

schedule amounts adjusted in accordance with § 414.210(g)(1)(iv) if the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b-5(g)(1)(B)) ended before December 31, 2020. As this situation no longer applies and is in the past, we are proposing to remove this obsolete text from § 414.210(g)(9)(v).

We are proposing to revise § 414.210(g)(9)(vi) to state that for items and services furnished in all areas with dates of service on or after the date immediately following the duration of the emergency period described in section 1135(g)(1)(B) of the Act, or January 1, 2024, whichever is later, the fee schedule amount for the area is equal to the adjusted payment amount established under paragraph (g) of this section. Finally, we are proposing to make conforming changes to § 414.210(g)(2) for the rural and non-contiguous areas in order to specify the December 31, 2023 date specified in section 4139 of the CAA, 2023.

Finally, section 4139(c) of the CAA, 2023 authorizes the Secretary to implement the provisions of this section by program instruction or otherwise. Given that the PHE for COVID-19 ended on May 11, 2023, which is prior to when the proposed changes to the regulations would be finalized, we intend to issue program instructions or other subregulatory guidance to effectuate the changes, as previously described. We believe this approach will serve to ensure a smooth transition after the end of the PHE for COVID-19.

B. Scope of the Benefit and Payment for Lymphedema Compression Treatment Items

1. Statutory Authority

Effective for items furnished on or after January 1, 2024, section 4133(a)(1) of Division FF, Title V, Subtitle D of the CAA, 2023 amends section 1861 of the Act, adding subparagraph (JJ) to subsection (s)(2) and coverage under a new benefit category under Medicare Part B for lymphedema compression treatment items as defined in new subsection (mmm) of section 1861 of the Act. Section 4133(a)(2) of the CAA, 2023 amends section 1833(a)(1) of the Act, adding subparagraph (GG) to indicate that the amount paid for lymphedema compression treatment items defined in section 1861(mmm) of the Act shall be equal to 80 percent of the lesser of the

actual charge or the amount determined using the payment basis established by the Secretary under paragraph (1) of new subsection (z) of section 1834 of the Act. Paragraph (2) of new subsection (z) of section 1834 of the Act prohibits payments under Part B for lymphedema compression treatment items furnished other than at such frequency as the Secretary may establish. Paragraph (3) of new subsection (z) of section 1834 of the Act specifies that in the case of lymphedema compression treatment items that are included in a competitive bidding program under section 1847(a) of the Act, the payment basis under section 1847(a) of the Act shall be the payment basis determined under the competitive bidding program, and the Secretary may use information on the payment determined under the competitive bidding program to adjust the payment amount otherwise determined under section 1834(z) of the Act for an area that is not a competitive bidding area under section 1847 of the Act. Section 4133(a)(3) of the CAA, 2023 amends section 1847(a)(2) of the Act, adding lymphedema compression treatment items to the competitive bidding program under subparagraph (D) of section 1847(a)(2) of the Act. Finally, section 4133(b)(3) of the CAA, 2023 amends section 1834 of the Act under subsections (a)(20)(D) and (j)(5) to mandate application of the DMEPOS quality standards and accreditation and DMEPOS supplier enrollment and supplier standards requirements, respectively, to suppliers of lymphedema compression treatment items.

2. Background

Currently, Medicare Part B does not include coverage for lymphedema compression treatment items other than compression pumps and accessories that meet the definition of DME covered under the DME benefit category under section 1861(n) of the Act. Section 4133 of the CAA, 2023 amends the Act to establish a new Part B benefit category for lymphedema compression treatment items.

The lymphatic system is an integral component of the human circulatory system and consists of lymphatic vessels, lymph nodes and associated lymphoid organs.^{146,147} The International Society of Lymphology defines lymphedema as “an external (and/or internal) manifestation of lymphatic system insufficiency and deranged lymph transport” and is “a symptom or sign resulting from underlying lymphatic disease.”¹⁴⁸ The Centers for Disease Control and Prevention (CDC) defines lymphedema as swelling due to a buildup of lymph fluid in the body¹⁴⁹. According to the National Institutes of Health (NIH) National Library of Medicine, lymphedema is a chronic disorder characterized by swelling under the skin caused by the inability of protein rich lymph fluid to drain, usually due to a blockage or damage to the lymph system.¹⁵⁰ Additionally, according to the National Lymphedema Network, this swelling commonly occurs in the arm or leg, but it may also occur in other body areas including the breast, chest, head and neck, and genitals.¹⁵¹ Lymphedema develops when a body region, where lymphatic vessels and lymph nodes are missing or impaired, becomes overloaded with lymphatic fluid. Lymphedema is a chronic condition with no definitive curative treatment that can become progressive, so early detection and institution of decompressive measures are essential in avoiding its potentially disabling sequela.^{152,153,154,155} The gradual accumulation of plasma and cellular components into the interstitial tissue space leads to a chronic inflammatory process that

146 Aspelund A, Robciuc MR, Karaman S, Makinen T, Alitalo K. Lymphatic System in Cardiovascular Medicine. *Circulation Research*. 2016. Volume 118(3). 515-530

147 Suamia H, Scaglioni MF. Anatomy of the Lymphatic System and the Lymphosome Concept with Reference to Lymphedema. *Seminars in Plastic Surgery*. 2018 Feb; 32(1): 5-11

148 International Society of Lymphology Executive Committee. The Diagnosis and Treatment of Peripheral Lymphedema. *Lymphology* 28 (1995)

149 *Lymphedema* CDC.gov. <https://www.cdc.gov/cancer/survivors/patients/lymphedema.htm>

150 Lymphedema. Bryan C. Sleigh; Biagio Manna, September 2018. Found at <https://www.ncbi.nlm.nih.gov/books/NBK537239/>

151 <https://lymphnet.org/what-is-lymphedema>

152 Korpan MI, Crevenna R, Fialka-Moser V. Lymphedema a Therapeutic Approach in the Treatment and Rehabilitation of Cancer Patients. *American Journal of Physical Medicine and Rehabilitation*. 2011. May. 90(suppl). S69-S75

153 Preston NJ, Seers K, Mortimer PS. Physical therapies for reducing and controlling lymphoedema of the limbs. *Cochrane Database of Systematic Reviews* 2004, Issue 4. Art. No.: CD003141

154 The International Society of Lymphology. The Diagnosis and Treatment of Peripheral Lymphedema: 2020 Consensus Document of the International Society of Lymphology. *Lymphology*. 2020. 53: 3-19

155 King M, Deveaux A, White H, Rayson. Compression garments versus compression bandaging in decongestive lymphatic therapy for breast cancer-related lymphedema: a randomized controlled trial. *Support Care Cancer*. 2012; 20: 1031-1036

can result in long-term tissue changes and permanent structural damage to the affected anatomical site and its overlying skin layer.^{156,157,158} These changes also make the patient more susceptible to skin and potentially disabling or life-threatening soft tissue infections.^{159,160} The physical manifestations of lymphedema are tissue swelling, pain, heaviness and difficulty using the affected body part.¹⁶¹

Lymphedema occurs in four stages. Stage one may have no outward signs or symptoms but is evidenced by abnormal flow through the lymphatic system. When stage two is reached, there is some swelling that may be alleviated by elevation or compression. Stage three is diagnosed by swelling of an area that does not resolve with elevation and there may be skin thickening and scarring. The fourth stage is characterized by severe swelling and skin abnormalities.¹⁶² Infections such as cellulitis and sepsis may result from lymphedema due to the dense protein rich nature of the lymphatic fluid and requires treatment with antibiotics.¹⁶³ Studies have shown that gradient compression garments are effective in reducing and/or preventing progression of lymphedema in the arm and leg.¹⁶⁴ They have also shown to be effective in maintaining limb circumference.

Gradient compression garments designed for daytime use, while an individual is awake, are different than those for nighttime use, when an individual is asleep. Gradient compression

156 Korpan MI, Crevenna R, Fialka-Moser V. Lymphedema a Therapeutic Approach in the Treatment and Rehabilitation of Cancer Patients. *American Journal of Physical Medicine and Rehabilitation*. 2011. May. 90(suppl): S69-S75

157 Warren AG, Brorson H, Borud LJ, Slavin SA. Lymphedema A Comprehensive Review. *Annals of Plastic Surgery*. 2007. Vol 59, No. 4. 464-472

158 Ly CL, Kataru RO, Mehrara B. Inflammatory Manifestations of Lymphedema. *Int J Mol Scie*. 2017. Jan; 18(1): 171

159 Grada AA, Phillips TJ. Lymphedema, Pathophysiology and clinical manifestations. *J Am Academ Dermatol*. 2017;77: 1009-20

160 Bakar Y, Tugral A. Lower Extremity Lymphedema Management after Gynecologic Cancer Surgery: A Review of Current Management Strategies. *Ann of Vasc Surg*. 2017. Vol. 44; 442-450

161 Warren AG, Brorson H, Borud LJ, Slavin SA. Lymphedema A Comprehensive Review. *Annals of Plastic Surgery*. 2007. Vol 59, No. 4. 464-472

162 The Johns Hopkins Hospital <https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/treating-lymphedema>

163 <https://www.cancerresearchuk.org/about-cancer/coping/physically/lymphoedema-and-cancer/infection-lymphoedema#:~:text=Infection%20in%20people%20with%20lymphoedema,and%20will%20need%20antibiotic%20treatment.>

164 Yasuhara H, Shigematsu H, Muto T. A study of the advantages of elastic stockings for leg lymphedema. *Int Angiol*. 1996 Sep;15(3):272-7. PMID: 8971591. <https://pubmed.ncbi.nlm.nih.gov/8971591/>

garments meant for daytime (waking) provide a higher level of compression, and use of them while sleeping could cause new or additional damage to the affected tissue.¹⁶⁵ Additionally, gradient compression garments appropriate for daytime use can inadvertently become repositioned at night while the individual is sleeping and cause a tourniquet effect, essentially cutting off circulation to the limb and resulting in further swelling.¹⁶⁵ In contrast, gradient compression garments made for nighttime use or times of low activity offer milder compression and are less snug against the skin.¹⁶⁶ Wearing gradient compression garments designed for nighttime use may also help with skin abnormalities resulting from lymphedema and can help prevent a phenomenon called “creeping refill,” where swelling reoccurs during sleep.¹⁶⁷ Generally, more serious cases require gradient compression garments for both daytime and nighttime use. Various types of nighttime garments have been designed as alternatives to the daytime compression system garments. Nighttime garments apply gentle gradient pressure to the limb through a garment with a foam liner and a series of adjustable straps. The garments are non-elastic and provide low resting pressure on the limb, making them safe to wear while sleeping at night.¹⁶⁸ Many of these garments are custom-made, but there are ready-to-wear options available as well. The elastic fibers of daytime compression garments will break down with wear. Because nighttime garments are made of inelastic components, compared to the day-time garments, they do not commonly break down with wear and last longer. While proper care will increase the lifespan of garments, they will need to be replaced sometime within 1 to 3 years if used daily. Studies showed if the garments are used with aftercare regimen, that is, they are in minimum contact with moisturizer during use, they could last longer.¹⁶⁹ In meetings with CMS, some

165 Lymphedema Products, LLC. (2019, September 11). *Day Compression vs Night Compression*. Lymphedemaproducts.com. <https://www.lymphedemaproducts.com/blog/day-vs-night-compression-wear/>

166 Caring Touch Medical, Inc. *Can You Sleep in a Lymphedema Sleeve?* Caringtouchmed.com. <https://www.caringtouchmed.com/can-you-sleep-in-a-lymphedema-sleeve/>

167 Mastectomy Shop. *Can You Sleep in a Lymphedema Sleeve?* Mastectomyshop.com. <https://www.mastectomyshop.com/blogs/can-you-sleep-in-a-lymphedema-sleeve/>

168 McNeely, M. L. *et al.* Nighttime compression supports improved self-management of breast cancer related lymphedema: A multicenter randomized controlled trial. *Cancer* 128, 587–596 (2021).

169 Macintyre, Lisa PhD; Gilmartin, Sian BSc; Rae, Michelle BSc; *Journal of Burn Care & Research*: September/October 2007 – Volume 28 – Issue 5 – pp 725-733

clinicians and lymphologists indicated that they believe that the nighttime garments are quite durable and can last for 2 to 3 years because the materials are more durable than the materials used with the daytime garments. They also indicated that previous versions used strapping in addition to more durable foam materials and could last for up to 5 years. In comparison, daytime garments are elastic garments that are typically made of breathable elastic fabrics such as nylon, cotton, spandex or natural rubber to provide compression and therefore have a much shorter lifespan of approximately 6 months.¹⁷⁰

Gradient compression garments are either standard fit or custom-fit. 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. Individuals with mild or moderate lymphedema can often use standard fit garments. Standard gradient compression garments are easier to measure and are readily available at retailers without requiring a prescription, but they do not conform as well to limbs or provide homogenous compression. Standard fit compression wear for all gradient compression garments come in different compression classification ranges specified in mmHg. While there are no national standards for gradient compression hosiery,¹⁷¹ the most common compression classification ranges for hosiery in the U.S. include: 8-15 mmHg (mild), 15-20 mmHg (medium or over the counter), 20-30 mmHg (firm or medical class 1), 30-40 mmHg (extra firm or medical class 2), and 40-50 mmHg (medical class 3).¹⁷² For all compression ranges, the highest compression is at the ankle or wrist, and compression slowly decreases as it moves up the extremity. Some manufacturers' compression class pressure ranges for hosiery may be different from the compression class ranges used for upper limb gradient compression garment.¹⁷³

170 Mukhopadhyay, A., & Shaw, V. P. (2022). Reliability analysis of stretchable workwear fabric under abrasive damage: Influence of stretch yarn composition. *Journal of Natural Fibers*, 20(1).

171 Lymphedema Framework. Best Practice for the Management of Lymphoedema. International Consensus. London. MEP Ltd, 2006. https://www.woundsme.com/uploads/resources/content_11160.pdf

172 Lymphedema Products, LLC. *Determining Compression Levels*. Lymphedemaproducts. Com. <https://www.lymphedemaproducts.com/blog/how-to-determine-compression-levels-for-your-garments/>

173 Lymphoedema Framework. Best Practice for the Management of Lymphoedema. International Consensus. London. MEP Ltd, 2006. https://www.woundsme.com/uploads/resources/content_11160.pdf

Alternatively, 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 one and a half to two inches) and provide more accurate and consistent gradient compression to manage the individual's symptoms.¹⁷⁴ The type of gradient compression garment prescribed is influenced by the site and extent of the swelling, together with the individual's comfort, lifestyle, preferences, and ability to apply and remove garments. Poorly fitting gradient compression garments may not contain or resolve the lymphedema, can cause tissue damage, may be uncomfortable, and can dissuade a patient from long-term usage.¹⁷⁵

Custom-fit gradient compression garments are typically required when an individual has severe shape distortion and/or short, long, or bulky limbs.¹⁷⁶ In addition, individuals with complex lower limb and torso lymphedema often require custom-fit gradient compression garments, as do those who need special adaptations or when there is need for varying levels of pressure within the same garment.¹⁷⁷ Some studies indicate that approximately 50 percent of lymphedema patients require custom-fit gradient compression garments versus standard fit gradient compression garments for effective treatment, although estimates vary.^{178,179} Patients requiring custom-fit gradient compression garments must be properly evaluated and fitted by a qualified practitioner with appropriate training and specialized skills in the evaluation of gradient compression, such as a physical or occupational therapist, or a physician.

174 https://www.forwardhealth.wi.gov/kw/html/3485_Compression_Garments.html

175 Doherty DC, Morgan PA, & Moffatt CJ (2009). Hosiery in Lower Limb Lymphedema. *J Lymphoedema*, 4(1), 30-

37. https://www.woundsme.com/uploads/resources/content_11160.pdf

176 Chang M-H, Chang DW, & Patel KM (2022). "Lymphedema Risk Reduction and Management" in *Principles and Practice of Lymphedema Surgery*, 2nd Ed., 78-90. <https://www.sciencedirect.com/topics/medicine-and-dentistry/compression-garment>

177 Doherty DC, Morgan PA, & Moffatt CJ (2009). Hosiery in Lower Limb Lymphedema. *J Lymphoedema*, 4(1), 30-37. https://www.woundsme.com/uploads/resources/content_11160.pdf

178 Lymphedema Advocacy Group (2021 Apr). "Cost and Utilization of Lymphedema Compression Garments." <https://lymphedematreatmentact.org/wp-content/uploads/2021/04/Cost-and-Utilization-of-Lymphedema-Compression-Garments.pdf>

179 Boyages J, Xu Y, Kalfa S, Koelmeyer L, Parkinson B, Mackie H, Viveros H, Gollan P, & Taksa L (2017). Financial cost of lymphedema borne by women with breast cancer. *Psychooncology*, 26(6), 849-855. doi: 10.1002/pon.4239. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5484300/>

3. Current Issues: Scope of the Benefit for Lymphedema Compression Treatment Items

This proposed rule would implement a new benefit category established at section 1861(s)(2)(JJ) of the Act for “lymphedema compression treatment items” defined at section 1861(mmm) of the Act as standard and custom fitted gradient compression garments and other items determined by the Secretary that are--

- Furnished on or after January 1, 2024, to an individual with a diagnosis of lymphedema for the treatment of such condition;
- Primarily and customarily used to serve a medical purpose and for the treatment of lymphedema, as determined by the Secretary; and
- Prescribed by a physician (or a physician assistant, nurse practitioner, or a clinical nurse specialist (as these terms are defined in section 1861(aa)(5)) to the extent authorized under State law).

We are proposing that any other items covered under this new benefit category in addition to gradient compression garments must also use compression in treating lymphedema since the specific category of medical items to be covered under section 1861(s)(2) of the Act are “lymphedema compression treatment items.” Similarly, we are proposing that this benefit category is limited to compression treatment items and does not include professional lymphedema treatment services or other services not directly related to the furnishing of the lymphedema compression treatment items. Payment for any covered professional service related to these items would be made under the Medicare Physician Fee Schedule. The statute limits the benefit to items used for the treatment of lymphedema as determined by the Secretary, and we are proposing that this includes items used to treat all types or diagnoses of lymphedema, but does not include the same items when used to treat injuries or illnesses other than lymphedema. In other words, if a gradient compression garment or other lymphedema compression treatment item is furnished to treat an injury or illness other than lymphedema, those items would not be classified under the Medicare benefit category for lymphedema compression treatment items.

We are proposing that other compression items used to treat lymphedema that would be covered under this benefit category in addition to gradient compression garments would include ready-to-wear, non-elastic, gradient compression wraps with adjustable straps such as the items described by HCPCS code A6545. In addition, we are proposing that compression bandaging systems applied in a clinical setting as part of phase one decongestive therapy would also be items covered under the new benefit category for lymphedema compression treatment items if this rule is finalized. However, as discussed in section VII.B.6. of this rule, section 1834(j) of the Act, as amended by section 4133(b)(2) of the CAA, 2023, requires the therapists that furnish these items to become enrolled and accredited DMEPOS suppliers in order to bill for these items as lymphedema compression treatment items per section 1834(j)(5) of the Act or payment for the items applied during phase one of decongestive therapy would not be allowed. We also note that while these items may be covered under the new Part B benefit for lymphedema compression treatment items, the professional services of applying these items would not and would need to be covered under a different Medicare benefit category in order for Medicare payments to be made for these services. We are specifically soliciting comments on the topic of coverage of compression bandaging items under the new benefit for lymphedema compression treatment items. We are also soliciting comments on whether the professional services of applying these bandages could be covered under another Medicare benefit category, such as outpatient physical therapy services under section 1861(p) of the Act or physician services under section 1861(s) of the Act.

With regard to custom garments, we understand that therapists often take measurements of affected body areas and perform other fitting services related to the furnishing of these items. Since these measurements are necessary for the furnishing of the custom garments and are part of what makes the garments custom garments rather than standard garments, these measurements are an integral part of furnishing the custom garments and the suppliers of the garments are responsible for fitting the garments they furnish. Typically, DMEPOS suppliers are responsible

for all aspects of furnishing the item. Following that approach, a supplier receiving payment for furnishing a lymphedema compression treatment item to a beneficiary has responsibility for ensuring that any necessary fitting, training (how to appropriately don/doff and maintain), and adjustment services are provided as part of furnishing the item. Payment for all services necessary for furnishing a gradient compression garment are included in the rates paid by the Medicaid State agencies and we are proposing to use the average Medicaid payment rate plus twenty percent as the payment basis for Medicare (when such Medicaid rates are available).

Therefore, the Medicare payments would likewise include payment for all services necessary for furnishing the gradient compression garment; this is consistent with how Medicare payment is made for DMEPOS. We understand that in many cases a therapist may take measurements and provide other fitting services necessary for furnishing a gradient compression garment that is then furnished by a separate supplier. Under this scenario, the supplier receiving payment for the garment would be responsible for paying the therapist for the fitting component that is an integral part of furnishing the item. An alternative option, which we are not proposing but are seeking comment on, would be to pay separately for the fitting component furnished by the therapist and then back this payment out of the payment for the garment. If a separate Medicare payment amount was made to an entity other than the supplier of the garment for fitting services necessary for furnishing the garment, this amount would have to be subtracted from the payment to the supplier of the garment in order to avoid paying twice for these services. For example, if code Axxx1 describes a “Gradient compression arm sleeve and glove combination, custom, each,” with a payment amount of \$350 established for each garment, a supplier furnishing two of these garments to a beneficiary for daytime use would receive \$700 if the garments are furnished on an assignment basis, and part of this payment would cover the cost of the fitting of the garment that is furnished by the supplier or a separate therapist that is then paid by the supplier for the cost of taking the fitting measurements. Alternatively, a separate allowance and code could be established for the fitting component, such as \$80 for Axxx2 for “Fitting of gradient

compression arm sleeve and glove combination, custom, per two garments.” Under this scenario, it would be necessary to back out the payment for the cost of the separate fitting component from the payment for the two garments ($\$700 - \$80 = \$620$), since the payment for the garments already includes payment for all services necessary for furnishing the garment. As a result, the supplier furnishing the garments would be paid \$310 for each garment rather than \$350 since they did not conduct the fitting component that is paid for separately. We are not proposing this alternative because of many complexities. For example, the therapist providing the fitting component would be required to become an enrolled DMEPOS supplier, accredited for furnishing the garment fitting component, and responsible for meeting all of the requirements for being a DMEPOS supplier, such as meeting the DMEPOS supplier standards and quality standards, obtaining a surety bond, and submitting claims to the appropriate DME MAC. As part of the DMEPOS supplier standards, a supplier must accept return of substandard items. In cases where a mistake is made in measuring and fitting the beneficiary for two custom gradient compression garments, resulting in the furnishing and payment for custom gradient compression garments that do not properly fit the patient, the risk would be assumed by the fitter and not the supplier to accept return of the garments and cover the cost of two replacement garments. Again, we are not proposing to make separate payment for the fitting services under this benefit when furnished by a supplier other than the supplier of the garments; however, we are specifically soliciting comments on the topic and comments on options to resolve the issues we outlined previously. We recognize that there is not necessarily a standard industry practice for the fitting and training components for furnishing lymphedema compression garments and seek comment on whether there are best practices in this space that CMS should consider further in the future. We also welcome comment on whether any HCPCS level I (Current Procedural Terminology or CPT®) codes may describe the services of the therapist in these scenarios.

Finally, there are accessories such as zippers in garments, liners worn under garments or wraps with adjustable straps, and padding or fillers that are not compression garments but may

be necessary for the effective use of a gradient compression garment or wraps with adjustable straps. There are also accessories like donning and doffing aids for different body parts such as lower limb butlers or foot slippers that allow the patients to put on the compression stockings with minimum effort and are not used with compression bandaging systems or supplies. We are proposing that accessories necessary for the effective use of gradient compression garments and gradient compression wraps with adjustable straps would also fall under this new benefit for lymphedema compression treatment items. For example, a liner that is used with a garment because it is needed to prevent skin breakdown could be covered under the new benefit because it is necessary for the effective use of the garment. We are specifically soliciting comments on the topic of coverage of accessories necessary for the effective use of gradient compression garment or wraps with adjustable straps, including what HCPCS codes should be established to describe these items, as well as comments on whether there are additional items other than the gradient compression garments, gradient compression wraps with adjustable straps, and compression bandaging supplies that could potentially fall under the new benefit category for lymphedema compression treatment items.

4. Healthcare Common Procedure Coding System (HCPCS) Codes for Lymphedema Compression Treatment Items

HCPCS codes are divided into two principal subsystems, referred to as Level I and Level II of the HCPCS. Level I of the HCPCS is comprised of Current Procedural Terminology (CPT), a numeric coding system maintained by the American Medical Association (AMA). HCPCS Level II is a standardized coding system that is used primarily to identify drugs, biologicals and non-drug and non-biological items, supplies, and services not included in the CPT codes, such as ambulance services and DMEPOS when used outside a physician's office. As shown in Table FF-A 1, there are currently Level II HCPCS codes for compression garments (stockings, sleeves,

gloves, and gauntlets) and compression wraps with adjustable straps that may be used in the treatment of lymphedema and other conditions.

TABLE FF-A 1: EXISTING HCPCS CODES FOR COMPRESSION TREATMENT ITEMS

Code	Description
A6530	Gradient compression stocking, below knee, 18-30 mmhg, each
A6531	Gradient compression stocking, below knee, 30-40 mmhg, each
A6532	Gradient compression stocking, below knee, 40-50 mmhg, each
A6533	Gradient compression stocking, thigh length, 18-30 mmhg, each
A6534	Gradient compression stocking, thigh length, 30-40 mmhg, each
A6535	Gradient compression stocking, thigh length, 40-50 mmhg, each
A6536	Gradient compression stocking, full length/chap style, 18-30 mmhg, each
A6537	Gradient compression stocking, full length/chap style, 30-40 mmhg, each
A6538	Gradient compression stocking, full length/chap style, 40-50 mmhg, each
A6539	Gradient compression stocking, waist length, 18-30 mmhg, each
A6540	Gradient compression stocking, waist length, 30-40 mmhg, each
A6541	Gradient compression stocking, waist length, 40-50 mmhg, each
A6545	Gradient compression wrap, non-elastic, below knee, 30-50 mmhg, each
A6549	Gradient compression stocking/sleeve, not otherwise specified
S8420	Gradient pressure aid (sleeve and glove combination), custom made
S8421	Gradient pressure aid (sleeve and glove combination), ready made
S8422	Gradient pressure aid (sleeve), custom made, medium weight
S8423	Gradient pressure aid (sleeve), custom made, heavy weight
S8424	Gradient pressure aid (sleeve), ready made
S8425	Gradient pressure aid (glove), custom made, medium weight
S8426	Gradient pressure aid (glove), custom made, heavy weight
S8427	Gradient pressure aid (glove), ready made
S8428	Gradient pressure aid (gauntlet), ready made
S8429	Gradient pressure exterior wrap
S8430	Padding for compression bandage, roll
S8431	Compression bandage, roll

The items described by HCPCS codes A6531, A6532, and A6545 are covered by Medicare under the Part B benefit for surgical dressings at section 1861(s)(5) of the Act, when used in the treatment of an open venous stasis ulcer. Total allowed charges for these three codes in 2022 was approximately \$2.5 million, with around \$1.9 million for the non-elastic, below knee, gradient compression wrap with adjustable straps described by code A6545, \$500,000 for the below knee, gradient compression stocking code A6531, and \$100,000 for the below knee, gradient compression stocking code A6532. We are not proposing to change this policy with this

rule, but we must address the codes for items when they are covered under Medicare Part B as surgical dressing versus when they are covered under Medicare Part B as lymphedema compression treatment for billing and claims processing purposes. We are therefore proposing to add three new HCPCS codes for use when billing for A6531, A6532, and A6545 items used as surgical dressings. The proposed codes are as follows:

- A---- Gradient compression stocking, below knee, 30-40 mmhg, used as surgical dressing in treatment of open venous stasis ulcer, each
- A---- Gradient compression stocking, below knee, 40-50 mmhg, used as surgical dressing in treatment of open venous stasis ulcer, each
- A---- Gradient compression wrap with adjustable straps, non-elastic, below knee, 30-50 mmhg, used as surgical dressing in treatment of open venous stasis ulcer, each

The surgical dressing fee schedule amounts for codes A6531, A6532, and A6545 would be applied to the three new codes. The remaining discussion in this section addresses the coding for the lymphedema compression treatment items.

For gradient compression stockings, we are proposing to use existing codes A6530 through A6541, and code A6549 from Table FFA-1. For codes A6530 through A6541, we are soliciting comments on whether we should maintain the three pressure level differentiations in the codes and whether these differentiations should be something other than 18-30, 30-40, and 40-50 mmHg. We are also soliciting comments on whether there is a better way to describe the body areas these garments cover rather than “below knee,” “thigh-length,” “full-length/chap style,” and “waist-length.” For each code, we propose to add a matching code for the custom version of the garment. For example, if we continue to use codes A6530 through A6532 for below knee stockings with the current descriptions, we would add corresponding codes for the custom versions of these garments, such as the following:

- A---- Gradient compression stocking, below knee, 18-30 mmhg, custom, each
- A---- Gradient compression stocking, below knee, 30-40 mmhg, custom, each

- A---- Gradient compression stocking, below knee, 40-50 mmhg, custom, each

For gradient compression garments for the upper extremities and areas of the body, we propose to use existing codes A6549 and S8420 through S8428. We propose renumbering codes S8420 through S8428 as “A” codes rather than S codes. We also propose removing the words “ready-made” and revising “custom made” to “custom” for the codes for the upper extremity gradient compression garments and replacing the word “pressure” with “compression,” in order to be consistent with the wording for the codes for the lower extremity garments. We propose to add the word “arm” in front of the word “sleeve” for the upper extremity garments. We also propose to add a code for a custom gauntlet. Finally, we propose to add the word “each” to the description for each code. If no other changes are made, the new codes would be as follows:

- ---- Gradient compression arm sleeve and glove combination, each
- A---- Gradient compression arm sleeve and glove combination, custom, each
- A---- Gradient compression arm sleeve, each
- A---- Gradient compression arm sleeve, custom, medium weight, each
- A---- Gradient compression arm sleeve, custom, heavy weight, each
- A---- Gradient compression glove, each
- A---- Gradient compression glove, custom, medium weight, each
- A---- Gradient compression glove, custom, heavy weight, each
- A---- Gradient compression gauntlet, each
- A---- Gradient compression gauntlet, custom, each

We are soliciting comment on whether separate codes are needed for mastectomy sleeves or whether these items can be grouped together under the same codes used for other arm sleeves (S8422 thru S8424). We are soliciting comments on whether there is a need to retain codes S8420 through S8428, in addition to the renumbered A code versions, for use by other payers other than Medicare. If these codes are retained, they would be invalid for Medicare use, but could be used by other payers in lieu of the new A codes.

We are also proposing to add the following new codes for other upper body areas:

- A---- Gradient compression garment, neck/head, each
- A---- Gradient compression garment, neck/head, custom, each
- A---- Gradient compression garment, torso and shoulder, each
- A---- Gradient compression garment, torso/shoulder, custom, each
- A---- Gradient compression garment, genital region, each
- A---- Gradient compression garment, genital region, custom, each

For all of the codes for the upper extremities and upper body areas, we are soliciting comments on whether we should establish codes for pressure level differentiations similar to the pressure level differentiations in codes A6530 through A6541, possibly replacing the words medium and heavy weight, as well as whether codes are needed for additional upper body areas.

We are proposing the following new codes for nighttime garments:

- A---- Gradient compression garment, glove, padded, for nighttime use, each
- A---- Gradient compression garment, arm, padded, for nighttime use, each
- A---- Gradient compression garment, lower leg and foot, padded, for nighttime use, each
- A---- Gradient compression garment, full leg and foot, padded, for nighttime use, each

For gradient compression wraps with adjustable straps, we are proposing to use code A6545 in Table FF-A 1 for below knee wraps and solicit comments on whether additional codes or coding revisions are needed for the purpose of submitting claims for gradient compression wraps with adjustable straps. Regarding HCPCS codes for compression bandaging systems, we believe more codes are needed than existing codes S8430 (Padding for compression bandage, roll) and S8431 (Padding for compression bandage, roll), for example, to describe the supplies used in a compression bandaging system consisting of more than two layers. We also believe that specific base sizes should be added to the code, for example “10cm by 2.9m” rather than the

vague unit of “roll” and are soliciting comments on HCPCS coding changes needed to adequately describe the various compression bandaging systems used for the treatment of lymphedema. Finally, as noted in section VII.B.3. of this rule, we are soliciting comments on HCPCS codes needed to describe accessories necessary for the effective use of gradient compression garments or wraps with adjustable straps.

5. Procedures for Making Benefit Category Determinations and Payment Determinations for New Lymphedema Compression Treatment Items

We are proposing to implement the new Part B benefit for lymphedema compression treatment items and the initial set of HCPCS codes to identify these items for claims processing purposes, effective January 1, 2024. In the future, as new products come on the market and refinements are made to existing technology, there will be a need to determine whether these newer technology items are lymphedema compression treatment items covered under this new benefit and what changes to the HCPCS are needed to identify these items for claims processing purposes. There will also be a need to establish payment amounts for the newer items in accordance with the payment rules established as part of this rulemaking.

Currently, CMS uses the procedures at 42 CFR 414.114 to make benefit category determinations and payment determinations for new splints and casts, parenteral and enteral nutrition (PEN) items and services covered under the prosthetic device benefit, and intraocular lenses (IOLs) inserted in a physician’s office covered under the prosthetic device benefit. CMS uses the same procedures at 42 CFR 414.240 to make benefit category determinations and payment determinations for new DME items and services, prosthetics and orthotics, surgical dressings, therapeutic shoes and inserts, and other prosthetic devices other than PEN items and services and IOLs inserted in a physician’s office. These procedures involve the use of the HCPCS public meetings where consultation from the public is obtained on preliminary HCPCS coding determinations for new items and services. Public consultation is also obtained at these meetings on preliminary benefit category determinations and preliminary payment

determinations for the new items and services. To ensure appropriate and timely consideration of future items that may qualify as lymphedema compression treatment items, we are proposing to use these same procedures to make benefit category determinations and payment determinations for new lymphedema compression treatment items. Future changes to the HCPCS codes established in section 2 of this rule for lymphedema compression treatment items would also be made using this public meeting process.

We are proposing to use the same process described in §414.240 to obtain public consultation on preliminary coding, benefit category, and payment determinations for new lymphedema compression treatment items. That is, when a request is received for a new HCPCS code or change to an existing HCPCS code(s) for a lymphedema compression treatment item, CMS would perform an analysis to determine if a new code or other coding change is warranted and if the item meets the definition of lymphedema compression treatment item at section 1861(mmm) of the Act. A preliminary payment determination would also be developed for items determined to be lymphedema compression treatment items and are implemented in April or October of each year. The preliminary determinations would be posted on CMS.gov approximately 2 weeks prior to a public meeting. As part of this coding and payment determination process, it may be necessary to combine or divide existing codes; in this situation, we are proposing to follow the same process as outlined in 42 CFR 414.236. After consideration of public input on the preliminary determinations, CMS would post final HCPCS coding decisions, benefit category determinations, and payment determinations on CMS.gov, and then issue program instructions to implement the changes.

In addition to these proposals for initial payment determinations for lymphedema treatment items and the proposed process for addressing new lymphedema treatment items, as required by the Act, we also propose to revise the DMEPOS regulations to include lymphedema treatment items in the competitive bidding process. We are proposing changes to 42 CFR 414.402 to add lymphedema treatment items to the definition of “items” for competitive

bidding, § 414.408 to include lymphedema treatment items in the list of items for which payment would be made on a lump sum purchase basis under the competitive bidding program in accordance with any frequency limitations established under proposed subpart Q in accordance with section 1834(z)(2) of the Act, and § 414.412 to add reference to the proposed subpart Q to the bid rules.

6. Enrollment, Quality Standards, and Accreditation Requirements for Suppliers of Lymphedema Compression Treatment Items and Medicare Claims Processing Contractors for these Items

Section 1834(a)(20) of the Act requires the establishment of quality standards for suppliers of DMEPOS that are applied by independent accreditation organizations. Section 4133(b)(1) of the CAA, 2023 amends section 1834(a)(20)(D) of the Act to apply these requirements to lymphedema compression treatment items as medical equipment and supplies.

Section 1834(j) of the Act requires that suppliers of medical equipment and supplies obtain and continue to periodically renew a supplier number in order to be allowed to submit claims and receive payment for furnishing DMEPOS items and services. The suppliers must meet certain supplier standards in order to possess a supplier number and are also subject to other requirements specified in section 1834(j) of the Act. Section 4133(b)(2) of the CAA, 2023 amends section 1834(j)(5) of the Act to include lymphedema compression treatment items as medical equipment and supplies subject to the requirements of section 1834(j) of the Act.

Suppliers of DMEPOS meeting the requirements of sections 1834(a)(20) and 1834(j) of the Act, and related implementing regulations at 42 CFR 424.57 must enroll in Medicare or change their enrollment using the paper application Medicare Enrollment Application for DMEPOS Suppliers (CMS-855S) or through the Medicare Provider Enrollment, Chain, and Ownership System (PECOS). For more information on supplier enrollment, go to:

<https://www.cms.gov/medicare/provider-enrollment-and-certification/become-a-medicare-provider-or-supplier>

Regulations at 42 CFR 421.210 establish regional contractors to process Medicare claims for DMEPOS items and services. These contractors are known as Durable Medical Equipment Medicare Administrative Contractors (DME MACs). We are proposing to include lymphedema compression treatment items as DMEPOS items that fall within the general text of section 421.210(b)(7) for other items or services which are designated by CMS. Thus, claims for these items would be processed by the DME MACs.

7. Payment Basis and Frequency Limitations for Lymphedema Compression Treatment Items

Section 1834(z)(1) of the 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.

Based on our research, Medicaid state plans generally classify and provide lymphedema compression treatment items in the same manner as other durable medical equipment and supplies for home health. While State Medicaid Director Letter #18-001 focuses on how states may demonstrate compliance with the restriction on claiming federal financial participation for “excess” durable medical equipment spending, it describes how Medicaid state plan payment for the broader category of such items (outside of a managed care contract) is usually made either through established fee schedules, a competitive bidding process of the state’s design, or through a manual pricing methodology based on the invoice submitted with each claim.¹⁸⁰ For the purpose of this proposed rule, we took into account the average Medicaid fee schedule payment

¹⁸⁰ Available at <https://www.medicaid.gov/federal-policy-guidance/downloads/smd18001.pdf>

amounts across all states that have published fee schedule amounts for these items in developing, in part, an appropriate payment basis for lymphedema compression treatment items under Medicare.

The VHA does not have established fee schedules for lymphedema compression treatment items, but rather follows a policy of paying for these items based on the reasonableness of vendor pricing. Based on our conversations with the VHA, we understand that for these items, vendor prices at or below acquisition cost plus 50 percent is typically considered reasonable, while Medicaid state plans typically pay for DMEPOS items that do not have fee schedule amounts at acquisition cost plus 20 to 30 percent. Given this difference in the allowed supplier margin, the amounts determined to be reasonable payment rates for these items by the VHA may be approximated by increasing the average Medicaid payment rate by 20 to 30 percent. While the VHA may not have fee schedule amounts for these items, the Department of Defense's TRICARE system maintains fee schedule amounts for lower-extremity lymphedema compression garments. These amounts are approximately equal to the average Medicaid fee schedule amount plus 20 percent. We therefore believe that the average Medicaid fee schedule amount plus 20 percent represents what other government payers such as the VHA and TRICARE consider an appropriate payment basis for these items and a slightly higher payment basis than the average payment rates established by Medicaid state plans that have fee schedule amounts for these items; we are specifically soliciting comments on this. We also conducted a search of internet prices for lymphedema compression treatment items and found these prices to be in line with the TRICARE fee schedule amounts and average Medicaid fee schedule amounts plus 20 percent. We believe that appropriate payment amounts for Medicare for lymphedema compression treatment items would be payment amounts that approximate the payment rates determined to be reasonable by other government payers such as TRICARE, State Medicaid agencies, and, as previously explained, estimates of the payment rates determined to be reasonable by the VHA based on 120 percent of the average Medicaid state plan rates. Because

these rates are in line with internet retail prices, we have not closely examined non-government payers.

Having taken into account the payment amounts from the various sources, as previously described, as required by Act, we propose to set payment amounts for lymphedema compression treatment items using the following methodology. Where Medicaid state plan payment amounts are available for a lymphedema compression treatment item, we propose to 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 propose to 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 propose to base payment amounts based on 100 percent of average internet retail prices for that item. We seek comment on these payment methodologies and whether further adjustments are appropriate.

As previously noted, payment rates for the supply of these items includes payment for fitting services and any other services necessary for furnishing the item. As noted earlier, taking measurements of affected body areas and other fitting services necessary for furnishing lymphedema compression treatment items are an integral part of furnishing the items and the suppliers receiving payment for furnishing lymphedema compression treatment items are responsible for ensuring that any necessary fitting services are provided as part of furnishing the items.

The following table presents a preliminary example of what payment amounts may be, based on the proposed methodology described, as previously detailed, and certain HCPCS codes that we are proposing to be classified under the Medicare Part B benefit category for lymphedema treatment items.

**TABLE FF-A 2: EXAMPLE PAYMENT AMOUNTS FOR LYMPHEDEMA
COMPRESSION TREATMENT ITEMS**

Code	Description	Example Payment Amount
A6530	Gradient compression stocking, below knee, 18-30 mmhg, each	\$37.95
A6531	Gradient compression stocking, below knee, 30-40 mmhg, each	\$54.92
A6532	Gradient compression stocking, below knee, 40-50 mmhg, each	\$73.49
A6533	Gradient compression stocking, thigh length, 18-30 mmhg, each	\$50.24
A6534	Gradient compression stocking, thigh length, 30-40 mmhg, each	\$60.32
A6535	Gradient compression stocking, thigh length, 40-50 mmhg, each	\$68.45
A6536	Gradient compression stocking, full length/chap style, 18-30 mmhg, each	\$70.12
A6537	Gradient compression stocking, full length/chap style, 30-40 mmhg, each	\$83.26
A6538	Gradient compression stocking, full length/chap style, 40-50 mmhg, each	\$97.81
A6539	Gradient compression stocking, waist length, 18-30 mmhg, each	\$92.01
A6540	Gradient compression stocking, waist length, 30-40 mmhg, each	\$110.04
A6541	Gradient compression stocking, waist length, 40-50 mmhg, each	\$128.85
A6545	Gradient compression wrap, non-elastic, below knee, 30-50 mmhg, each	\$110.95
Axxxx	Gradient compression arm sleeve and glove combination, custom, each	\$369.90
Axxxx	Gradient compression arm sleeve and glove combination, each	\$94.55
Axxxx	Gradient compression arm sleeve, custom, medium weight, each	\$172.29
Axxxx	Gradient compression arm sleeve, custom, heavy weight, each	\$177.98
Axxxx	Gradient compression arm sleeve, each	\$58.10
Axxxx	Gradient compression glove, custom, medium weight, each	\$283.50
Axxxx	Gradient compression glove, custom, heavy weight, each	\$349.33
Axxxx	Gradient compression glove, each	\$92.24
Axxxx	Gradient compression gauntlet, each	\$42.85

Where new items are added to this benefit category, following the process outlined in section 3 of this section of this rule, the data sources (Medicaid, TRICARE, VHA, or internet prices) may not initially be available for establishing an appropriate payment amount. We are proposing 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.

Section 1834(z)(2) of the Act authorizes the establishment of frequency limitations for lymphedema compression treatment items and specifies that no payment may be made for lymphedema compression treatment items furnished other than at a frequency established in accordance with this provision of the Act. Gradient compression garments are designed differently depending on whether for daytime or nighttime use. Those meant for daytime provide a higher level of compression while those for nighttime offer milder compression and are less snug against the skin. We are seeking comment on our proposal to cover and make payment for

two garments or wraps with adjustable straps for daytime use (one to wear while another is being washed), per affected extremity, or part of the body, to be replaced every 6 months or when the items is lost, stolen, or irreparably damaged, or if needed based on a change in the beneficiary's medical or physical condition such as an amputation, complicating injury or illness, or a significant change in body weight. In order to maintain mobility, patients may require separate garments or wraps above and below the joint of the affected extremity or part of the body. As discussed in section B of this section of this rule, nighttime garments are inelastic and more durable than the elastic daytime garments and we believe it would be appropriate to replace these garments once per year. We are proposing to cover one nighttime garment per affected extremity or part of the body to be replaced once a year or when the garment is lost, stolen, or irreparably damaged, or if needed based on a change in the beneficiary's medical or physical condition such as an amputation, complicating injury or illness, or a significant change in body weight. Lymphedema is a chronic condition that can be stabilized if properly treated. It may also worsen as the result of infection, radiation and chemotherapy, or progression of comorbid conditions such as obesity. At this point, patients may require changes in their garment prescription. Such changes due to medical necessity will not be subject to the frequency limitations, as previously described. In addition, as with other DMEPOS items, payment could be made for replacement of garments and other items when they are lost, stolen, or irreparably damaged. Examples of lost items include items left behind after evacuating due to a disaster like a hurricane or tornado. Examples of irreparably damaged items include items that burn in a fire, are exposed to toxic chemicals, or are damaged by some other event and does not include items that wear out over time.

With regard to replacement frequencies for compression bandaging systems and supplies, the weekly frequency and overall length of phase one (active) treatment is dependent on the severity of lymphedema. Some patients may require treatment 4 to 5 days per week in phase one while others may only need treatment 2 to 3 days per week. Bandages are used following some

form of hands-on decompression to maintain the reduction. Therefore, we are not proposing specific replacement frequencies for the compression bandaging systems and supplies. We are proposing that the DME MACs would make determinations regarding whether the quantities of compression bandaging supplies furnished and billed during phase one of treatment of the beneficiary's lymphedema are reasonable and necessary.

As previously discussed, section 4133(a)(3) of the CAA, 2023 adds subparagraph D to section 1847(a)(2) of the Act to add lymphedema compression treatment items to the DMEPOS competitive bidding program. Section 1834(z)(3)(A) of the Act specifies that the payment basis under section 1847(a) of the Act becomes the payment basis for lymphedema compression treatment items furnished under the competitive bidding program. Section 1834(z)(3)(B) of the Act provides authority to use information on the payment determined for these items under the competitive bidding program to adjust the payment amounts otherwise determined under section 1834(z) for an area that is not a competitive bidding area under section 1847 of the Act, and in the case of such adjustment, section 1842(b)(8) and (9) of the Act shall not be applied.

8. Proposed Changes

We are proposing to amend 42 CFR 410.36 to add paragraph (a)(4) for lymphedema compression treatment items as a new category of medical supplies, appliances, and devices covered and payable under Medicare Part B, including: standard and custom fitted gradient compression garments; gradient compression wraps with adjustable straps; compression bandaging systems; other items determined to be lymphedema compression treatment items under the process established under §414.1670; and accessories such as zippers in garments, liners worn under garments or wraps with adjustable straps, and padding or fillers that are necessary for the effective use of a gradient compression garment or wrap with adjustable straps. In order to maintain mobility, patients may require separate garments or wraps above and below the joint of the affected extremity or part of the body, and we are proposing that payment may be made in these circumstances. We are proposing that payment may be made for multiple

garments used on different parts of the body when the multiple garments are determined to be reasonable and necessary for the treatment of lymphedema. For example, if it is determined that a beneficiary needs three daytime garments to cover one affected area for the treatment of lymphedema, Medicare would pay for two sets of those three garments for that specific affected area, as well as any other areas of the body affected by lymphedema. For the purpose of establishing the scope of the benefit for these items, we are seeking comment on the following definitions we are proposing to add to 42 CFR 410.2 as they apply to lymphedema compression treatment items:

Gradient compression means the ability to apply a higher level of compression or pressure to the distal (farther) end of the limb or body part affected by lymphedema with lower, decreasing compression or pressure at the proximal (closer) end of the limb or body part affected by lymphedema.

Custom fitted gradient compression garment means a garment that is uniquely sized and shaped to fit the exact dimensions of the affected extremity or part of the body of an individual to provide accurate gradient compression to treat lymphedema.

The proposed definition of “gradient compression” would apply to all lymphedema compression treatment items (garments, wraps, etc.) that utilize gradient compression in treating lymphedema. The proposed definition of “custom fitted gradient compression garment” would apply to custom fitted gradient compression garments covered under the new benefit category for lymphedema compression treatment items. We believe these definitions are necessary for establishing the scope of this new benefit.

Lymphedema compression treatment item means standard and custom fitted gradient compression garments and other items specified under § 410.36(a)(4) that are--

- Furnished on or after January 1, 2024, to an individual with a diagnosis of lymphedema for treatment of such condition;

- Primarily and customarily used to serve a medical purpose and for the treatment of lymphedema; and

- Prescribed by a physician (or a physician assistant, nurse practitioner, or a clinical nurse specialist (as those terms are defined in section 1861(aa)(5) of the Social Security Act) to the extent authorized under State law.

We are proposing to modify and add to the existing HCPCS codes for surgical dressings and lymphedema compression treatment items as explained in section VII.B.4. of this rule. We are proposing that future changes to the HCPCS codes for these items based on external requests for changes to the HCPCS or internal CMS changes would be made through the HCPCS public meeting process described at:

<https://www.cms.gov/medicare/coding/medhcpcsgeninfo/hcpcspublicmeetings>

We are proposing to add §414.1670 under new subpart Q and use the same process described in §414.240 to obtain public consultation on preliminary benefit category determinations and payment determinations for new lymphedema compression treatment items. The preliminary determinations would be posted on CMS.gov in advance of a public meeting. After consideration of public input on the preliminary determinations, CMS would post final HCPCS coding decisions, benefit category determinations, and payment determinations on CMS.gov, and then issue program instructions to implement the changes.

We are proposing to add a new subpart Q under the regulations at 42 CFR part 414 titled, “Payment for Lymphedema Compression Treatment Items” to implement the provisions of section 1834(z) of the Act. We are proposing to add § 414.1600 to our regulations explaining the purpose and definitions under the new subpart Q. We are proposing to add § 414.1650 and paragraph (a) to establish the payment basis equal to 80 percent of the lesser of the actual charge for the item or the payment amounts established for the item under paragraph (b). We are proposing under § 414.1650(b) to establish the payment amounts for lymphedema compression treatment items based on the average of state Medicaid fee schedule amounts plus 20 percent.

Where Medicaid rates are not available, we are proposing to use the average of average internet retail prices and payment amounts established by TRICARE (or, where there is no TRICARE fee schedule rate, the average of internet retail prices alone). We propose under § 414.1650(c) that, beginning January 1, 2025, and on January 1 of each subsequent year, the Medicare payment rates established for these items in accordance with section 1834(z)(1) of the Act and § 414.1650(b) would be increased by the percentage change in the Consumer Price Index for All Urban Consumers (CPI-U) for the 12-month period ending June of the preceding year. For example, effective beginning January 1, 2025, the payment rates that were in effect on January 1, 2024 would be increased by the percentage change in the CPI-U from June 2023 to June 2024.

We are also proposing to add § 414.1660 to address continuity of pricing when HCPCS codes for lymphedema compression treatment items are divided or combined. Similar to current regulations at 42 CFR 414.110 and 414.236, we propose that when there is a single HCPCS code that describes two or more distinct complete items (for example, two different but related or similar items), and separate codes are subsequently established for each item, the payment amounts that applied to the single code continue to apply to each of the items described by the new codes. We propose that when the HCPCS codes for several different items are combined into a single code, the payment amounts for the new code are established using the average (arithmetic mean), weighted by allowed services, of the payment amounts for the formerly separate codes.

We are proposing to add § 414.1680 and the following frequency limitations for lymphedema compression treatment items established in accordance with section 1834(z)(2) of the Act under new subpart Q:

- Two daytime garments or wraps with adjustable straps for each affected limb or area of the body, replaced every 6 months.
- One nighttime garment for each affected limb or area of the body, replaced once a year.

We are soliciting comments on whether two nighttime garments should be allowed, with both garments being replaced once every 2 years, to allow for more than 1 day for washing and drying of the garment(s). We are also proposing to cover replacements of garments or wraps that are lost, stolen, irreparably damaged, or when needed due to a change in the patient's medical or physical condition. We are not proposing specific replacement frequencies for compression bandaging systems or supplies. We are proposing that determinations regarding the quantity of compression bandaging supplies covered for each beneficiary during phase one of decongestive therapy would be made by the DME MAC that processes the claims for the supplies.

We are proposing to revise the regulations for competitive bidding under subpart F at 42 CFR 414 to include lymphedema compression treatment items under the competitive bidding program as mandated by section 1847(a)(2)(D) of the Act. We propose to modify the list of items that may be included in competitive bidding described in § 414.402 to include lymphedema treatment items and revise § 414.408 to include lymphedema treatment items in the list of items for which payment would be made on a lump sum purchase basis under the competitive bidding program in accordance with any frequency limitations established under proposed subpart Q in accordance with section 1834(z)(2) of the Act. Finally, we propose to add reference the proposed subpart Q to the bid rules described at § 414.412.

The methodologies for adjusting DMEPOS payment amounts for items included in the DMEPOS Competitive Bidding Program (CBP) that are furnished in non-CBAs based on the payments determined under the DMEPOS CBP are set forth at § 414.210(g). Section 4133(a)(3) of the CAA, 2023 amended section 1847(a)(2) of the Act to include lymphedema compression treatment items under the DMEPOS CBP, and section 4133(a)(2) of the CAA, 2023 amended section 1834 of the Act to provide authority to adjust the payment amounts established for lymphedema compression treatment items in accordance with new subsection z based on the payments determined for these items under the DMEPOS CBP. We believe the methodologies for adjusting DMEPOS payment amounts at § 414.210(g) should also be used to adjust the

payment amounts for lymphedema compression treatment items included in the DMEPOS CBP that are furnished in non-CBAs. We see no reason why different methodologies for adjusting payment amounts based on payments determined under the DMEOPS CBP would need to be established for lymphedema compression treatment items. We are therefore proposing to add § 414.1690 indicating that the payment amounts established under § 414.1650(b) for lymphedema compression treatment items may be adjusted using information on the payment determined for lymphedema compression treatment items as part of implementation of the DMEPOS CBP under subpart F using the methodologies set forth at § 414.210(g).

C. Definition of Brace

1. Background

The Social Security Act of 1965 (the Act) defines the scope of benefits available to eligible Medicare beneficiaries under Medicare Part B, the voluntary supplementary medical insurance program defined by section 1832 of the Act. Section 1832(a)(1) of the Act establishes the Medicare Part B benefit for “medical and other health services.” Section 1861(s) of the Act further defines “medical and other health services” to include under paragraph (9) leg, arm, back, and neck braces, and artificial legs, arms, and eyes. Artificial legs, arms, and eyes are artificial replacements for missing legs, arms, and eyes and this rule does not address the scope of the Medicare benefit for these items. Section 1834(h)(4)(C) of the Act details the payment rules for particular items and services including specifying that “the term ‘orthotics and prosthetics’ has the meaning given to such term in section 1861(s)(9).” Regulations at 42 CFR 410.36(a)(3) include leg, arm, back, and neck braces under the list of medical supplies, appliances, and devices in the scope of items paid for under Part B of Medicare. However, the term “brace” is not defined in the Act or in regulation. Specifically, the term brace is not defined in 42 CFR 410.2 Definitions for supplementary medical insurance benefits for Medicare.

The Medicare program instruction that defines the term brace is located at CMS Pub. 100–02, Chapter 15, §130 of the Medicare Benefit Policy Manual for Part B coverage of “Leg, Arm,