

Summary of Applicant's Submission

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

CMS Preliminary HCPCS Coding Recommendation

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

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

The current Medicare policy and prior established benefit category determination for HCPCS Level II code A9279, “Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified” applies to this item.

Preliminary Medicare Payment Determination

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

No Medicare Payment. Pricing Indicator = 00

Agenda Item # 2
Firesafe Cannula Valve - HCP24042519Q9M

Topic/Issue

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

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

Summary of Applicant's Submission

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

CMS Preliminary HCPCS Coding Recommendation

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

Preliminary Medicare Benefit Category Determination

No Medicare DMEPOS benefit category.

Preliminary Medicare Payment Determination

No Medicare Payment. Pricing Indicator = 00

Agenda Item # 3
Portable Neuromodulation Stimulator (PoNS™) Controller - HCP2306299CNLN

Topic/Issue

Request for Medicare payment determination for Portable Neuromodulation Stimulator (PoNS™) Controller.

Summary of Applicant's Submission

Helius Medical Inc. submitted a request to establish a new HCPCS Level II code to identify Portable Neuromodulation Stimulator (PoNS™) controller. PoNS™ received the Food and Drug Administration's (FDA's) De Novo clearance on March 25, 2021. PoNS™ is a translingual, non-implantable tongue stimulator. The PoNS™ device provides therapy through two primary components: a controller and a mouthpiece. The controller is a programmable, electronic, durable medical device, when connected to the mouthpiece, orally generates electrical pulses for electrotactile stimulation of the nerves in the tongue. The controller generates and controls the delivery of electrotactile stimulation to the trigeminal and facial nerves through the mouthpiece while the individual is performing prescribed therapeutic exercises to directly activate brainstem areas and trigger neuroplastic changes in the brain (cerebral cortex) over a 14-week therapeutic period. The PoNS™ device is indicated for use as a short-term treatment of gait deficit due to mild to moderate symptoms of multiple sclerosis. The PoNS™ is used as an adjunct to a supervised therapeutic exercise program in patients 22 years of age and over. It is available by prescription only. The PoNS™ device is prescribed by a health care provider, typically a neurologist. The therapeutic exercise regimen is developed by a separate health care provider, typically a physical rehabilitation professional. The controller is packaged separately from the mouthpiece.

CMS HCPCS Coding Determination

CMS established a new HCPCS Level II code A4593, "Neuromodulation stimulator system, adjunct to rehabilitation therapy regime, controller" to describe Portable Neuromodulation Stimulator (PoNS™) Controller, effective April 1, 2024.

Medicare Benefit Category Determination

CMS determined that the PoNS™ Controller is DME, effective April 1, 2024.

Summary of Public Feedback

Helius Medical Inc. disagreed with CMS' published preliminary payment determination in the B1 2024 cycle and maintained that the Controller is not comparable to existing fee schedule items. The speaker said that the Controller generates and controls delivery of electrotactile stimulation to the trigeminal and facial nerve endings in the tongue, leading to neuromodulation in the brainstem, which triggers long-term neuroplastic changes that correlate with improvement in gait deficits. The speaker went on to say that the PoNS™ System does not stimulate muscles or nerve endings in muscles. The speaker also discussed a letter from the FDA dated September 20, 2022, that corrected the FDA's previous classification order, dated March 25, 2021, to correct the regulation name to more accurately

describe the target of the electrical stimulation provided by devices of this generic type. Per the letter, the "FDA identifies this generic type of device as: Electrical tongue nerve stimulator to treat motor deficits. An electrical tongue nerve stimulator to treat motor deficits is a prescription device that consists of a non-implantable apparatus to generate electrical pulses for stimulation of the nerves in the tongue to provide treatment of motor deficits." Thus, the FDA changed the regulation name for the PoNS™ from "Neuromuscular tongue stimulator to treat motor deficits" to "Electrical tongue nerve stimulator to treat motor deficits." The speaker also requested that CMS calculate the payment rate for the Controller based on gap-filling, using a starting price based on insurer claims and Veterans Administration (VA) fee schedule amounts of $16,499 - $16,554. The speaker stated that the $16,499 is from the VA fee schedule, and the $16,554 is from an insurer claim.

Preliminary Medicare Payment Determination

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

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

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

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

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

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

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

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

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

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

	Worn on the neck For short-term treatment of gait deficit due to mild to moderate symptoms from multiple sclerosis (MS)	To treat individuals with acute and chronic injuries and pain[1]
Additional Aspects and Features	Intensity of stimulation adjusted by the beneficiary Connects to the mouthpiece via an electrical cord	Intensity of stimulation adjusted by the beneficiary Connects to the electrode patches or garment via an electrical cord

Per this preliminary determination, the 2024 fee schedule amounts for new HCPCS Level II code A4593 would be based on the unadjusted purchase fee schedule amounts for HCPCS Level II code E0730 of approximately $495.03. As the purchase price for this item is greater than $150 in the base period, payment would be made on a capped rental basis in accordance with our regulations at 42 CFR 414.229, with the capped rental fee schedule amounts for months 1 thru 3 based on 10 percent of the purchase price and months 4 thru 13 based on 7.5 percent of the purchase price. Therefore, the monthly capped rental fee schedule amount for new HCPCS Level II code A4593 would be approximately $49.50 on average for months 1 through 3, and approximately $37.13 on average for months 4 through 13, resulting in a total capped payment of $519.80 should there be 13 months of continuous use. Fee schedules are updated annually.

Pricing Indicator = 36

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

Agenda Item # 4
VRTX - HCP240625VDHC7

Topic/Issue

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

The applicant did not submit any suggested language.

Summary of Applicant's Submission

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

CMS Preliminary HCPCS Coding Recommendation

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

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

Preliminary Medicare Benefit Category Determination

Back Brace.

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

Preliminary Medicare Payment Determination

In accordance with Medicare regulations at 42 CFR 414.238, fee schedule amounts for new HCPCS Level II codes for items and services without a fee schedule pricing history are established using existing fee schedule amounts for comparable items when items with existing fee schedule amounts are determined to be comparable to the new items and services based on a comparison of: physical components, mechanical components, electrical components, function and intended use, and additional attributes and features. As a result, the preliminary pricing methodology for new HCPCS Level II code LXXXX is to use the existing fee schedule amounts for comparable items described by HCPCS Level II code L0464 (“Tlso, triplanar control, modular segmented spinal system, four rigid plastic shells, posterior extends from sacrococcygeal junction and terminates just inferior to scapular spine, anterior extends from symphysis pubis to the sternal notch, soft liner, restricts gross trunk motion in sagittal, coronal, and transverse planes, lateral strength is provided by overlapping plastic and stabilizing closures, includes straps and closures, prefabricated, includes fitting and adjustment”) for the thoracic lumbar sacral orthosis portion of the CTLSO and HCPCS Level II code L0180 ("Cervical, multiple post collar, occipital/mandibular supports, adjustable") to account for the cervical collar portion of the CTLSO.

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

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

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

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

The 2024 average purchase fee schedule amount for HCPCS Level II code LXXXX would be approximately $2,201.41. The average fee schedule amount is the average of the 2024 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 38

Agenda Item # 5
Swedo-Step Smart Brace (2007.115) - HCP211020NP3A5

Topic/Issue

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

The applicant did not submit any suggested language.

Summary of Applicant's Submission

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

CMS Preliminary HCPCS Coding Recommendation

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

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

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

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

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

Preliminary Medicare Benefit Category Determination

Leg Brace.

The application supports a preliminary benefit category determination that the Swedo-Step Smart Brace is used as a lower extremity brace and would fall under the Medicare benefit for leg brace. Section 130 of Chapter 15 of the Medicare Benefit Policy Manual (CMS Pub. 100-02) states that braces are covered under Medicare Part B when furnished incident to physicians' services or on a physician's order. This section of the Manual defines a brace as a rigid or semi-rigid device used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body. This definition is also in Medicare regulations at 42 CFR 410.2. The Swedo-Step Smart Brace is a rigid device that is used to control drop foot and to mitigate shock absorption dynamics at the initial contact and loading response of stance phase.

Preliminary Medicare Payment Determination

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

The average fee schedule amount is the average of the 2024 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 38

Agenda Item # 6
Power Knee™ - HCP2406216Y4P8

Topic/Issue

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

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

Summary of Applicant's Submission

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

CMS Preliminary HCPCS Coding Recommendation

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

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

Preliminary Medicare Benefit Category Determination

Artificial Leg.

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

Preliminary Medicare Payment Determination

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

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

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

Additional Aspects and Features	NA	NA	NA

Based on this preliminary determination, the average 2024 fee schedule amount for HCPCS Level II code LXXXX would be based on the sum of the purchase fee schedule amounts for HCPCS Level II codes L5828, L5845 and L5848 of approximately $7,072.52 on average. As stated in the CMS Preliminary HCPCS Coding Recommendation, LXXXX would be used in conjunction with existing HCPCS Level II codes L5859 and L5856 to describe the Power Knee™

The average fee schedule amount is the average of the 2024 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 38

Agenda Item # 7
Static Progressive Stretching Finger Device - HCP220222U1GRE

Topic/Issue

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

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

Summary of Applicant's Submission

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

CMS Preliminary HCPCS Coding Recommendation

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

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

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

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

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

All five of these conditions must be met in order for equipment to be classified as DME.

We believe that there is currently one product that would fall under new HCPCS Level II code EXXXX and that is the EZ Turnbuckle Finger Orthosis, which is manufactured by Joint

Active Systems (JAS) Inc. The Pricing, Data Analysis and Coding (PDAC) contractor has code verified this product under HCPCS Level II code E1399. Our preliminary HCPCS coding recommendation would assign this product to newly established HCPCS Level II code EXXXX.

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

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

With regard to the device's durability, our assessment of the JAS's EZ product line is that its features and functions are similar/same to the JAS's original SPS line, which have met our 3-year minimum lifetime requirement. The JAS EZ product line is made of a thermoplastic alternative to that of a metal frame design. Based on our understanding of thermoplastics, and the rigidity of the devices themselves, they are durable and exceed the 3-year minimum lifetime requirement.[2]

Preliminary Medicare Payment Determination

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

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

Although they have different designs and mechanisms of action, both devices promote the extension and flexion of joints, whether they are for fingers or toes. Essentially, both provide a stretching effect on the phalanges of the toes and fingers. While their features may differ, their functions are quite similar. This comparability is also supported by the fact that the

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

dynamic splint fee schedule amounts for the finger (HCPCS Level II code E1825) and toe (HCPCS Level II code E1830) devices are the same.

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

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

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

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

	EXXXX	**E1831**
Physical Components	Hand and finger splint (frame) Turnbuckle Cuffs Straps	Air bag Straps Rigid frame
Mechanical Components	NA	Air bladder
Electrical Components	NA	NA

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

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

Pricing Indicator = 36

Agenda Item # 8
Partial Hand and Finger Prostheses - HCP240701W4N75

Topic/Issue

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

Applicant's suggested language:

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

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

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

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

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

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

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

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

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

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

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

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

Summary of Applicant's Submission

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

CMS Preliminary HCPCS Coding Recommendation

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

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

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

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

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

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

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

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

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

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

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

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

Preliminary Medicare Benefit Category Determination

Artificial Arm.

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

Preliminary Medicare Payment Determination

No determination.

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

Walkasins® Lower Extremity Sensory Prosthesis – HCP230630P62DH

Topic/Issue

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

Summary of Applicant's Submission

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

CMS Final HCPCS Coding Decision

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

Medicare Benefit Category Determination

CMS determined that Walkasins® lower extremity sensory prosthesis is a Prosthetic Device, effective October 1, 2024.

Preliminary Medicare Payment Determination

In accordance with Medicare regulations at 42 CFR 414.238, fee schedule amounts for new HCPCS Level II codes for items and services without a fee schedule pricing history are established using existing fee schedule amounts for comparable items when items with existing fee schedule amounts are determined to be comparable to the new items and services based on a comparison of: physical components, mechanical components, electrical

components, function and intended use, and additional attributes and features. In determining whether the device described by this code are comparable to items with existing codes and fee schedule amounts, we undertook a detailed examination of the physical, mechanical, and electrical components along with the function and intended use, in comparison with HCPCS Level II code E0734, “external upper limb tremor stimulator of the peripheral nerves of the wrist”. See table below.

The device named Cala kIQ™ (formerly known as CalaTrio™) is coded under HCPCS Level II code E0734.We do not think that they are comparable given the significant differences in their technologies and functions. In particular, Cala kIQ™ employs transcutaneous afferent patterned stimulation (TAPS) and uses triaxial accelerometers to measure tremor. The device then adjusts the stimulation pattern based on this data. It operates on a biphasic waveform, delivering rectangular pulses at 150 Hz with a 300 μs pulse width and a 50 μs interpulse period, alternating between the median and radial nerves to match the tremor frequency. In contrast, Walkasins® uses mechanical tactile stimulation to target the plantar mechanoreceptors in the feet. It features sensors embedded in the soles to detect changes in foot pressure and maintain balance. Walkasins® operates on a monophasic waveform, providing tactile stimuli at a frequency similar to a 128 Hz tuning fork. Unlike Cala kIQ™, Walkasins® does not use triaxial accelerometers but instead focuses on replacing lost mechanoreceptor function to aid in gait and balance.

In addition, Cala kIQ™ utilizes TAPS, a non-invasive neuromodulation therapy designed for treating hand tremors in individuals with essential tremor. This FDA-cleared, wrist-worn neurostimulation device customizes stimulation based on each individual’s unique physiology, delivering alternating signals to the median and radial peripheral nerves. In contrast, Walkasins® provides afferent nerve stimulation aimed at addressing peripheral neuropathy. It focuses on replacing the ability to sense and communicate critical plantar pressure information needed for gait and balance. Unlike Cala kIQ™, Walkasins® does not alternate stimulation signals between different nerves. Instead, it aims to compensate for lost plantar mechanoreceptor function.

While both Walkasins® and Cala kIQ™ are non-invasive and use advanced technology to assist in sensorimotor control, their approaches are fundamentally different. Walkasins® is tailored to enhance lower limb sensory feedback and balance in individuals with peripheral neuropathy, whereas Cala kIQ™ is designed to modulate neural activity in the upper limbs to alleviate hand tremors associated with essential tremor.

Regarding their technology, Walkasins® utilizes pressure sensors integrated into the insoles of footwear to monitor and respond to variations in foot pressure. This setup allows the device to provide feedback that helps with balance and gait. On the other hand, Cala kIQ™ employs electrodes placed on the wrist to deliver electrical stimulation directly to the peripheral nerves, targeting tremor control.

The fundamental differences in their mechanisms, therapeutic goals, and technological approaches emphasize the necessity of a thorough evaluation when assessing their effectiveness and appropriateness for their specific conditions. Each device's unique method of intervention highlights the need for careful consideration to determine which is more suitable for addressing the distinct issues faced by their respective individual populations.

For these reasons, we have determined that no items described by HCPCS Level II codes with existing fee schedule amounts are comparable to HCPCS Level II code E0734 and it is most appropriate to determine the Medicare payment amount in accordance with the "gap filling" procedure outlined in 42 CFR 414.238(c).

	L8720	**E0734**
Physical Components	Haptic module worn around the ankle Charging adapter and cable	Stimulator AC-powered base station
Mechanical Components	-	Tri-axial accelerometer
Electrical Components	Monophasic wave Vibrotactile stimulation Lithium-Ion rechargeable battery	Biphasic waveform On-board motion sensors on the stimulator Lithium-Ion rechargeable battery
Function and Intended Use	Delivers mechanical tactile stimulation with the intent to naturally stimulate intact mechanoreceptors above the ankle while avoiding sensation adaptation effects (no numbing) To treat various types of peripheral neuropathy and gait and standing imbalance	Delivers transcutaneous afferent patterned stimulation (TAPS) for hand tremors in essential tremor individuals The Cala kIQ™ stimulator is attached to the wrist band, which includes integrated electrodes placed at appropriate intervals around the inner diameter of the band to properly target the median and radial nerves. To aid in the temporary relief of hand tremors in adults with essential tremor.
Additional Aspects and Features	10-week treatment Used as needed by the individual	2-week treatment with at least 5 sessions Used as needed by the individual

In accordance with regulations at 42 CFR 414.238(c), items and services described by new HCPCS Level II codes that do not have a fee schedule pricing history and that are not comparable to items and services with existing fee schedule amounts may be established using supplier price lists, including catalogs and other retail price lists (such as internet retail prices) that provide information on commercial pricing for the item. Potential appropriate sources for such commercial pricing information can also include payments made by Medicare Advantage plans, as well as verifiable information from supplier invoices and non-Medicare payer data. If the only available price information is from a period other than the fee schedule base period, deflation factors are applied against current pricing in order to approximate the base period price. The annual deflation factors are specified in program instructions (Medicare Claims Processing Manual, Chapter 23, Section 60.3) and the deflated amounts are then increased by the update factors also listed in these program instructions.

The applicant has sent us several invoices for the Walkasins® Lower Extremity Sensory Prosthesis. These invoices are mainly from VA locations across the country, as well as some invoices from individuals who self-pay for the device. The median invoice price is $2,485 for

each unit (one unit being one Walkasins® Lower Extremity Sensory Prosthesis, per leg). The applicant has also informed us that the supplier retail price is $3,350 for each unit. However, we have not received any invoices from the applicant showing that this amount has been paid. Therefore, we will not be including this $3,350 amount in our median calculation.

In accordance with regulations at 42 CFR 414.238(c), $2,485 is deflated to the 1986 fee schedule base period using the percentage change in the consumer price index for all urban consumers (CPI-U) from the mid-point of the year the prices are in effect to the mid-point of the fee schedule base period. The price is then updated to the current year using the covered item update factors specified in program instructions (Medicare Claims Processing Manual, Chapter 23, Section 60.3). After applying the annual deflation and update factors, the 2024 payment amount for HCPCS Level II code L8720 would be approximately $1,667.29. It is our understanding that when a Walkasins® Lower Extremity Sensory Prosthesis is furnished it also includes a Walkasins® Receptor Sole. As such, HCPCS Level II code L8720 includes payment for one Walkasins® Receptor Sole.

Pricing Indicator = 38

Agenda Item # 9
Walkasins® Receptor Sole - HCP230630JGDD5

Topic/Issue

Request for Medicare payment determination for Walkasins® receptor sole.

Summary of Applicant's Submission

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

CMS Final HCPCS Coding Decision

CMS established HCPCS Level II code L8721, “Receptor sole for use with L8720, replacement, each” to describe Walkasins® receptor sole, effective October 1, 2024.

Medicare Benefit Category Determination

CMS determined that Walkasins® receptor sole is an accessory for a prosthetic device, effective October 1, 2024.

Preliminary Medicare Payment Determination

In accordance with Medicare regulations at 42 CFR 414.238, fee schedule amounts for new HCPCS Level II codes for items and services without a fee schedule pricing history are established using existing fee schedule amounts for comparable items when items with existing fee schedule amounts are determined to be comparable to the new items and services based on a comparison of: physical components, mechanical components, electrical components, function and intended use, and additional attributes and features. In determining whether the device described by this code are comparable to items with existing codes and fee schedule amounts, we undertook a detailed examination of the physical, mechanical, and electrical components along with the function and intended use, in comparison with HCPCS Level II code A4542, "supplies and accessories for external upper limb tremor stimulator of the peripheral nerves of the wrist." See table below.

The wrist worn connector for the device named Cala kIQ™ (formerly known as CalaTrio) is coded under HCPCS Level II code A4542. In sum, the two systems are designed to trigger different types of sensory receptors, which implies that they deliver different forms of stimulation. The mechanisms for how each system delivers frequencies also differ. These variations suggest that their approaches to stimulation are not directly comparable. While both hand tremors and gait imbalance are neurological disorders, they do not necessarily require the same type of intervention or follow the same treatment protocols. For these reasons, we have determined it is most appropriate to determine the Medicare payment amount in accordance with the "gap filling" procedure outlined in 42 CFR 414.238(c).

	L8721	**A4542**
Physical Components	Plantar pressure sensor	Wrist-worn band
Mechanical Components	-	-
Electrical Components	Force Sensor resistors	Three electrodes embedded in the wrist-worn band
Function and Intended Use	Detect pressure information from the bottom of the feet that is no longer detected by the damaged plantar mechanoreceptors. This information is analyzed and transmitted via the connection between the Receptor Sole and the Haptic Module which then stimulates a different set of healthy mechanoreceptors around/above the ankle. Through a proprietary algorithm, vibration stimuli communicate the lost plantar pressure information to the central nervous system. Receptor sole is placed under the foot	Applies transcutaneous afferent patterned stimulation (TAPS) to the median and radial nerves of an individual's wrist on the wrist band The stimulation delivery and device operation are managed through the embedded firmware control. The electrode band is worn around the wrist Indicated to aid in the temporary relief of hand tremors in adults with essential tremor. Intended to properly target the median and radial nerves through integrated electrodes placed at appropriate

	Indicated for individuals with lower limb sensory peripheral neuropathy who present with gait and balance impairments Intended to replace part of nerve function used for detection and signaling of foot pressure sensation	intervals around the inner diameter of the band
Additional Aspects and Features	Disposable pressure sensors Sole receptor is available in one size	Disposable electrodes Biocompatible wrist band Wrist band is available in different sizes (small, medium, and large) Wrist bands are available in right- or left-handed version

In accordance with regulations at 42 CFR 414.238(c), items and services described by new HCPCS Level II codes that do not have a fee schedule pricing history and that are not comparable to items and services with existing fee schedule amounts may be established using supplier price lists, including catalogs and other retail price lists (such as internet retail prices) that provide information on commercial pricing for the item. Potential appropriate sources for such commercial pricing information can also include payments made by Medicare Advantage plans, as well as verifiable information from supplier invoices and non-Medicare payer data. If the only available price information is from a period other than the fee schedule base period, deflation factors are applied against current pricing in order to approximate the base period price. The annual deflation factors are specified in program instructions (Medicare Claims Processing Manual, Chapter 23, Section 60.3) and the deflated amounts are then increased by the update factors also listed in these program instructions.

To develop an appropriate Medicare payment amount in accordance with the "gap filling" procedure, we must identify appropriate commercial pricing for the underlying items. We emphasize that a Manufacturer Suggested Retail Price (MSRP) is not, by itself, an adequate source of commercial pricing. Only verifiable supplier or commercial pricing may be used for gap-filling purposes (84 FR 60739).

The applicant has sent us several invoices for the Walkasins® Receptor Sole. These invoices are mainly from VA locations across the country, as well one invoice from an individual who self-paid for the Walkasins® Receptor Sole. The median invoice price is $220 for each Walkasins® Receptor Sole.

In accordance with regulations at 42 CFR 414.238(c), $220 is deflated to the 1986 fee schedule base period using the percentage change in the consumer price index for all urban consumers (CPI-U) from the mid-point of the year the prices are in effect to the mid-point of the fee schedule base period. The price is then updated to the current year using the covered item update factors specified in program instructions (Medicare Claims Processing Manual, Chapter 23, Section 60.3). After applying the annual deflation and update factors, the 2024 payment amount for HCPCS Level II code L8721 would be approximately $147.59.

It is our understanding that when a Walkasins® Lower Extremity Sensory Prosthesis is furnished it also includes a Walkasins® Receptor Sole. As such, HCPCS Level II code L8721 is only for the replacement of a Walkasins® Receptor Sole.

Pricing Indicator = 38

Agenda Item # 10
Breast Prosthesis, Mastectomy Sleeve - IHC2407191WHRL

Topic/Issue

Discontinue existing HCPCS Level II code L8010, "Breast prosthesis, mastectomy sleeve."

Summary of Applicant's Submission

Medicare pays for lymphedema compression treatment items under the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) benefit for individuals with Medicare Part B. The lymphedema compression treatment items benefit category is defined in section 1861(s)(2)(JJ) of the Social Security Act, and further defined in Medicare regulations at 42 Code of Federal Regulations (CFR) 410.36(a)(4). When defining the scope of this benefit category in rulemaking (CMS-1780-F), CMS received public input suggesting deletion of HCPCS Level II code L8010, "Breast prosthesis, mastectomy sleeve" and CMS indicated that proposal would be taken into consideration at a future date.

CMS Preliminary HCPCS Coding Recommendation

After further consideration of the public input received when defining the scope of this benefit category in rulemaking (CMS-1780-F), CMS is now recommending that this code be removed from the HCPCS Level II code set. As such, CMS is proposing to:

Discontinue existing HCPCS Level II code L8010, "Breast prosthesis, mastectomy sleeve" as there are other HCPCS Level II codes that should be used in its place. Existing HCPCS Level II codes A6576, A6577, or A6578 can instead be used in place of HCPCS Level II code L8010.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

As discussed in the CMS Preliminary HCPCS Coding Recommendation, HCPCS Level II codes A6576, A6577, or A6578 can be used in place of HCPCS Level II code L8010.

The payment rules and pricing associated with existing HCPCS Level II codes A6576, A6577, and A6578 apply to this product, if covered. The current average 2024 fee schedule amount for HCPCS Level II code A6576 is $184.50. The current average 2024 fee schedule amount for HCPCS Level II code A6577 is $152.70. The current average 2024 fee schedule amount for HCPCS Level II code A6578 is $75.20.

The average fee schedule amount is the average of the 2024 fee schedule amounts for the code for each of the 50 states, Washington D.C., Puerto Rico, and the Virgin Islands. Fee schedules are updated annually.

Pricing Indicator = 40

Agenda Item # 11
Gradient Compression Nighttime Garment, Not Otherwise Specified - HCP2406275UFBP

Topic/Issue

Request to establish a new HCPCS Level II code to identify a not otherwise classified (NOC) code for a nighttime gradient compression garment.

Applicant's suggested language: XXXXX, "Gradient compression garment, not otherwise specified, padded, for nighttime use, each"

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code to identify a NOC code for a nighttime gradient compression garment. Nighttime garments are manufactured to incorporate a textured surface against the skin, which is achieved in a few different formats based on current technology on the market, such as: chip foam, flat foam, channel foam, polyfill, and 3D knit structure. These garments are primarily cut or knit to size, filled with texture-based solution/knit with texture, and lastly sewn. Many of them also integrate built-in directional channeling based on the lymphatic pathways. Nighttime garments have the unique ability to maintain lymphedema safely overnight / during low activity with its lower levels of compression and containment based on medium-stretch fabric properties. Additionally, its textured surface provides a unique pressure differential on the tissue with high and low pressures designed to help stimulate the tissue, break up and soften fibrosis and support long term tissue health for lymphedema. A NOC nighttime HCPCS Level II code would allow for submission of claims for nighttime products that do not fall within the existing HCPCS Level II codes (e.g., head and neck, torso, genital). The addition of a nighttime specific NOC HCPCS Level II code would also aid in the prevention of unintentional denials or overlap with HCPCS Level II code A6549, "Gradient compression garment, not otherwise specified," which would be utilized for daytime products. Without delineation between daytime and nighttime for NOC codes, it will be difficult to track and respond to claims for the two different quantity and replacement frequency allotments per individual.

CMS Preliminary HCPCS Coding Recommendation

The applicant has requested a new HCPCS Level II code (gradient compression garment, not otherwise specified, padded for nighttime use, each), because the existing nighttime HCPCS Level II code set is limited to codes for limbs and a bra. The applicant has explained that a not otherwise specified HCPCS Level II code is necessary to allow for submission of claims for nighttime products that do not fall within the published HCPCS Level II codes for nighttime garments (e.g., head and neck, torso, genital).

Currently, HCPCS Level II code A6549 was intended for use for daytime and nighttime garments. However, we agree with adding a new "not otherwise specified" code for nighttime gradient compression garments given that utilization limits for nighttime garments are different than for daytime garments. However, we have not included the requested word "padded" to achieve the requested effect, e.g., create a not otherwise specified code for nighttime garments to differentiate from the existing not otherwise specified code for daytime

garments. We are also revising existing HCPCS Level II code A6549 to be clear that it would not be intended for use with daytime garments. As such, CMS is proposing to:

1. Establish new HCPCS Level II code AXXXX, "Gradient compression garment, not otherwise specified, for nighttime use, each" to describe a nighttime gradient compression garment.

2. Revise HCPCS Level II code A6549, "Gradient compression garment, not otherwise specified" to instead read "Gradient compression garment, not otherwise specified, for daytime use, each" to describe a daytime gradient compression garment.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for claims submitted using HCPCS Level II "Not Otherwise Specified" codes are made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Agenda Item # 11
Gradient Compression Wrap Below Knee - HCP240625X0PEW

Topic/Issue

Request to revise existing HCPCS Level II code A6583, “Gradient compression wrap with adjustable straps, below knee, 30-50 mmhg, each” to remove “30-50 mmhg.”

Applicant's suggested language: A6583, "Gradient compression wrap with adjustable straps, Below Knee, each"

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to revise existing HCPCS Level II code A6583 to remove “30-50 mmHg.” The current long description of existing HCPCS Level II code A6583 includes “30-50 mmhg”, however, due to the variations in levels of adjustability and to align language with the other adjustable wrap codes that do not specify mmHg, the code language should be revised. Gradient compression wraps with adjustable straps are uniquely constructed from multiple layers of textiles that are sewn, laminated or bonded together to create a fabric that has minimal stretch (inelastic) and high rigidity. The textiles may include but are not limited to nylon, foam, and textured fabric delivering the highest stiffness/containment compared to other compression garments. These garments use clasps or hook and loop closures to enable adjustability providing greater independence, adherence, and efficacy for individual management of their lymphedema symptoms. HCPCS Level II code A6583 maintained the 30-50 mmHg language from the pre-existing surgical dressing HCPCS Level II code A6545. A revised description is necessary for proper product selection to effectively manage an individual’s lymphedema and to align with the other gradient compression wrap with adjustable straps HCPCS Level II codes that do not specify mmHg.

CMS Preliminary HCPCS Coding Recommendation

CMS agrees with the request to remove the “30-50 mmhg” portion of the description for HCPCS Level II code A6583 so that it aligns with the other gradient compression wrap with adjustable wrap HCPCS Level II codes that do not specify mmHg. As such, CMS is proposing to:

Revise existing HCPCS Level II code A6583, “Gradient compression wrap with adjustable straps, below knee, 30-50 mmhg, each” to instead read “Gradient compression wrap with adjustable straps, below knee, each” to describe below knee gradient compression wraps.

Preliminary Medicare Benefit Category Determination

The current Medicare policy and prior established benefit category determination for HCPCS Level II code A6583 applies.

Preliminary Medicare Payment Determination

The payment rules and pricing associated with the existing HCPCS Level II code A6583 apply to this product, if covered. Fee schedules are updated annually. Pricing Indicator = 40

Agenda Item # 11
Gradient Compression Custom Wrap Above Knee - HCP240626P6WKG

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression custom wrap for above the knee.

Applicant's suggested language: XXXXX, “Gradient compression wrap with adjustable straps, Above Knee, each, custom”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression custom wrap for above knee. The proposed code is necessary to recognize the specific textile/technology, precise anatomical location of lymphedema, and custom version of the product. Adjustable wrap items are uniquely constructed from multiple layers of textiles that are sewn, laminated or bonded together to create a fabric that has minimal stretch (inelastic) and high rigidity. The textiles may include but are not limited to nylon, foam, and textured fabric delivering the highest stiffness/containment compared to other compression garments. These garments use clasps or hook and loop closures to enable adjustability providing greater patient independence, adherence, and efficacy. The Lymphedema Treatment Act amended title XVIII of the Social Security Act to provide coverage of certain lymphedema compression treatment items under Medicare. The term ‘lymphedema compression treatment items’ means standard and custom fitted gradient compression garments determined to serve a medical purpose and for the treatment of lymphedema.

CMS Preliminary HCPCS Coding Recommendation

CMS has generally created custom made and corresponding non-custom-made codes for lymphedema compression treatment items in the HCPCS Level II code set. We understand that lymphedema compression treatment items can come in both standard and custom-fitted form, and that there are distinct differences between the two. CMS described these differences in the Background section of the 2023 Lymphedema Compression Treatment Items Rule (88 FR 77812), “Standard compression garments are also referred to as ready-made or ready-to wear and are widely available pre-made, off-the-shelf and in a range of standard sizes;” and, “Custom-fit gradient compression garments are garments that are uniquely sized, shaped, and custom made to fit the exact dimensions of the affected extremity (circumferential measurements are every 1 and a half to 2 inches) and provide more accurate and consistent gradient compression to manage the individual’s symptoms.” Given these distinct differences CMS agrees with the request to create a new HCPCS Level II code. This code request is for a custom-made equivalent code to correspond with the non-custom HCPCS Level II code A6585. As such, CMS is proposing to:

Establish a new HCPCS Level II code AXXXX, “Gradient compression wrap with adjustable straps, above knee, each, custom” to describe custom above knee gradient compression wraps.

In addition, we would revise the description for HCPCS Level II code A6585 to replace the word “pressure” with “compression” so that the description is more consistent with the HCPCS Level II code descriptions used for lymphedema compression treatment items. CMS is also proposing to:

Revise existing HCPCS Level II code A6585, “Gradient pressure wrap with adjustable straps, above knee, each” to instead read “Gradient compression wrap with adjustable straps, above knee, each” to describe above knee gradient compression wraps.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

Section 1834(z)(1) of the Social Security Act mandates an appropriate payment basis for lymphedema compression treatment items defined in section 1861(mmm) of the Act and specifically identifies payment rates from other government and private sector payers that may be taken into account in establishing the payment basis for these items. These sources include payment rates used by Medicaid state plans, the Veterans Health Administration (VHA), group health plans, and health insurance coverage (as defined in section 2791 of the Public Health Service Act). Section 1834(z)(1) of the Act also indicates that other information determined to be appropriate may be taken into account in establishing the payment basis for lymphedema compression treatment items.

In accordance with 42 CFR 414.1650(b), and as discussed in our CY 2024 rule (88 FR 77831), where Medicaid state plan payment amounts are available for a lymphedema compression treatment item, we set payment amounts at 120 percent of the average of the Medicaid payment amounts for the lymphedema compression treatment item. Where Medicaid payment amounts are not available for an item, we set payment amounts at 100 percent of the average of internet retail prices and payment amounts for that item from TRICARE. Where payment amounts are not available from Medicaid state plans or TRICARE for a given lymphedema compression treatment item, we base payment amounts based on 100 percent of average internet retail prices for that item.

We discussed in our CY 2024 rule (88 FR 77832) that when new items are added to this Lymphedema Compression Treatment Item benefit category, the data sources (Medicaid, TRICARE, VHA, or internet prices) may not initially be available for establishing an appropriate payment amount. We said that in this situation, until the data necessary for establishing the payment amount becomes available, the DME MACs would consider what an appropriate payment amount would be for each item on an individual, claim-by-claim basis and may consider using pricing for similar items that already have established payment amounts.

We have not been able to identify payment amounts from any of the data sources (Medicaid, TRICARE, VHA, or internet prices). As such, claims for new HCPCS Level II code AXXXX will be priced by the DME MACs on a claim-by-claim basis.

Pricing Indicator = 46

Agenda Item # 11
Gradient Compression Custom Wrap Arm - HCP240626R5DGX

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression custom wrap for the arm.

Applicant's suggested language: XXXXX, "Gradient compression wrap with adjustable straps, Arm, each, custom"

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression custom wrap for the arm. The proposed code is necessary to recognize the specific textile/technology, precise anatomical location of lymphedema, and specification of customization. Adjustable wrap items are uniquely constructed from multiple layers of textiles that are sewn, laminated or bonded together to create a fabric that has minimal stretch (inelastic) and high rigidity. The textiles may include but are not limited to nylon, foam, and textured fabric delivering the highest stiffness/containment compared to other compression garments. These garments use clasps and hook and loop closures to enable adjustability providing greater patient independence, adherence, and efficacy. The Lymphedema Treatment Act amended title XVIII of the Social Security Act to provide coverage of certain lymphedema compression treatment items under Medicare. The term 'lymphedema compression treatment items' means standard and custom fitted gradient compression garments determined to serve a medical purpose and for the treatment of lymphedema.

CMS Preliminary HCPCS Coding Recommendation

CMS has generally created custom made and corresponding non-custom-made codes for lymphedema compression treatment items in the HCPCS Level II code set. We understand that lymphedema compression treatment items can come in both standard and custom-fitted form, and that there are distinct differences between the two. CMS described these differences in the Background section of the 2023 Lymphedema Compression Treatment Items Rule (88 FR 77812), "Standard compression garments are also referred to as ready-made or ready-to wear and are widely available pre-made, off-the-shelf and in a range of standard sizes;" and, "Custom-fit gradient compression garments are garments that are uniquely sized, shaped, and custom made to fit the exact dimensions of the affected extremity (circumferential measurements are every 1 and a half to 2 inches) and provide more accurate and consistent gradient compression to manage the individual's symptoms." Given these distinct differences CMS agrees with the request to create a new HCPCS Level II code. This code request is for a custom-made equivalent code to correspond with the non-custom HCPCS Level II code A6588. As such, CMS is proposing to:

Establish a new HCPCS Level II code AXXXX, "Gradient compression wrap with adjustable straps, arm, each, custom" to describe custom arm gradient compression wraps.

In addition, we would revise the description for HCPCS Level II code A6588 to replace the word "pressure" with "compression" so that the description is more consistent with the

HCPCS Level II code descriptions used for lymphedema compression treatment items. CMS is also proposing to:

Revise existing HCPCS Level II code A6588, “Gradient pressure wrap with adjustable straps, arm, each” to instead read “Gradient compression wrap with adjustable straps, arm, each” o describe arm gradient compression wraps.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

Section 1834(z)(1) of the Social Security Act mandates an appropriate payment basis for lymphedema compression treatment items defined in section 1861(mmm) of the Act and specifically identifies payment rates from other government and private sector payers that may be taken into account in establishing the payment basis for these items. These sources include payment rates used by Medicaid state plans, the Veterans Health Administration (VHA), group health plans, and health insurance coverage (as defined in section 2791 of the Public Health Service Act). Section 1834(z)(1) of the Act also indicates that other information determined to be appropriate may be taken into account in establishing the payment basis for lymphedema compression treatment items.

In accordance with 42 CFR 414.1650(b), and as discussed in our CY 2024 rule (88 FR 77831), where Medicaid state plan payment amounts are available for a lymphedema compression treatment item, we set payment amounts at 120 percent of the average of the Medicaid payment amounts for the lymphedema compression treatment item. Where Medicaid payment amounts are not available for an item, we set payment amounts at 100 percent of the average of internet retail prices and payment amounts for that item from TRICARE. Where payment amounts are not available from Medicaid state plans or TRICARE for a given lymphedema compression treatment item, we base payment amounts based on 100 percent of average internet retail prices for that item.

We discussed in our CY 2024 rule (88 FR 77832) that when new items are added to this Lymphedema Compression Treatment Item benefit category, the data sources (Medicaid, TRICARE, VHA, or internet prices) may not initially be available for establishing an appropriate payment amount. We said that in this situation, until the data necessary for establishing the payment amount becomes available, the DME MACs would consider what an appropriate payment amount would be for each item on an individual, claim-by-claim basis and may consider using pricing for similar items that already have established payment amounts.

We have not been able to identify payment amounts from any of the data sources (Medicaid, TRICARE, VHA, or internet prices). As such, claims for new HCPCS Level II code AXXXX will be priced by the DME MACs on a claim-by-claim basis.

Pricing Indicator = 46

Agenda Item # 11
Gradient Compression Custom Wrap Below Knee - HCP240626KQ3P4

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression custom wrap for below the knee.

Applicant's suggested language: XXXXX, "Gradient compression wrap with adjustable straps, Below Knee, each, custom"

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression custom wrap for below the knee. The proposed code is necessary to recognize the specific textile/technology, precise anatomical location of lymphedema, and custom version of the product. Adjustable wrap items are uniquely constructed from multiple layers of textiles that are sewn, laminated or bonded together to create a fabric that has minimal stretch (inelastic) and high rigidity. The textiles may include but are not limited to nylon, foam, and textured fabric delivering the highest stiffness/containment compared to other compression garments. These garments use clasps or hook and loop closures to enable adjustability providing greater patient independence, adherence, and efficacy. The Lymphedema Treatment Act amended title XVIII of the Social Security Act to provide coverage of certain lymphedema compression treatment items under Medicare. The term 'lymphedema compression treatment items' means standard and custom fitted gradient compression garments determined to serve a medical purpose and for the treatment of lymphedema.

CMS Preliminary HCPCS Coding Recommendation

CMS has generally created custom made and corresponding non-custom-made codes for lymphedema compression treatment items in the HCPCS Level II code set. We understand that lymphedema compression treatment items can come in both standard and custom-fitted form, and that there are distinct differences between the two. CMS described these differences in the Background section of the 2023 Lymphedema Compression Treatment Items Rule (88 FR 77812), "Standard compression garments are also referred to as ready-made or ready-to wear and are widely available pre-made, off-the-shelf and in a range of standard sizes;" and, "Custom-fit gradient compression garments are garments that are uniquely sized, shaped, and custom made to fit the exact dimensions of the affected extremity (circumferential measurements are every 1 and a half to 2 inches) and provide more accurate and consistent gradient compression to manage the individual's symptoms." Given these distinct differences CMS agrees with the request to create a new HCPCS Level II code. This code request is for a custom-made equivalent code to correspond with the non-custom HCPCS Level II code A6583. As such, CMS is proposing to:

Establish a new HCPCS Level II code AXXXX, "Gradient compression wrap with adjustable straps, below knee, each, custom" to describe custom below knee gradient compression wraps.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

Section 1834(z)(1) of the Social Security Act mandates an appropriate payment basis for lymphedema compression treatment items defined in section 1861(mmm) of the Act and specifically identifies payment rates from other government and private sector payers that may be taken into account in establishing the payment basis for these items. These sources include payment rates used by Medicaid state plans, the Veterans Health Administration (VHA), group health plans, and health insurance coverage (as defined in section 2791 of the Public Health Service Act). Section 1834(z)(1) of the Act also indicates that other information determined to be appropriate may be taken into account in establishing the payment basis for lymphedema compression treatment items.

In accordance with 42 CFR 414.1650(b), and as discussed in our CY 2024 rule (88 FR 77831), where Medicaid state plan payment amounts are available for a lymphedema compression treatment item, we set payment amounts at 120 percent of the average of the Medicaid payment amounts for the lymphedema compression treatment item. Where Medicaid payment amounts are not available for an item, we set payment amounts at 100 percent of the average of internet retail prices and payment amounts for that item from TRICARE. Where payment amounts are not available from Medicaid state plans or TRICARE for a given lymphedema compression treatment item, we base payment amounts based on 100 percent of average internet retail prices for that item.

We discussed in our CY 2024 rule (88 FR 77832) that when new items are added to this Lymphedema Compression Treatment Item benefit category, the data sources (Medicaid, TRICARE, VHA, or internet prices) may not initially be available for establishing an appropriate payment amount. We said that in this situation, until the data necessary for establishing the payment amount becomes available, the DME MACs would consider what an appropriate payment amount would be for each item on an individual, claim-by-claim basis and may consider using pricing for similar items that already have established payment amounts.

We have not been able to identify payment amounts from any of the data sources (Medicaid, TRICARE, VHA, or internet prices). As such, claims for new HCPCS Level II code AXXXX will be priced by the DME MACs on a claim-by-claim basis.

Pricing Indicator = 46

Agenda Item # 11
Gradient Compression Custom Wrap Foot - HCP240626K1QT5

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression custom wrap for the foot.

Applicant's suggested language: XXXXX, "Gradient compression wrap with adjustable straps, Foot, each, custom"

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression custom wrap for the foot. The proposed code is necessary to recognize the specific textile/technology, precise anatomical location of lymphedema, and custom version of the product. Adjustable wrap items are uniquely constructed from multiple layers of textiles that are sewn, laminated or bonded together to create a fabric that has minimal stretch (inelastic) and high rigidity. The textiles may include but are not limited to nylon, foam, and textured fabric delivering the highest stiffness/containment compared to other compression garments. These garments use clasps or hook and loop closures to enable adjustability providing greater patient independence, adherence, and efficacy. The Lymphedema Treatment Act amended title XVIII of the Social Security Act to provide coverage of certain lymphedema compression treatment items under Medicare. The term 'lymphedema compression treatment items' means standard and custom fitted gradient compression garments determined to serve a medical purpose and for the treatment of lymphedema.

CMS Preliminary HCPCS Coding Recommendation

CMS has generally created custom made and corresponding non-custom-made codes for lymphedema compression treatment items in the HCPCS Level II code set. We understand that lymphedema compression treatment items can come in both standard and custom-fitted form, and that there are distinct differences between the two. CMS described these differences in the Background section of the 2023 Lymphedema Compression Treatment Items Rule (88 FR 77812), "Standard compression garments are also referred to as ready-made or ready-to wear and are widely available pre-made, off-the-shelf and in a range of standard sizes;" and, "Custom-fit gradient compression garments are garments that are uniquely sized, shaped, and custom made to fit the exact dimensions of the affected extremity (circumferential measurements are every 1 and a half to 2 inches) and provide more accurate and consistent gradient compression to manage the individual's symptoms." Given these distinct differences CMS agrees with the request to create a new HCPCS Level II code. This code request is for a custom-made equivalent code to correspond with the non-custom HCPCS Level II code A6587. As such, CMS is proposing to:

Establish a new HCPCS Level II code AXXXX, "Gradient compression wrap with adjustable straps, foot, each, custom" to describe custom foot gradient compression wraps.

In addition, we would revise the description for HCPCS Level II code A6587 to replace the word "pressure" with "compression" so that the description is more consistent with the

HCPCS Level II code descriptions used for lymphedema compression treatment items. CMS is also proposing to:

Revise existing HCPCS Level II code A6587, "Gradient pressure wrap with adjustable straps, foot, each" to instead read "Gradient compression wrap with adjustable straps, foot, each" to describe foot gradient compression wraps.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

Section 1834(z)(1) of the Social Security Act mandates an appropriate payment basis for lymphedema compression treatment items defined in section 1861(mmm) of the Act and specifically identifies payment rates from other government and private sector payers that may be taken into account in establishing the payment basis for these items. These sources include payment rates used by Medicaid state plans, the Veterans Health Administration (VHA), group health plans, and health insurance coverage (as defined in section 2791 of the Public Health Service Act). Section 1834(z)(1) of the Act also indicates that other information determined to be appropriate may be taken into account in establishing the payment basis for lymphedema compression treatment items.

In accordance with 42 CFR 414.1650(b), and as discussed in our CY 2024 rule (88 FR 77831), where Medicaid state plan payment amounts are available for a lymphedema compression treatment item, we set payment amounts at 120 percent of the average of the Medicaid payment amounts for the lymphedema compression treatment item. Where Medicaid payment amounts are not available for an item, we set payment amounts at 100 percent of the average of internet retail prices and payment amounts for that item from TRICARE. Where payment amounts are not available from Medicaid state plans or TRICARE for a given lymphedema compression treatment item, we base payment amounts based on 100 percent of average internet retail prices for that item.

We discussed in our CY 2024 rule (88 FR 77832) that when new items are added to this Lymphedema Compression Treatment Item benefit category, the data sources (Medicaid, TRICARE, VHA, or internet prices) may not initially be available for establishing an appropriate payment amount. We said that in this situation, until the data necessary for establishing the payment amount becomes available, the DME MACs would consider what an appropriate payment amount would be for each item on an individual, claim-by-claim basis and may consider using pricing for similar items that already have established payment amounts.

We have not been able to identify payment amounts from any of the data sources (Medicaid, TRICARE, VHA, or internet prices). As such, claims for new HCPCS Level II code AXXXX will be priced by the DME MACs on a claim-by-claim basis.

Pricing Indicator = 46

Agenda Item # 11
Gradient Compression Custom Wrap Full Leg - HCP2406263JJDM

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression custom wrap for the full leg.

Applicant's suggested language: XXXXX, “Gradient pressure wrap with adjustable straps, full leg, each, custom”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression custom wrap for the full leg. The proposed code is necessary to recognize the specific textile/technology, precise anatomical location of lymphedema, and custom version of the product. Adjustable wrap items are uniquely constructed from multiple layers of textiles that are sewn, laminated or bonded together to create a fabric that has minimal stretch (inelastic) and high rigidity. The textiles may include but are not limited to nylon, foam, and textured fabric delivering the highest stiffness/containment compared to other compression garments. These garments use clasps or hook and loop closures to enable adjustability providing greater patient independence, adherence, and efficacy. The Lymphedema Treatment Act amended title XVIII of the Social Security Act to provide coverage of certain lymphedema compression treatment items under Medicare. The term ‘lymphedema compression treatment items’ means standard and custom fitted gradient compression garments determined to serve a medical purpose and for the treatment of lymphedema.

CMS Preliminary HCPCS Coding Recommendation

CMS has generally created custom made and non-custom-made (“standard”) codes for lymphedema compression treatment items in the HCPCS Level II code set. We understand that lymphedema compression treatment items can come in both standard and custom-fitted form, and that there are distinct differences between the two. CMS described these differences in the Background section of the 2023 Lymphedema Compression Treatment Items Rule (88 FR 77812), “Standard compression garments are also referred to as ready-made or ready-to wear and are widely available pre-made, off-the-shelf and in a range of standard sizes;” and, “Custom-fit gradient compression garments are garments that are uniquely sized, shaped, and custom made to fit the exact dimensions of the affected extremity (circumferential measurements are every 1 and a half to 2 inches) and provide more accurate and consistent gradient compression to manage the individual’s symptoms.” Given these distinct differences CMS agrees with the request to create a new HCPCS Level II code. However, we would revise the requested description to replace the word “pressure” with “compression” so that the description is more consistent with the HCPCS Level II code descriptions used for lymphedema compression treatment items. This code request is for a custom-made equivalent code to correspond with the non-custom HCPCS Level II code A6586. As such, CMS is proposing to:

Establish a new HCPCS Level II code AXXXX, “Gradient compression wrap with adjustable straps, full leg, each, custom” to describe custom full leg gradient compression wraps.

In addition, we would revise the description for HCPCS Level II code A6586 to replace the word “pressure” with “compression” so that the description is more consistent with the HCPCS Level II code descriptions used for lymphedema compression treatment items. CMS is also proposing to:

Revise existing HCPCS Level II code A6586, “Gradient pressure wrap with adjustable straps, full leg, each” to instead read “Gradient compression wrap with adjustable straps, full leg, each” to describe full leg gradient compression wraps.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

Section 1834(z)(1) of the Social Security Act mandates an appropriate payment basis for lymphedema compression treatment items defined in section 1861(mmm) of the Act and specifically identifies payment rates from other government and private sector payers that may be taken into account in establishing the payment basis for these items. These sources include payment rates used by Medicaid state plans, the Veterans Health Administration (VHA), group health plans, and health insurance coverage (as defined in section 2791 of the Public Health Service Act). Section 1834(z)(1) of the Act also indicates that other information determined to be appropriate may be taken into account in establishing the payment basis for lymphedema compression treatment items.

In accordance with 42 CFR 414.1650(b), and as discussed in our CY 2024 rule (88 FR 77831), where Medicaid state plan payment amounts are available for a lymphedema compression treatment item, we set payment amounts at 120 percent of the average of the Medicaid payment amounts for the lymphedema compression treatment item. Where Medicaid payment amounts are not available for an item, we set payment amounts at 100 percent of the average of internet retail prices and payment amounts for that item from TRICARE. Where payment amounts are not available from Medicaid state plans or TRICARE for a given lymphedema compression treatment item, we base payment amounts based on 100 percent of average internet retail prices for that item.

We discussed in our CY 2024 rule (88 FR 77832) that when new items are added to this Lymphedema Compression Treatment Item benefit category, the data sources (Medicaid, TRICARE, VHA, or internet prices) may not initially be available for establishing an appropriate payment amount. We said that in this situation, until the data necessary for establishing the payment amount becomes available, the DME MACs would consider what an appropriate payment amount would be for each item on an individual, claim-by-claim basis and may consider using pricing for similar items that already have established payment amounts.

We have not been able to identify payment amounts from any of the data sources (Medicaid, TRICARE, VHA, or internet prices). As such, claims for new HCPCS Level II code AXXXX will be priced by the DME MACs on a claim-by-claim basis.

Pricing Indicator = 46

Agenda Item # 11
Gradient Compression Below Knee Bandage Liner - HCP2407019YVJC

Topic/Issue

Request to revise existing HCPCS Level II code A6594, “Gradient compression bandaging supply, bandage liner, lower extremity, any size or length, each” and to expand the HCPCS Level II code to also specify anatomical segments for foot, knee and thigh, and full leg bandage liners.

Applicant's suggested language: A6594, “Gradient compression accessory - bandage liner, below knee, any size or length, each”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to revise existing HCPCS Level II code A6594 to expand the HCPCS Level II code to also specify anatomical segments for foot, knee and thigh, and full leg bandage liners. The more specific anatomical locations are necessary to address the individual’s clinical characteristics and any unique individual shapes which require adaptation in targeted segments. The request is to also expand the HCPCS Level II code set to include four distinct codes for lower extremity bandage liners: foot, below knee, knee and thigh, and a full leg. Additionally, the January 2024 DMEPOS Fee Schedule published on December 19, 2023, lists a price of $33.14. The published national payment amount is not reflective of a true bandage liner and a reconsideration is requested as it is possible that incorrect products were selected for the initial review. There are no previous Medicaid fee schedules for bandage liners, and a review of internet pricing reveals substantially higher costs.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code A6594, “Gradient compression bandaging supply, bandage liner, lower extremity, any size or length, each” describes gradient compression bandage liners and supplies for the lower extremities.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

In accordance with 42 CFR 414.1650(b), and as discussed in our CY 2024 Home Health (HH) Prospective Payment System final rule (88 FR 77831), where Medicaid state plan payment amounts are available for a lymphedema compression treatment item, we set payment amounts at 120 percent of the average of the Medicaid payment amounts for the lymphedema compression treatment item. Where Medicaid payment amounts are not available for an item, we set payment amounts at 100 percent of the average of internet retail prices and payment amounts for that item from TRICARE. Where payment amounts are not available from Medicaid state plans or TRICARE for a given lymphedema compression treatment item, we base payment amounts based on 100 percent of average internet retail prices for that item.

When originally determining the payment amount for HCPCS Level II code A6594, we followed the process outlined in 42 CFR 414.1650(b) and since there was no Medicaid or TRICARE pricing available, took 100 percent of the average of average internet retail prices. After finding several internet retail prices for lower extremity bandage liners, the average price was $33.14. The applicant has sent us internet retail pricing for items they believe should have been included in this average calculation. We can confirm that we already included one of these products and its price in the average calculation. Although there may be products with a higher price than $33.14, the average still reflects the spectrum of pricing on the internet. We noted in the CY 2024 HH Prospective Payment System final rule that when collecting internet retail prices for use in any such averages, we only consider prices for items that meet the requirements for payment under each code in question (88 FR 77833). As such, we can confirm that the products included in this average are indeed bandage liners.

The payment rules and pricing associated with the existing HCPCS Level II code A6594 apply to this product, if covered. Fee schedules are updated annually.

Pricing Indicator = 40

Agenda Item # 11
Gradient Compression Bra Bandage Liner - HCP240701KEDHA

Topic/Issue

Request to establish a new HCPCS Level II code to identify a bra bandage liner.

Applicant's suggested language: XXXXX, “Gradient compression bandaging supply, bandage liner, bra, any size or length, each”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a bra bandage liner. The existing codes acknowledge upper and lower extremity bandage areas, and do not include a bra version. It is necessary to identify this anatomical location for individuals with lymphedema to the chest/breast area who utilize the prescribed compression bandage system.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. Existing HCPCS Level II code A6609, “Gradient compression bandaging supply, not otherwise specified” is used when submitting claims for this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II “Not Otherwise Specified” codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Agenda Item # 11
Gradient Compression Arm Bandage Liner - HCP240701FWP0N

Topic/Issue

Request to revise existing HCPCS Level II code A6595, “Gradient compression bandaging supply, bandage liner, upper extremity, any size or length, each” to include more specific anatomical locations.

Applicant's suggested language: A6595, “Gradient compression accessory - bandage liner, arm, any size or length, each” to specify wrist to axilla coverage and expand the HCPCS code set to also specify anatomical segments for hand and an arm & hand combination bandage liner.

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to revise existing HCPCS Level II code A6595 to include more specific anatomical locations. The existing code description generalizes the product as upper extremity, but more specific anatomical locations are necessary to address the individual’s clinical characteristics and any unique individual shapes which require adaptation in targeted segments. The request is to expand the HCPCS Level II code set to include three distinct codes for the arm, hand, and a combination of arm and hand. Additionally, the January 2024 DMEPOS Fee Schedule published on December 19, 2023 lists a price of $32.59. The published national payment amount is not reflective of a true bandage liner and a reconsideration is requested as it is possible that incorrect products were selected for the initial review. There are no previous Medicaid fee schedules for bandage liners, and a review of internet pricing reveals substantially higher costs.

CMS Preliminary HCPCS Coding Recommendation

Existing HCPCS Level II code A6595, “Gradient compression bandaging supply, bandage liner, upper extremity, any size or length, each” describes gradient compression bandage liners and supplies for the upper extremities.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

In accordance with 42 CFR 414.1650(b), and as discussed in our CY 2024 Home Health (HH) Prospective Payment System final rule (88 FR 77831), where Medicaid state plan payment amounts are available for a lymphedema compression treatment item, we set payment amounts at 120 percent of the average of the Medicaid payment amounts for the lymphedema compression treatment item. Where Medicaid payment amounts are not available for an item, we set payment amounts at 100 percent of the average of internet retail prices and payment amounts for that item from TRICARE. Where payment amounts are not available from Medicaid state plans or TRICARE for a given lymphedema compression treatment item, we base payment amounts based on 100 percent of average internet retail prices for that item. When originally determining the payment amount for HCPCS Level II

code A6595, we followed the process outlined in 42 CFR 414.1650(b) and since there was no Medicaid or TRICARE pricing available, took 100 percent of the average of average internet retail prices. After finding several internet retail prices for lower extremity bandage liners, the average price was $32.59. The applicant has sent us internet retail pricing for items they believe should have been included in this average calculation. We can confirm that we already included one of these products and its price in the average calculation. Although there may be products with a higher price than $32.59, the average still reflects the spectrum of pricing on the internet. We noted in the CY 2024 Home Health (HH) Prospective Payment System final rule that when collecting internet retail prices for use in any such averages, we only consider prices for items that meet the requirements for payment under each code in question (88 FR 77833). As such, we can confirm that the products included in this average are indeed bandage liners.

The payment rules and pricing associated with the existing HCPCS Level II code A6595 apply to this product, if covered. Fee schedules are updated annually.

Pricing Indicator = 40

Agenda Item # 11
Gradient Compression Custom Padded Nighttime Garment, Torso/Abdomen - HCP240627LVYYT

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression custom padded nighttime garment for the torso/abdomen.

Applicant's suggested language: XXXXX, “Gradient compression garment, torso - abdomen, padded, for nighttime use, each, custom”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression custom padded nighttime garment for the torso/abdomen. This is a medical gradient compression garment for the treatment of lymphedema. The proposed code language is necessary to recognize the specific textile/technology and anatomical location of lymphedema. Nighttime garments are manufactured to incorporate a textured surface against the skin, which is achieved in a few different formats based on current technology on the market, such as chip foam, flat foam, channel foam, polyfill, and 3D knit structure. These garments are primarily cut or knit to size, filled with texture-based solution/knit with texture, and lastly sewn. Many of them also integrate built-in directional channeling based on the lymphatic pathways. Nighttime garments have the unique ability to maintain lymphedema safely overnight/during low activity with its lower levels of compression and containment based on medium-stretch fabric properties. Additionally, its textured surface provides a unique pressure differential on the tissue with high and low pressures designed to help stimulate the tissue, break up and soften fibrosis and support long term tissue health for lymphedema. Additional HCPCS Level II codes for abdomen are necessary for proper identification and product selection to effectively manage lymphedema overnight or during periods of low activity.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. CMS is proposing (in our CMS Preliminary HCPCS Coding Recommendation, see application HCP2406275UFBP) to revise HCPCS Level II code A6549, “Gradient compression garment, not otherwise specified” to instead read “Gradient compression garment, not otherwise specified, for daytime use, each” to describe this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Note that in our CMS Preliminary HCPCS Coding Recommendation, we are proposing establishment of new HCPCS Level II code AXXXX, “Gradient compression garment, not otherwise specified, for nighttime use, each” to describe nighttime gradient compression garments (see application HCP2406275UFBP). If this code is established, suppliers would begin using this new code when submitting claims for this nighttime garment.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II “Not Otherwise Specified” codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Agenda Item # 11
Gradient Compression Custom Padded Nighttime Garment, Arm Sleeve and Glove - HCP2406264KDYN

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression custom padded nighttime garment for the combination of the arm sleeve and glove.

Applicant's suggested language: XXXXX, “Gradient compression garment, arm sleeve and glove combination, padded, for nighttime use, each, custom”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression custom padded nighttime garment for the combination of the arm sleeve and glove. This is a medical gradient compression garment for the treatment of lymphedema. The proposed code language is necessary to recognize the specific textile/technology and combined anatomical locations of lymphedema. Nighttime garments are manufactured to incorporate a textured surface against the skin, which is achieved in a few different formats based on current technology on the market, such as chip foam, flat foam, channel foam, polyfill, and 3D knit structure. These garments are primarily cut or knit to size, filled with texture-based solution/knit with texture, and lastly sewn. Many of them also integrate built-in directional channeling based on the lymphatic pathways. Nighttime garments have the unique ability to maintain lymphedema safely overnight/during low activity with its lower levels of compression and containment based on medium-stretch fabric properties. Additionally, its textured surface provides a unique pressure differential on the tissue with high and low pressures designed to help stimulate the tissue, break up and soften fibrosis and support long term tissue health for lymphedema. Additional codes are necessary for proper identification and product selection to effectively manage lymphedema overnight or during periods of low activity.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. CMS is proposing (in our CMS Preliminary HCPCS Coding Recommendation, see application HCP2406275UFBP) to revise HCPCS Level II code A6549, “Gradient compression garment, not otherwise specified” to instead read “Gradient compression garment, not otherwise specified, for daytime use, each” to describe this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Note that in our CMS Preliminary HCPCS Coding Recommendation, we are proposing establishment of new HCPCS Level II code AXXXX, “Gradient compression garment, not otherwise specified, for nighttime use, each” to describe nighttime gradient compression garments (see application HCP2406275UFBP). If this code is established, suppliers would begin using this new code when submitting claims for this nighttime garment.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II “Not Otherwise Specified” codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Agenda Item # 11
Gradient Compression Padded Nighttime Garment, Arm Sleeve and Glove - HCP240626N5LFM

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression padded nighttime garment for the combination of the arm sleeve and glove.

Applicant's suggested language: XXXXX, “Gradient compression garment, arm sleeve and glove combination, padded, for nighttime use, each”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression padded nighttime garment for the combination of the arm sleeve and glove. The item is a medical gradient compression garment for the treatment of lymphedema. The proposed code language is necessary to recognize the specific textile/technology and combined anatomical locations of lymphedema. Nighttime garments are manufactured to incorporate a textured surface against the skin, which is achieved in a few different formats based on current technology on the market, such as chip foam, flat foam, channel foam, polyfill, and 3D knit structure. These garments are primarily cut or knit to size, filled with texture-based solution/knit with texture, and lastly sewn. Many of them also integrate built-in directional channeling based on the lymphatic pathways. Nighttime garments have the unique ability to maintain lymphedema safely overnight/during low activity with its lower levels of compression and containment based on medium-stretch fabric properties. Additionally, its textured surface provides a unique pressure differential on the tissue with high and low pressures designed to help stimulate the tissue, break up and soften fibrosis and support long term tissue health for lymphedema. Additional codes are necessary for proper identification and product selection to effectively manage lymphedema overnight or during periods of low activity.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. CMS is proposing (in our CMS Preliminary HCPCS Coding Recommendation, see application HCP2406275UFBP) to revise HCPCS Level II code A6549, “Gradient compression garment, not otherwise specified” to instead read “Gradient compression garment, not otherwise specified, for daytime use, each” to describe this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Note that in our CMS Preliminary HCPCS Coding Recommendation we are proposing establishment of new HCPCS Level II code AXXXX, “Gradient compression garment, not otherwise specified, for nighttime use, each” to describe nighttime gradient compression garments (see application HCP2406275UFBP). If this code is established, suppliers would begin using this new code when submitting claims for this nighttime garment.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II “Not Otherwise Specified” codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Agenda Item # 11
Gradient Compression Custom Padded Nighttime Garment, Body Suit - HCP240627PCD0U

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression custom padded nighttime garment body suit.

Applicant's suggested language: XXXXX, “Gradient compression garment, body suit, padded, for nighttime use, each, custom”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression custom padded nighttime garment body suit. The item is a medical gradient compression garment for the treatment of lymphedema. The proposed code language is necessary to recognize the specific textile/technology and combined anatomical locations of lymphedema. Nighttime garments are manufactured to incorporate a textured surface against the skin, which is achieved in a few different formats based on current technology on the market, such as chip foam, flat foam, channel foam, polyfill, and 3D knit structure. These garments are primarily cut or knit to size, filled with texture-based solution/knit with texture, and lastly sewn. Many of them also integrate built-in directional channeling based on the lymphatic pathways. Nighttime garments have the unique ability to maintain lymphedema safely overnight/during low activity with its lower levels of compression and containment based on medium-stretch fabric properties. Additionally, its textured surface provides a unique pressure differential on the tissue with high and low pressures designed to help stimulate the tissue, break up and soften fibrosis and support long term tissue health for lymphedema. Additional HCPCS Level II code for a custom nighttime body suit is needed for comprehensive coverage to effectively manage multiple body parts lymphedema overnight or during periods of low activity.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. CMS is proposing (in our CMS Preliminary HCPCS Coding Recommendation, see application HCP2406275UFBP) to revise HCPCS Level II code A6549, “Gradient compression garment, not otherwise specified” to instead read “Gradient compression garment, not otherwise specified, for daytime use, each” to describe this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Note that in our CMS Preliminary HCPCS Coding Recommendation we are proposing establishment of new HCPCS Level II code AXXXX, “Gradient compression garment, not otherwise specified, for nighttime use, each” to describe nighttime gradient compression garments (see application HCP2406275UFBP). If this code is established, suppliers would begin using this new code when submitting claims for this nighttime garment.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II “Not Otherwise Specified” codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Agenda Item # 11
Gradient Compression Padded Nighttime Garment, Genital/Capri - HCP2406276225W

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression padded nighttime garment for genital/capri.

Applicant's suggested language: XXXXX, “Gradient compression garment, genital - capri, padded, for nighttime use, each”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression padded nighttime garment for genital/capri. The item is a medical gradient compression garment for the treatment of lymphedema. The proposed code language is necessary to recognize the specific textile/technology and anatomical locations of lymphedema. Nighttime garments are manufactured to incorporate a textured surface against the skin, which is achieved in a few different formats based on current technology on the market, such as chip foam, flat foam, channel foam, polyfill, and 3D knit structure. These garments are primarily cut or knit to size, filled with texture-based solution/knit with texture, and lastly sewn. Many of them also integrate built-in directional channeling based on the lymphatic pathways. Nighttime garments have the unique ability to maintain lymphedema safely overnight/during low activity with its lower levels of compression and containment based on medium-stretch fabric properties. Additionally, its textured surface provides a unique pressure differential on the tissue with high and low pressures designed to help stimulate the tissue, break up and soften fibrosis and support long term tissue health for lymphedema. Additional HCPCS Level II code for a nighttime capri is needed for comprehensive coverage to effectively manage multiple body parts lymphedema (e.g., genital, torso, lower extremities) overnight or during periods of low activity.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. CMS is proposing (in our CMS Preliminary HCPCS Coding Recommendation, see application HCP2406275UFBP) to revise HCPCS Level II code A6549, “Gradient compression garment, not otherwise specified” to instead read “Gradient compression garment, not otherwise specified, for daytime use, each” to describe this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Note that in our CMS Preliminary HCPCS Coding Recommendation we are proposing establishment of new HCPCS Level II code AXXXX, “Gradient compression garment, not otherwise specified, for nighttime use, each” to describe nighttime gradient compression garments (see application HCP2406275UFBP). If this code is established, suppliers would begin using this new code when submitting claims for this nighttime garment.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II "Not Otherwise Specified" codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Agenda Item # 11
Gradient Compression Custom Padded Nighttime Garment, Foot - HCP240626FGCQC

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression custom padded nighttime garment for the foot.

Applicant's suggested language: XXXXX, “Gradient compression garment, foot, padded, for nighttime use, custom, each”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression custom padded nighttime garment for the foot. This is a medical gradient compression garment for the treatment of lymphedema. The proposed code language is necessary to recognize the specific textile/technology and anatomical location of lymphedema. Nighttime garments are manufactured to incorporate a textured surface against the skin, which is achieved in a few different formats based on current technology on the market, such as chip foam, flat foam, channel foam, polyfill, and 3D knit structure. These garments are primarily cut or knit to size, filled with texture-based solution/knit with texture, and lastly sewn. Many of them also integrate built-in directional channeling based on the lymphatic pathways. Nighttime garments have the unique ability to maintain lymphedema safely overnight/during low activity with its lower levels of compression and containment based on medium-stretch fabric properties. Additionally, its textured surface provides a unique pressure differential on the tissue with high and low pressures designed to help stimulate the tissue, break up and soften fibrosis and support long term tissue health for lymphedema. Additional codes are necessary for proper identification and product selection to effectively manage lymphedema overnight or during periods of low activity.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. CMS is proposing (in our CMS Preliminary HCPCS Coding Recommendation, see application HCP2406275UFBP) to revise HCPCS Level II code A6549, “Gradient compression garment, not otherwise specified” to instead read “Gradient compression garment, not otherwise specified, for daytime use, each” to describe this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Note that in our CMS Preliminary HCPCS Coding Recommendation we are proposing establishment of new HCPCS Level II code AXXXX, “Gradient compression garment, not otherwise specified, for nighttime use, each” to describe nighttime gradient compression garments (see application HCP2406275UFBP). If this code is established, suppliers would begin using this new code when submitting claims for this nighttime garment.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II "Not Otherwise Specified" codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Agenda Item # 11
Gradient Compression Padded Nighttime Garment, Foot - HCP2406275H7WW

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression padded nighttime garment for the foot.

Applicant's suggested language: XXXXX, "Gradient compression garment, foot, padded, for nighttime use, each"

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression padded nighttime garment for the foot. The item is a medical gradient compression garment for the treatment of lymphedema. The proposed code language is necessary to recognize the specific textile/technology and anatomical location of lymphedema. Nighttime garments are manufactured to incorporate a textured surface against the skin, which is achieved in a few different formats based on current technology on the market, such as chip foam, flat foam, channel foam, polyfill, and 3D knit structure. These garments are primarily cut or knit to size, filled with texture-based solution/knit with texture, and lastly sewn. Many of them also integrate built-in directional channeling based on the lymphatic pathways. Nighttime garments have the unique ability to maintain lymphedema safely overnight/during low activity with its lower levels of compression and containment based on medium-stretch fabric properties. Additionally, its textured surface provides a unique pressure differential on the tissue with high and low pressures designed to help stimulate the tissue, break up and soften fibrosis and support long term tissue health for lymphedema. Additional codes are necessary for proper identification and product selection to effectively manage lymphedema overnight or during periods of low activity.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. CMS is proposing (in our CMS Preliminary HCPCS Coding Recommendation, see application HCP2406275UFBP) to revise HCPCS Level II code A6549, "Gradient compression garment, not otherwise specified" to instead read "Gradient compression garment, not otherwise specified, for daytime use, each" to describe this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Note that in our CMS Preliminary HCPCS Coding Recommendation we are proposing establishment of new HCPCS Level II code AXXXX, "Gradient compression garment, not otherwise specified, for nighttime use, each" to describe nighttime gradient compression garments (see application HCP2406275UFBP). If this code is established, suppliers would begin using this new code when submitting claims for this nighttime garment.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II "Not Otherwise Specified" codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Agenda Item # 11
Gradient Compression Custom Padded Nighttime Garment, Gauntlet - HCP240626GHYEP

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression custom padded nighttime garment for gauntlet.

Applicant's suggested language: XXXXX, “Gradient compression garment, gauntlet, padded, for nighttime use, each, custom”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression custom padded nighttime garment for gauntlet. This is a medical gradient compression garment for the treatment of lymphedema. The proposed code language is necessary to recognize the specific textile/technology and anatomical location of lymphedema. Nighttime garments are manufactured to incorporate a textured surface against the skin, which is achieved in a few different formats based on current technology on the market, such as chip foam, flat foam, channel foam, polyfill, and 3D knit structure. These garments are primarily cut or knit to size, filled with texture-based solution/knit with texture, and lastly sewn. Many of them also integrate built-in directional channeling based on the lymphatic pathways. Nighttime garments have the unique ability to maintain lymphedema safely overnight/during low activity with its lower levels of compression and containment based on medium-stretch fabric properties. Additionally, its textured surface provides a unique pressure differential on the tissue with high and low pressures designed to help stimulate the tissue, break up and soften fibrosis and support long term tissue health for lymphedema. The existing HCPCS Level II codes in the nighttime category are limited to an "arm", and there are no HCPCS Level II codes for segmented anatomical locations and their custom counterparts. Additional codes are necessary for proper identification and product selection to effectively manage lymphedema overnight or during periods of low activity.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. CMS is proposing (in our CMS Preliminary HCPCS Coding Recommendation, see application HCP2406275UFBP) to revise HCPCS Level II code A6549, “Gradient compression garment, not otherwise specified” to instead read “Gradient compression garment, not otherwise specified, for daytime use, each” to describe this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Note that in our CMS Preliminary HCPCS Coding Recommendation we are proposing establishment of new HCPCS Level II code AXXXX, “Gradient compression garment, not otherwise specified, for nighttime use, each” to describe nighttime gradient compression garments (see application HCP2406275UFBP). If this code is established, suppliers would begin using this new code when submitting claims for this nighttime garment.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II “Not Otherwise Specified” codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Agenda Item # 11
Gradient Compression Padded Nighttime Garment, Gauntlet - HCP240627PWHRD

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression padded nighttime garment for gauntlet.

Applicant's suggested language: XXXXX, “Gradient compression garment, gauntlet, padded, for nighttime use, each”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression padded nighttime garment for gauntlet. This is a medical gradient compression garment for the treatment of lymphedema. The proposed code language is necessary to recognize the specific textile/technology and anatomical location of lymphedema. Nighttime garments are manufactured to incorporate a textured surface against the skin, which is achieved in a few different formats based on current technology on the market, such as chip foam, flat foam, channel foam, polyfill, and 3D knit structure. These garments are primarily cut or knit to size, filled with texture-based solution/knit with texture, and lastly sewn. Many of them also integrate built-in directional channeling based on the lymphatic pathways. Nighttime garments have the unique ability to maintain lymphedema safely overnight/during low activity with its lower levels of compression and containment based on medium-stretch fabric properties. Additionally, its textured surface provides a unique pressure differential on the tissue with high and low pressures designed to help stimulate the tissue, break up and soften fibrosis and support long term tissue health for lymphedema. The existing HCPCS Level II codes in the nighttime category are limited to an "arm", and there are no HCPCS Level II codes for segmented anatomical locations and their custom counterparts. Additional codes are necessary for proper identification and product selection to effectively manage lymphedema overnight or during periods of low activity.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. CMS is proposing (in our CMS Preliminary HCPCS Coding Recommendation, see application HCP2406275UFBP) to revise HCPCS Level II code A6549, “Gradient compression garment, not otherwise specified” to instead read “Gradient compression garment, not otherwise specified, for daytime use, each” to describe this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Note that in our CMS Preliminary HCPCS Coding Recommendation we are proposing establishment of new HCPCS Level II code AXXXX, “Gradient compression garment, not otherwise specified, for nighttime use, each” to describe nighttime gradient compression garments (see application HCP2406275UFBP). If this code is established, suppliers would begin using this new code when submitting claims for this nighttime garment.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II “Not Otherwise Specified” codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Agenda Item # 11
Gradient Compression Padded Nighttime Garment, Head and Neck - HCP240626Y4RCN

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression padded nighttime garment for the head and neck.

Applicant's suggested language: XXXXX, “Gradient compression garment, head and neck, padded, for nighttime use, each”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression padded nighttime garment for the head and neck. The item is a medical gradient compression garment for the treatment of lymphedema. The proposed code language is necessary to recognize the specific textile/technology and anatomical location of lymphedema. Nighttime garments are manufactured to incorporate a textured surface against the skin, which is achieved in a few different formats based on current technology on the market, such as chip foam, flat foam, channel foam, polyfill, and 3D knit structure. These garments are primarily cut or knit to size, filled with texture-based solution/knit with texture, and lastly sewn. Many of them also integrate built-in directional channeling based on the lymphatic pathways. Nighttime garments have the unique ability to maintain lymphedema safely overnight/during low activity with its lower levels of compression and containment based on medium-stretch fabric properties. Additionally, its textured surface provides a unique pressure differential on the tissue with high and low pressures designed to help stimulate the tissue, break up and soften fibrosis and support long term tissue health for lymphedema. The existing HCPCS Level II codes in the nighttime category are limited as there are no HCPCS Level II codes for several anatomical locations and their custom counterparts. Specifically, there are no codes for a head and neck garment which is especially important as head and neck swelling is worse in the morning, even when individuals sleep with their head and neck well supported and elevated. Additional codes are necessary for proper identification and product selection to effectively manage lymphedema overnight or during periods of low activity.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. CMS is proposing (in our CMS Preliminary HCPCS Coding Recommendation, see application HCP2406275UFBP) to revise HCPCS Level II code A6549, “Gradient compression garment, not otherwise specified” to instead read “Gradient compression garment, not otherwise specified, for daytime use, each” to describe this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Note that in our CMS Preliminary HCPCS Coding Recommendation we are proposing establishment of new HCPCS Level II code AXXXX, “Gradient compression garment, not otherwise specified, for nighttime use, each” to describe nighttime gradient compression

garments (see application HCP2406275UFBP). If this code is established, suppliers would begin using this new code when submitting claims for this nighttime garment.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II "Not Otherwise Specified" codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Agenda Item # 11
Gradient Compression Custom Padded Nighttime Garment, Head and Neck - HCP240627X41TJ

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression custom padded nighttime garment for the head and neck.

Applicant's suggested language: XXXXX, “Gradient compression garment, head and neck, padded, for nighttime use, each, custom”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression custom padded nighttime garment for the head and neck. This is a medical gradient compression garment for the treatment of lymphedema. The proposed code language is necessary to recognize the specific textile/technology and anatomical location of lymphedema. Nighttime garments are manufactured to incorporate a textured surface against the skin, which is achieved in a few different formats based on current technology on the market, such as chip foam, flat foam, channel foam, polyfill, and 3D knit structure. These garments are primarily cut or knit to size, filled with texture-based solution/knit with texture, and lastly sewn. Many of them also integrate built-in directional channeling based on the lymphatic pathways. Nighttime garments have the unique ability to maintain lymphedema safely overnight/during low activity with its lower levels of compression and containment based on medium-stretch fabric properties. Additionally, its textured surface provides a unique pressure differential on the tissue with high and low pressures designed to help stimulate the tissue, break up and soften fibrosis and support long term tissue health for lymphedema. The existing HCPCS Level II codes in the nighttime category are limited as there are no HCPCS Level II codes for several anatomical locations and their custom counterparts. Specifically, there are no codes for a head and neck garment which is especially important as head and neck swelling is worse in the morning, even when individuals sleep with their head and neck well supported and elevated. Additional codes are necessary for proper identification and product selection to effectively manage lymphedema overnight or during periods of low activity.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. CMS is proposing (in our CMS Preliminary HCPCS Coding Recommendation, see application HCP2406275UFBP) to revise HCPCS Level II code A6549, “Gradient compression garment, not otherwise specified” to instead read “Gradient compression garment, not otherwise specified, for daytime use, each” to describe this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Note that in our CMS Preliminary HCPCS Coding Recommendation we are proposing establishment of new HCPCS Level II code AXXXX, “Gradient compression garment, not otherwise specified, for nighttime use, each” to describe nighttime gradient compression

garments (see application HCP2406275UFBP). If this code is established, suppliers would begin using this new code when submitting claims for this nighttime garment.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II "Not Otherwise Specified" codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Agenda Item # 11
Gradient Compression Custom Padded Nighttime Garment, Torso and Arm, Long Sleeve Shirt - HCP240627W1DEW

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression custom padded nighttime garment, long sleeve shirt, for the torso and arm.

Applicant's suggested language: XXXXX, “Gradient compression garment, torso and arm, long sleeve shirt, padded, for nighttime use, each, custom”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression custom padded nighttime garment, long sleeve shirt, for the torso and arm. The item is a medical gradient compression garment for the treatment of lymphedema. The proposed code language is necessary to recognize the specific textile/technology and combined anatomical locations of lymphedema. Nighttime garments are manufactured to incorporate a textured surface against the skin, which is achieved in a few different formats based on current technology on the market, such as chip foam, flat foam, channel foam, polyfill, and 3D knit structure. These garments are primarily cut or knit to size, filled with texture-based solution/knit with texture, and lastly sewn. Many of them also integrate built-in directional channeling based on the lymphatic pathways. Nighttime garments have the unique ability to maintain lymphedema safely overnight/during low activity with its lower levels of compression and containment based on medium-stretch fabric properties. Additionally, its textured surface provides a unique pressure differential on the tissue with high and low pressures designed to help stimulate the tissue, break up and soften fibrosis and support long term tissue health for lymphedema. Additional HCPCS Level II code for a custom nighttime long sleeve shirt is needed for comprehensive coverage to effectively manage multiple body parts lymphedema overnight or during periods of low activity.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. CMS is proposing (in our CMS Preliminary HCPCS Coding Recommendation, see application HCP2406275UFBP) to revise HCPCS Level II code A6549, “Gradient compression garment, not otherwise specified” to instead read “Gradient compression garment, not otherwise specified, for daytime use, each” to describe this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Note that in our CMS Preliminary HCPCS Coding Recommendation we are proposing establishment of new HCPCS Level II code AXXXX, “Gradient compression garment, not otherwise specified, for nighttime use, each” to describe nighttime gradient compression garments (see application HCP2406275UFBP). If this code is established, suppliers would begin using this new code when submitting claims for this nighttime garment.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II “Not Otherwise Specified” codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Agenda Item # 11
Gradient Compression Custom Padded Nighttime Garment, Genital, Shorts - HCP240627RKU6Y

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression custom padded nighttime garment shorts for the torso.

Applicant's suggested language: XXXXX, “Gradient compression garment, torso - shorts, padded, for nighttime use, custom, each”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression custom padded nighttime garment shorts for the torso. The item is a medical gradient compression garment for the treatment of lymphedema. The proposed code language is necessary to recognize the specific textile/technology and anatomical locations of lymphedema. Nighttime garments are manufactured to incorporate a textured surface against the skin, which is achieved in a few different formats based on current technology on the market, such as: chip foam, flat foam, channel foam, polyfill, and 3D knit structure. These garments are primarily cut or knit to size, filled with texture-based solution/knit with texture, and lastly sewn. Many of them also integrate built-in directional channeling based on the lymphatic pathways. Nighttime garments have the unique ability to maintain lymphedema safely overnight/during low activity with its lower levels of compression and containment based on medium-stretch fabric properties. Additionally, its textured surface provides a unique pressure differential on the tissue with high and low pressures designed to help stimulate the tissue, break up and soften fibrosis and support long term tissue health for lymphedema. Additional HCPCS Level II codes are necessary for comprehensive coverage to effectively manage multiple body parts lymphedema (e.g., genital, torso) overnight or during periods of low activity.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. CMS is proposing (in our CMS Preliminary HCPCS Coding Recommendation, see application HCP2406275UFBP) to revise HCPCS Level II code A6549, “Gradient compression garment, not otherwise specified” to instead read “Gradient compression garment, not otherwise specified, for daytime use, each” to describe this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Note that in our CMS Preliminary HCPCS Coding Recommendation we are proposing establishment of new HCPCS Level II code AXXXX, “Gradient compression garment, not otherwise specified, for nighttime use, each” to describe nighttime gradient compression garments (see application HCP2406275UFBP). If this code is established, suppliers would begin using this new code when submitting claims for this nighttime garment.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II “Not Otherwise Specified” codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Agenda Item # 11
Gradient Compression Custom Padded Nighttime Garment, Torso and Shoulder, Short Sleeve Shirt - HCP240627U11R3

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression custom padded nighttime garment short sleeve shirt for the torso and shoulder.

Applicant's suggested language: XXXXX, “Gradient compression garment, torso and shoulder, short sleeve shirt, padded, for nighttime use, each, custom”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression custom padded nighttime garment short sleeve shirt for the torso and shoulder. This is a medical gradient compression garment for the treatment of lymphedema. The proposed code language is necessary to recognize the specific textile/technology and combined anatomical locations of lymphedema. Nighttime garments are manufactured to incorporate a textured surface against the skin, which is achieved in a few different formats based on current technology on the market, such as chip foam, flat foam, channel foam, polyfill, and 3D knit structure. These garments are primarily cut or knit to size, filled with texture-based solution/knit with texture, and lastly sewn. Many of them also integrate built-in directional channeling based on the lymphatic pathways. Nighttime garments have the unique ability to maintain lymphedema safely overnight / during low activity with its lower levels of compression and containment based on medium-stretch fabric properties. Additionally, its textured surface provides a unique pressure differential on the tissue with high and low pressures designed to help stimulate the tissue, break up and soften fibrosis and support long term tissue health for lymphedema. Additional HCPCS Level II code for a nighttime custom short sleeve shirt is needed for comprehensive coverage to effectively manage multiple body parts lymphedema.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. CMS is proposing (in our CMS Preliminary HCPCS Coding Recommendation, see application HCP2406275UFBP) to revise HCPCS Level II code A6549, “Gradient compression garment, not otherwise specified” to instead read “Gradient compression garment, not otherwise specified, for daytime use, each” to describe this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Note that in our CMS Preliminary HCPCS Coding Recommendation we are proposing establishment of new HCPCS Level II code AXXXX, “Gradient compression garment, not otherwise specified, for nighttime use, each” to describe nighttime gradient compression garments (see application HCP2406275UFBP). If this code is established, suppliers would begin using this new code when submitting claims for this nighttime garment.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II “Not Otherwise Specified” codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Agenda Item # 11
Gradient Compression Padded Nighttime Garment, Upper Leg - HCP240626MJV5R

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression padded nighttime garment for the upper leg.

Applicant's suggested language: XXXXX, “Gradient compression garment, upper leg, padded, for nighttime use, each”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression padded nighttime garment for the upper leg. This is a medical gradient compression garment for the treatment of lymphedema. The proposed code language is necessary to recognize the specific textile/technology and anatomical location of lymphedema. Nighttime garments are manufactured to incorporate a textured surface against the skin, which is achieved in a few different formats based on current technology on the market, such as: chip foam, flat foam, channel foam, polyfill, and 3D knit structure. These garments are primarily cut or knit to size, filled with texture-based solution/knit with texture, and lastly sewn. Many of them also integrate built-in directional channeling based on the lymphatic pathways. Nighttime garments have the unique ability to maintain lymphedema safely overnight / during low activity with its lower levels of compression and containment based on medium-stretch fabric properties. Additionally, its textured surface provides a unique pressure differential on the tissue with high and low pressures designed to help stimulate the tissue, break up and soften fibrosis and support long term tissue health for lymphedema. The existing HCPCS Level II codes in the nighttime category are limited as there no HCPCS Level II codes for several anatomical locations and their custom counterparts. Additional codes are necessary for proper identification and product selection to effectively manage lymphedema overnight or during periods of low activity.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. CMS is proposing (in our CMS Preliminary HCPCS Coding Recommendation, see application HCP2406275UFBP) to revise HCPCS Level II code A6549, “Gradient compression garment, not otherwise specified” to instead read “Gradient compression garment, not otherwise specified, for daytime use, each” to describe this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Note that in our CMS Preliminary HCPCS Coding Recommendation we are proposing establishment of new HCPCS Level II code AXXXX, “Gradient compression garment, not otherwise specified, for nighttime use, each” to describe nighttime gradient compression garments (see application HCP2406275UFBP). If this code is established, suppliers would begin using this new code when submitting claims for this nighttime garment.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II “Not Otherwise Specified” codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Agenda Item # 11
Gradient Compression Custom Nighttime Garment, Upper Leg - HCP240626VPRN2

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression custom nighttime garment for the upper leg.

Applicant's suggested language: XXXXX, “Gradient compression garment, upper leg, for nighttime use, each, custom”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression custom nighttime garment for the upper leg. This is a medical gradient compression garment for the treatment of lymphedema. The proposed code language is necessary to recognize the specific textile/technology and anatomical location of lymphedema. Nighttime garments are manufactured to incorporate a textured surface against the skin, which is achieved in a few different formats based on current technology on the market, such as chip foam, flat foam, channel foam, polyfill, and 3D knit structure. These garments are primarily cut or knit to size, filled with texture-based solution/knit with texture, and lastly sewn. Many of them also integrate built-in directional channeling based on the lymphatic pathways. Nighttime garments have the unique ability to maintain lymphedema safely overnight/during low activity with its lower levels of compression and containment based on medium-stretch fabric properties. Additionally, its textured surface provides a unique pressure differential on the tissue with high and low pressures designed to help stimulate the tissue, break up and soften fibrosis and support long term tissue health for lymphedema. The existing HCPCS Level II codes in the nighttime category are limited as there are no HCPCS Level II codes for several anatomical locations and their custom counterparts. Additional codes are necessary for proper identification and product selection to effectively manage lymphedema overnight or during periods of low activity.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. CMS is proposing (in our CMS Preliminary HCPCS Coding Recommendation, see application HCP2406275UFBP) to revise HCPCS Level II code A6549, “Gradient compression garment, not otherwise specified” to instead read “Gradient compression garment, not otherwise specified, for daytime use, each” to describe this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Note that in our CMS Preliminary HCPCS Coding Recommendation we are proposing establishment of new HCPCS Level II code AXXXX, “Gradient compression garment, not otherwise specified, for nighttime use, each” to describe nighttime gradient compression garments (see application HCP2406275UFBP). If this code is established, suppliers would begin using this new code when submitting claims for this nighttime garment.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II “Not Otherwise Specified” codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Agenda Item # 11
Gradient Compression Custom Padded Nighttime Garment, Torso, Vest - HCP2406277F2M1

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression custom padded nighttime garment vest for the torso.

Applicant's suggested language: XXXXX, “Gradient compression garment, torso - vest, padded, for nighttime use, each, custom”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression custom padded nighttime garment vest for the torso. This is a medical gradient compression garment for the treatment of lymphedema. The proposed code language is necessary to recognize the specific textile/technology and anatomical locations of lymphedema. Nighttime garments are manufactured to incorporate a textured surface against the skin, which is achieved in a few different formats based on current technology on the market, such as: chip foam, flat foam, channel foam, polyfill, and 3D knit structure. These garments are primarily cut or knit to size, filled with texture-based solution/knit with texture, and lastly sewn. Many of them also integrate built-in directional channeling based on the lymphatic pathways. Nighttime garments have the unique ability to maintain lymphedema safely overnight/during low activity with its lower levels of compression and containment based on medium-stretch fabric properties. Additionally, its textured surface provides a unique pressure differential on the tissue with high and low pressures designed to help stimulate the tissue, break up and soften fibrosis and support long term tissue health for lymphedema. Additional HCPCS codes are necessary for comprehensive coverage to effectively manage multiple body parts lymphedema (e.g., chest and abdomen) overnight or during periods of low activity.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. CMS is proposing (in our CMS Preliminary HCPCS Coding Recommendation, see application HCP2406275UFBP) to revise HCPCS Level II code A6549, “Gradient compression garment, not otherwise specified” to instead read “Gradient compression garment, not otherwise specified, for daytime use, each” to describe this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Note that in our CMS Preliminary HCPCS Coding Recommendation we are proposing establishment of new HCPCS Level II code AXXXX, “Gradient compression garment, not otherwise specified, for nighttime use, each” to describe nighttime gradient compression garments (see application HCP2406275UFBP). If this code is established, suppliers would begin using this new code when submitting claims for this nighttime garment.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II “Not Otherwise Specified” codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Agenda Item # 11
Gradient Compression Garment with Adjustable Straps, Hand Gauntlet - HCP240625LVHRC

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression garment with adjustable straps for a hand gauntlet.

Applicant's suggested language: XXXXX, “Gradient compression wrap with adjustable straps, hand gauntlet, each”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression garment with adjustable straps for a hand gauntlet. The proposed code is necessary to recognize the specific textile/technology, and precise anatomical location of lymphedema. Adjustable wrap items are uniquely constructed from multiple layers of textiles that are sewn, laminated or bonded together to create a fabric that has minimal stretch (inelastic) and high rigidity. The textiles may include but are not limited to nylon, foam, and textured fabric delivering the highest stiffness/containment compared to other compression garments. These garments use clasps or hook and loop closures to enable adjustability providing greater patient independence, adherence, and efficacy. The Lymphedema Treatment Act amended title XVIII of the Social Security Act to provide coverage of certain lymphedema compression treatment items under the Medicare Program. The term “lymphedema compression treatment items” means standard and custom fitted gradient compression garments determined to serve a medical purpose and for the treatment of lymphedema. The newly published HCPCS Level II codes are limited in its description of adjustable wrap items as there are no custom HCPCS Level II codes and no codes for several anatomical locations.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. Existing HCPCS Level II code A6584, “Gradient compression wrap with adjustable straps, not otherwise specified” is used when submitting claims for this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II “Not Otherwise Specified” codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Agenda Item # 11
Gradient Compression Custom Garment with Adjustable Straps, Hand Gauntlet - HCP2406267T4RF

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression custom garment with adjustable straps for a hand gauntlet.

Applicant's suggested language: XXXXX, “Gradient compression wrap with adjustable straps, hand gauntlet, each, custom”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression custom garment with adjustable straps for a hand gauntlet. The proposed code is necessary to recognize the specific textile/technology, precise anatomical location of lymphedema, and custom version of the product. Adjustable wrap items are uniquely constructed from multiple layers of textiles that are sewn, laminated or bonded together to create a fabric that has minimal stretch (inelastic) and high rigidity. The textiles may include but are not limited to nylon, foam, and textured fabric delivering the highest stiffness/containment compared to other compression garments. These garments use clasps or hook and loop closures to enable adjustability providing greater patient independence, adherence, and efficacy. The Lymphedema Treatment Act amended title XVIII of the Social Security Act to provide coverage of certain lymphedema compression treatment items under the Medicare Program. The term “lymphedema compression treatment items” means standard and custom fitted gradient compression garments determined to serve a medical purpose and for the treatment of lymphedema. The newly published HCPCS Level II codes are limited in its description of adjustable wrap items as there are no custom HCPCS Level II codes and no codes for several anatomical locations.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. Existing HCPCS Level II code A6584, “Gradient compression wrap with adjustable straps, not otherwise specified” is used when submitting claims for this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II “Not Otherwise Specified” codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Agenda Item # 11
Gradient Compression Garment with Adjustable Straps, Hand Glove - HCP240625HTAQK

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression wrap with adjustable straps for a hand glove.

Applicant's suggested language: XXXXX, “Gradient compression wrap with adjustable straps, hand glove, each”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression wrap with adjustable straps for a hand glove. The proposed code is necessary to recognize the specific textile/technology, and precise anatomical location of lymphedema. Adjustable wrap items are uniquely constructed from multiple layers of textiles that are sewn, laminated or bonded together to create a fabric that has minimal stretch (inelastic) and high rigidity. The textiles may include but are not limited to nylon, foam, and textured fabric delivering the highest stiffness/containment compared to other compression garments. These garments use clasps or hook and loop closures to enable adjustability providing greater patient independence, adherence, and efficacy. The Lymphedema Treatment Act amended title XVIII of the Social Security Act to provide coverage of certain lymphedema compression treatment items under the Medicare Program. The term “lymphedema compression treatment items” means standard and custom fitted gradient compression garments determined to serve a medical purpose and for the treatment of lymphedema. The newly published HCPCS Level II codes are limited in its description of adjustable wrap items as there are no custom HCPCS Level II codes and no codes for several anatomical locations.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. Existing HCPCS Level II code A6584, “Gradient compression wrap with adjustable straps, not otherwise specified” is used when submitting claims for this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II “Not Otherwise Specified” codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Agenda Item # 11
Gradient Compression Custom Garment with Adjustable Straps, Hand Glove - HCP240626CP3CR

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression custom garment with adjustable straps for a hand glove.

Applicant's suggested language: XXXXX, “Gradient compression wrap with adjustable straps, hand glove, each, custom”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression custom garment with adjustable straps for a hand glove. The proposed code is necessary to recognize the specific textile/technology, precise anatomical location of lymphedema, and custom version of the product. Adjustable wrap items are uniquely constructed from multiple layers of textiles that are sewn, laminated or bonded together to create a fabric that has minimal stretch (inelastic) and high rigidity. The textiles may include but are not limited to nylon, foam, and textured fabric delivering the highest stiffness/containment compared to other compression garments. These garments use clasps or hook and loop closures to enable adjustability providing greater patient independence, adherence, and efficacy. The Lymphedema Treatment Act amended title XVIII of the Social Security Act to provide coverage of certain lymphedema compression treatment items under the Medicare Program. The term “lymphedema compression treatment items" means standard and custom fitted gradient compression garments determined to serve a medical purpose and for the treatment of lymphedema. The newly published HCPCS Level II codes are limited in its description of adjustable wrap items as there are no custom HCPCS Level II codes and no codes for several anatomical locations.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. Existing HCPCS Level II code A6584, “Gradient compression wrap with adjustable straps, not otherwise specified” is used when submitting claims for this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II “Not Otherwise Specified” codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Agenda Item # 11
Gradient Compression Garment with Adjustable Straps, Knee - HCP240625YVAET

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression garment with adjustable straps for the knee.

Applicant's suggested language: XXXXX, “Gradient compression wrap with adjustable straps, knee, each”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression wrap with adjustable straps for the knee. The proposed code is necessary to recognize the specific textile/technology, and precise anatomical location of lymphedema. Adjustable wrap items are uniquely constructed from multiple layers of textiles that are sewn, laminated or bonded together to create a fabric that has minimal stretch (inelastic) and high rigidity. The textiles may include but are not limited to nylon, foam, and textured fabric delivering the highest stiffness/containment compared to other compression garments. These garments use clasps or hook and loop closures to enable adjustability providing greater patient independence, adherence, and efficacy. The Lymphedema Treatment Act amended title XVIII of the Social Security Act to provide coverage of certain lymphedema compression treatment items under the Medicare Program. The term “lymphedema compression treatment items” means standard and custom fitted gradient compression garments determined to serve a medical purpose and for the treatment of lymphedema. The newly published HCPCS Level II codes are limited in its description of adjustable wrap items as there are no custom HCPCS Level II codes and no codes for several anatomical locations. Unique HCPCS Level II code for a knee wrap is needed to build a full leg, modular coverage with adjustable wraps to effectively manage lymphedema.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. Existing HCPCS Level II code A6584, “Gradient compression wrap with adjustable straps, not otherwise specified” is used when submitting claims for this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II “Not Otherwise Specified” codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Agenda Item # 11
Gradient Compression Custom Garment with Adjustable Straps, Knee - HCP240626ACU0W

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression custom garment with adjustable straps for the knee.

Applicant's suggested language: XXXXX, “Gradient compression wrap with adjustable straps, knee, each, custom”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression custom garment with adjustable straps for the knee. The proposed code is necessary to recognize the specific textile/technology, precise anatomical location of lymphedema, and custom version of the product. Adjustable wrap items are uniquely constructed from multiple layers of textiles that are sewn, laminated or bonded together to create a fabric that has minimal stretch (inelastic) and high rigidity. The textiles may include but are not limited to nylon, foam, and textured fabric delivering the highest stiffness/containment compared to other compression garments. These garments use clasps or hook and loop closures to enable adjustability providing greater patient independence, adherence, and efficacy. The Lymphedema Treatment Act amended title XVIII of the Social Security Act to provide coverage of certain lymphedema compression treatment items under the Medicare Program. The term “lymphedema compression treatment items” means standard and custom fitted gradient compression garments determined to serve a medical purpose and for the treatment of lymphedema. The newly published HCPCS Level II codes are limited in its description of adjustable wrap items as there are no custom HCPCS Level II codes and no codes for several anatomical locations.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. Existing HCPCS Level II code A6584, “Gradient compression wrap with adjustable straps, not otherwise specified” is used when submitting claims for this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II “Not Otherwise Specified” codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Agenda Item # 11
Gradient Compression Garment with Adjustable Straps, Lobe - HCP240625AGT7L

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression garment with adjustable straps for the lobe.

Applicant's suggested language: XXXXX, “Gradient compression wrap with adjustable straps, lobe, each”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression garment with adjustable straps for the lobe. The proposed code is necessary to recognize the specific textile/technology, and precise anatomical location of lymphedema. Adjustable wrap items are uniquely constructed from multiple layers of textiles that are sewn, laminated or bonded together to create a fabric that has minimal stretch (inelastic) and high rigidity. The textiles may include but are not limited to nylon, foam, and textured fabric delivering the highest stiffness/containment compared to other compression garments. These garments use clasps or hook and loop closures to enable adjustability providing greater patient independence, adherence, and efficacy. The Lymphedema Treatment Act amended title XVIII of the Social Security Act to provide coverage of certain lymphedema compression treatment items under the Medicare Program. The term “lymphedema compression treatment items” means standard and custom fitted gradient compression garments determined to serve a medical purpose and for the treatment of lymphedema. The newly published HCPCS Level II codes are limited in its description of adjustable wrap items as there are no custom HCPCS Level II codes and no codes for several anatomical locations.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. Existing HCPCS Level II code A6584, “Gradient compression wrap with adjustable straps, not otherwise specified” is used when submitting claims for this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II “Not Otherwise Specified” codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Agenda Item # 11
Gradient Compression Custom Garment with Adjustable Straps, Lobe - HCP240626J6KD6

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression custom garment with adjustable straps for the lobe.

Applicant's suggested language: XXXXX, “Gradient compression wrap with adjustable straps, lobe, each, custom”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression custom garment with adjustable straps for the lobe. The proposed code is necessary to recognize the specific textile/technology, precise anatomical location of lymphedema, and custom version of the product. Adjustable wrap items are uniquely constructed from multiple layers of textiles that are sewn, laminated or bonded together to create a fabric that has minimal stretch (inelastic) and high rigidity. The textiles may include but are not limited to nylon, foam, and textured fabric delivering the highest stiffness/containment compared to other compression garments. These garments use clasps or hook and loop closures to enable adjustability providing greater patient independence, adherence, and efficacy. The Lymphedema Treatment Act amended title XVIII of the Social Security Act to provide coverage of certain lymphedema compression treatment items under the Medicare Program. The term “lymphedema compression treatment items” means standard and custom fitted gradient compression garments determined to serve a medical purpose and for the treatment of lymphedema. The newly published HCPCS Level II codes are limited in its description of adjustable wrap items as there are no custom HCPCS Level II codes and no codes for several anatomical locations.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. Existing HCPCS Level II code A6584, “Gradient compression wrap with adjustable straps, not otherwise specified” is used when submitting claims for this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II “Not Otherwise Specified” codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Agenda Item # 11
Gradient Compression Garment with Adjustable Straps, Toe - HCP240625462HD

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression garment with adjustable straps for the toe.

Applicant's suggested language: XXXXX, “Gradient compression wrap with adjustable straps, toe, each”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression garment with adjustable straps for the toe. The proposed code is necessary to recognize the specific textile/technology, and precise anatomical location of lymphedema. Adjustable wrap items are uniquely constructed from multiple layers of textiles that are sewn, laminated or bonded together to create a fabric that has minimal stretch (inelastic) and high rigidity. The textiles may include but are not limited to nylon, foam, and textured fabric delivering the highest stiffness/containment compared to other compression garments. These garments use clasps or hook and loop closures to enable adjustability providing greater patient independence, adherence, and efficacy. The Lymphedema Treatment Act amended title XVIII of the Social Security Act to provide coverage of certain lymphedema compression treatment items under the Medicare Program. The term “lymphedema compression treatment items” means standard and custom fitted gradient compression garments determined to serve a medical purpose and for the treatment of lymphedema. The newly published HCPCS Level II codes are limited in its description of adjustable wrap items as there are no custom HCPCS Level II codes and no codes for several anatomical locations.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. Existing HCPCS Level II code A6584, “Gradient compression wrap with adjustable straps, not otherwise specified” is used when submitting claims for this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II “Not Otherwise Specified” codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Agenda Item # 11
Gradient Compression Custom Garment with Adjustable Straps, Toe - HCP240626HQRC0

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression custom garment with adjustable straps for the toe.

Applicant's suggested language: XXXXX, “Gradient compression wrap with adjustable straps, toe, each, custom”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression custom garment with adjustable straps for the toe. The proposed code is necessary to recognize the specific textile/technology, precise anatomical location of lymphedema, and custom version of the product. Adjustable wrap items are uniquely constructed from multiple layers of textiles that are sewn, laminated or bonded together to create a fabric that has minimal stretch (inelastic) and high rigidity. The textiles may include but are not limited to nylon, foam, and textured fabric delivering the highest stiffness/containment compared to other compression garments. These garments use clasps or hook and loop closures to enable adjustability providing greater patient independence, adherence, and efficacy. The Lymphedema Treatment Act amended title XVIII of the Social Security Act to provide coverage of certain lymphedema compression treatment items under the Medicare Program. The term “lymphedema compression treatment items" means standard and custom fitted gradient compression garments determined to serve a medical purpose and for the treatment of lymphedema. The newly published HCPCS Level II codes are limited in its description of adjustable wrap items as there are no custom HCPCS Level II codes and no codes for several anatomical locations.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. Existing HCPCS Level II code A6584, “Gradient compression wrap with adjustable straps, not otherwise specified” is used when submitting claims for this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II “Not Otherwise Specified” codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Agenda Item # 11
Gradient Compression Garment with Adjustable Straps, Torso, Vest - HCP240625GXD90

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression garment vest with adjustable straps for the torso.

Applicant's suggested language: XXXXX, “Gradient compression wrap with adjustable straps, torso, vest, each”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code for a gradient compression garment vest with adjustable straps for the torso. The proposed code is necessary to recognize the specific textile/technology, and precise anatomical location of lymphedema. Adjustable wrap items are uniquely constructed from multiple layers of textiles that are sewn, laminated or bonded together to create a fabric that has minimal stretch (inelastic) and high rigidity. The textiles may include but are not limited to nylon, foam, and textured fabric delivering the highest stiffness/containment compared to other compression garments. These garments use clasps or hook and loop closures to enable adjustability providing greater patient independence, adherence, and efficacy. There are mechanical and clinical differentiations discussed in this application to support a unique code for this medical device. The Lymphedema Treatment Act amended title XVIII of the Social Security Act to provide coverage of certain lymphedema compression treatment items under the Medicare Program. The term “lymphedema compression treatment items” means standard and custom fitted gradient compression garments determined to serve a medical purpose and for the treatment of lymphedema. The newly published HCPCS Level II codes are limited in its description of adjustable wrap items as there are no custom HCPCS Level II codes and no codes for several anatomical locations.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. Existing HCPCS Level II code A6584, “Gradient compression wrap with adjustable straps, not otherwise specified” is used when submitting claims for this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II “Not Otherwise Specified” codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Agenda Item # 11
Gradient Compression Custom Garment with Adjustable Straps, Torso, Vest - HCP240701TWK49

Topic/Issue

Request to establish a new HCPCS Level II code to identify a gradient compression custom garment vest with adjustable straps for the torso.

Applicant's suggested language: XXXXX, “Gradient compression wrap with adjustable straps, torso, vest, each, custom”

Summary of Applicant's Submission

US Medical Compression Alliance (USMCA) submitted a request to establish a new HCPCS Level II code a gradient compression custom garment vest with adjustable straps for the torso. The proposed code is necessary to recognize the specific textile/technology, precise anatomical location of lymphedema, and specification of customization. Adjustable wrap items are uniquely constructed from multiple layers of textiles that are sewn, laminated or bonded together to create a fabric that has minimal stretch (inelastic) and high rigidity. The textiles may include but are not limited to nylon, foam, and textured fabric delivering the highest stiffness/containment compared to other compression garments. These garments use clasps and hook and loop closures to enable adjustability providing greater individual independence, adherence, and efficacy. The Lymphedema Treatment Act amended title XVIII of the Social Security Act to provide coverage of certain lymphedema compression treatment items under the Medicare Program. The term “lymphedema compression treatment items” means standard and custom fitted gradient compression garments determined to serve a medical purpose and for the treatment of lymphedema. The newly published HCPCS Level II codes are limited in its description of adjustable wrap items as there are no custom HCPCS Level II codes and no codes for several anatomical locations.

CMS Preliminary HCPCS Coding Recommendation

CMS has not identified a need to establish a new HCPCS Level II code. Existing HCPCS Level II code A6584, “Gradient compression wrap with adjustable straps, not otherwise specified” is used when submitting claims for this lymphedema compression treatment item (LCTI). We will continue to monitor LCTI coding trends regularly and will propose new HCPCS Level II codes when appropriate.

Preliminary Medicare Benefit Category Determination

Lymphedema Compression Treatment Item.

Preliminary Medicare Payment Determination

The payment determination for HCPCS Level II “Not Otherwise Specified” codes is made by the DME MACs on an individual, claim-by-claim basis.

Pricing Indicator = 46

Agenda Item # 12
PROBUPHINE® (Buprenorphine Hydrochloride) Implant - IHC240918CTFFL

Topic/Issue

Request to discontinue existing HCPCS Level II code J0570 "Buprenorphine implant, 74.2 mg."

CMS Summary

HCPCS Level II code J0570 is no longer used because PROBUPHINE® was discontinued by the FDA on October 1, 2020. The expiration date of the last lot sold of PROBUPHINE® (as reported to CMS) was April 30, 2021.

HCPCS Level II code J0570, "Buprenorphine implant, 74.2 mg" identifies PROBUPHINE® (buprenorphine hydrochloride) implant. PROBUPHINE® (buprenorphine hydrochloride) implant was approved by the Food and Drug Administration (FDA) on May 26, 2016. PROBUPHINE® is indicated for the maintenance treatment of opioid dependence in individuals who have achieved and sustained prolonged clinical stability on low-to-moderate doses of a transmucosal buprenorphine containing product.

CMS Final HCPCS Coding Decision

CMS published a final determination for the third quarterly HCPCS Level II coding cycle of 2024 on October 2, 2024, to discontinue existing HCPCS Level II code J0570, "Buprenorphine implant, 74.2 mg" effective April 1, 2025. Consistent with our usual practice to discontinue a code, we welcome information from other insurers who are currently paying for this product.

Agenda Item # 13
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-Years-CMSHCPCSLevelII-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[3], 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-questions-single-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, they are single source drugs based on the statutory definition of "single source drug" in section 1847A(c)(6) of the Act. Because these are single source drugs, there is a programmatic need for each product to have a unique billing and payment code.

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

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

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

CMS Final HCPCS Coding Decision

We established or revised twelve HCPCS Level II codes within the fourth quarter (Q4) of 2023, effective April 1, 2024, ten HCPCS Level II codes within the first quarter (Q1) of 2024, effective July 1, 2024, nine HCPCS Level II codes within the second quarter (Q2) of 2024, effective October 1, 2024, and twelve HCPCS Level II codes within the third quarter (Q3) of 2024, effective January 1, 2025, to separately identify products approved by the FDA after October 2003, and not rated as therapeutically equivalent to a reference listed product in an existing code.

We seek comment on these code descriptors.

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

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

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

HCPCS Code	Action	Long Descriptor
J0139	Add	Injection, adalimumab, 1 mg
J0208	Revise	Injection, sodium thiosulfate (pedmark), 100 mg
J0209	Add	Injection, sodium thiosulfate (hope), 100 mg
J0211	Add	Injection, sodium nitrite 3 mg and sodium thiosulfate 125 mg (nithiodote)
J0612	Revise	Injection, calcium gluconate, not otherwise specified, 10 mg
J0613	Revise	Injection, calcium gluconate (wg critical care) not therapeutically equivalent to J0612, 10 mg
J0650	Add	Injection, levothyroxine sodium, not otherwise specified, 10 mcg
J0651	Add	Injection, levothyroxine sodium (fresenius kabi) not therapeutically equivalent to J0650, 10 mcg
J0652	Add	Injection, levothyroxine sodium (hikma) not therapeutically equivalent to J0650, 10 mcg
J0687	Add	Injection, cefazolin sodium (wg critical care), not therapeutically equivalent to j0690, 500 mg
J1010	Add	Injection, methylprednisolone acetate, 1 mg
J1171	Add	Injection, hydromorphone, 0.1 mg
J1552	Add	Injection, immune globulin (alyglo), 100 mg
J1597	Add	Injection, glycopyrrolate (glyrx-pf), 0.1 mg
J1598	Add	Injection, glycopyrrolate (fresenius kabi), not therapeutically equivalent to J1596, 0.1 mg
J2002	Add	Injection, lidocaine hcl in 5% dextrose, 1 mg
J2003	Add	Injection, lidocaine hydrochloride, 1 mg
J2004	Add	injection, lidocaine hcl with epinephrine, 1 mg
J2183	Add	Injection, meropenem (wg critical care), not therapeutically equivalent to j2185, 100 mg
J2251	Revise	Injection, midazolam in 0.9% sodium chloride, intravenous, not therapeutically equivalent to J2250, 1 mg
J2252	Add	Injection, midazolam in 0.8% sodium chloride, intravenous, not therapeutically equivalent to J2250, 1 mg
J2253	Add	Injection, midazolam (seizalam), 1 mg
J2290	Add	Injection, nafcillin sodium, 20 mg
J2373	Add	Injection, phenylephrine hydrochloride (immphentiv), 20 micrograms
J2470	Add	Injection, pantoprazole sodium, 40 mg
J2471	Add	Injection, pantoprazole (hikma), not therapeutically equivalent to J2470, 40 mg
J2802	Add	Injection, romiplostim, 1 microgram
J2919	Add	Injection, methylprednisolone sodium succinate, 5 mg

J3424	Add	Injection, hydroxocobalamin, intravenous, 25 mg
J8522	Add	Capecitabine, oral, 50 mg
J8541	Add	Dexamethasone (hemady), oral, 0.25 mg
J8611	Add	Methotrexate (jylamvo), oral, 2.5 mg
J8612	Add	Methotrexate (xatmep), oral, 2.5 mg
J9033	Revise	Injection, bendamustine hydrochloride, 1 mg
J9073	Add	Injection, cyclophosphamide (ingenus), 5 mg
J9075	Add	Injection, cyclophosphamide, not otherwise specified, 5mg
Q0155	Add	Dronabinol (syndros), 0.1 mg, oral, fda approved prescription anti-emetic, for use as a complete therapeutic substitute for an iv anti-emetic at the time of chemotherapy treatment, not to exceed a 48 hour dosage regimen
Q5140	Add	Injection, adalimumab-fkjp, biosimilar, 1 mg
Q5141	Add	Injection, adalimumab-aaty, biosimilar, 1 mg
Q5142	Add	Injection, adalimumab-ryvk biosimilar, 1 mg
Q5143	Add	Injection, adalimumab-adbm, biosimilar, 1 mg
Q5144	Add	Injection, adalimumab-aacf (idacio), biosimilar, 1 mg
Q5145	Add	Injection, adalimumab-afzb (abrilada), biosimilar, 1 mg

Appendix B: DMEPOS Payment Categories

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

Pricing = 00 Service Not Separately Priced

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

Pricing = 31 Frequently Serviced Items

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

Pricing = 32 Inexpensive and Other Routinely Purchased Items

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

Pricing = 33 Oxygen and Oxygen Equipment

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

Pricing = 34 Supplies Necessary for the Effective Use of DME

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

Pricing = 35 Surgical Dressings

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

Pricing = 36 Capped Rental Items

Payment is made on a monthly rental fee schedule basis. The beneficiary takes over ownership of the item after the 13th rental payment is made. The rental fee for capped rental items, other than power wheelchairs, for each of the first 3 months of rental is equal to 10 percent of the purchase fee for the item. The rental fee for months 4 through 13 is equal to 7.5 percent of the purchase fee for the item. The rental fee for power wheelchairs for each of the first 3 months of rental is equal to 15 percent of the purchase fee for the item. The rental fee for power wheelchairs for months 4 through 13 is equal to 6 percent of the purchase fee for the item. Complex rehabilitative power wheelchairs can also be purchased in the first month.

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

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

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

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

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

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