

COVID-19 ended on May 11, 2023, which is prior to when the proposed changes to the regulations would be finalized, we stated in the proposed rule that we intend to issue program instructions or other subregulatory guidance to effectuate the changes, as previously described (88 FR 43767). We stated that we believed this approach will serve to ensure a smooth transition after the end of the PHE for COVID-19. We issued Transmittal 12068 and 12228, which updated the quarterly DMEPOS Fee Schedule and included a discussion of the changes required by section 4139 of the CAA, 2023.^{163,164}

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

¹⁶³ <https://www.cms.gov/files/document/r12068cp.pdf>

¹⁶⁴ <https://www.cms.gov/files/document/r12228cp.pdf>

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.^{165,166} 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.¹⁶⁷” The Centers for Disease Control and Prevention (CDC) defines lymphedema as swelling due to a buildup of lymph fluid in the body¹⁶⁸. According to the National Institutes of Health (NIH) National Library of

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

166 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

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

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

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.¹⁶⁹ 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.¹⁷⁰ 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.^{171,172,173,174} The gradual accumulation of plasma and cellular components into the interstitial tissue space leads to a chronic inflammatory process that can result in long-term tissue changes and permanent structural damage to the affected anatomical site and its overlying skin layer.^{175,176,177} These changes also make the patient more susceptible to skin and potentially disabling or life-threatening soft tissue infections.^{178,179} The

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

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

171 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.

172 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.

173 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.

174 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.

175 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.

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

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

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

179 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.

physical manifestations of lymphedema are tissue swelling, pain, heaviness and difficulty using the affected body part.¹⁸⁰

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.¹⁸¹ 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.¹⁸²

Lymphedema is treated in two phases: an acute "intensive" phase (Phase 1) and a maintenance phase (Phase 2). In Phase 1 "the individual is typically wrapped with medical short-stretch compression bandages. In Phase 2, one goal is for the patient to be able to wear gradient pressure garments during the day and compression bandaging or alternatives (like nighttime garments) at night.¹⁸³ Studies have shown that gradient compression garments are effective in reducing and/or preventing progression of lymphedema in the arm and leg.¹⁸⁴ 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 garments meant for daytime (waking) provide a higher level of compression, and use of them

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

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

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

183 Korpan MI, Crevenna R, Fialka-Moser V. Lymphedema: a therapeutic approach in the treatment and rehabilitation of cancer patients. *Am J Phys Med Rehabil*. 2011 May;90(5 Suppl 1):S69-75. doi: 10.1097/PHM.0b013e31820be160. PMID: 21765266.

184 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/>

while sleeping could cause new or additional damage to the affected tissue.¹⁸⁵ 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.¹⁸⁵ In contrast, gradient compression garments made for nighttime use or times of low activity offer milder compression and are less snug against the skin.¹⁸⁶ 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.¹⁸⁷ 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.¹⁸⁸ 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 nighttime 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.¹⁸⁹ In meetings with CMS, some clinicians and lymphologists indicated that they believe that the nighttime garments are

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

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

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

188 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).

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

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.¹⁹⁰

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,¹⁹¹ 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).¹⁹² 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 garments.¹⁹³

190 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).

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

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

193 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 1 and a half to 2 inches) and provide more accurate and consistent gradient compression to manage the individual's symptoms.¹⁹⁴ 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 and adherence.¹⁹⁵

Custom-fit gradient compression garments are typically required when an individual has severe shape distortion and/or short, long, or bulky limbs.¹⁹⁶ 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.¹⁹⁷ 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.^{198,199}

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

In the CY 2024 HH PPS proposed rule (88 FR 43654), we proposed to implement a new benefit category established at section 1861(s)(2)(JJ) of the Act for "lymphedema compression

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

195 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

196 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>

197 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

198 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>

199 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/>

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).

In response to the CY 2024 HH PPS proposed rule (88 FR 43654), we received a number of comments from individuals health care providers and suppliers, medical associations, and medical device companies. More comments were received from healthcare consulting and medical technology organizations. In this section, we provide the proposed payment methodology, and a summary of the comments we received as well as our responses.

We proposed 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 proposed 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 proposed 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. The following is a summary of the comments we received and our responses.

Comment: A commenter recommended that CMS work with suppliers and manufacturers of compression garments, and the clinical community who have expertise in providing services to patients with lymphedema in developing the scope of benefit and payment for lymphedema compression treatment items. A commenter stated that the need for custom fit supplies should be based on the medical expertise of the prescribing healthcare provider and patients should not face undue burdens. A commenter expressed concern that the proposed provisions in this rule would not remove barriers to eligibility for custom garments.

Response: We are appreciative of these comments. During the process of developing scope of benefit, payment, and coding policies for the new benefit for lymphedema compression items, we consulted with medical professionals, suppliers, manufacturers, trade organizations, and patients via public comments and meetings. Concerning coverage and the determination of a specific beneficiary's medical need for lymphedema compression treatment items, these concerns are outside the scope of this rulemaking. The final rule implements the new benefit category for lymphedema compression treatment items established under section 4133 of the CAA, 2023, and does not address coverage for these items or the Medicare coverage process or criteria.

Comment: A commenter urged CMS to reconsider the interpretation section 4133 of the Consolidated Appropriations Act, 2023. The commenter stated that Congress intended to make lymphedema compression treatment items available and accessible to Medicare beneficiaries with illnesses other than lymphedema. The commenter supports Congress' intent to expand patient access to lymphedema compression treatment items and urged CMS to ensure that its coverage and payment policies are consistent with and promote Congress' intent of expanding patient access to lymphedema compression treatment items. Another commenter stated that

phlebolympheidema is lymphedema secondary to chronic venous insufficiency and that all patients with CVI (CEAP scores C3-C6) should be considered lymphedema patients.

Response: Section 4133 of the Consolidated Appropriations Act, 2023 establishes section 1861(mmm)(1) of the Act, stating that the new benefit is to be “furnished to the individual with a diagnosis of lymphedema for the treatment of such condition”. As such, we are finalizing the proposed rule to limit the scope of the new benefit for lymphedema compression treatment items to items furnished to an individual with a diagnosis of lymphedema and not illnesses other than lymphedema.

In accordance with section 1861(mmm)(2) of the Act we are defining, in addition to the standard and custom fitted gradient compression garments that are included in the scope of the benefit, what “other items as determined by the Secretary” are included within the scope of the benefit. We proposed 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 proposed that clinicians (or other qualified professionals) that furnish these items become enrolled and accredited as DMEPOS suppliers to bill for these items as lymphedema compression treatment items per section 1834(j)(5)(E) 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 associated with applying these items would need to be covered under a different Medicare benefit category for Medicare payments to be made for these services. We specifically solicited comments on the topic of coverage of compression bandaging items under the new benefit for lymphedema compression treatment items. We also solicited 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. The following is a summary of the comments we received and our responses.

Comment: Several commenters thanked and supported CMS for the inclusion of compression bandaging systems being covered during the intensive/decongestive phase of the treatment. However, many commenters were concerned about the proposal that compression bandaging systems applied in a clinical setting as part of phase one decongestive therapy would be covered to the exclusion of their coverage during other phases of the treatment despite being critical to improvement and maintenance phases of treatment. Several commenters requested CMS consider including coverage of bandaging not only for the initial acute or decongestive phase (Phase 1), but also for the maintenance phase (Phase 2) of treatment for patients who use compression wraps and bandaging systems in addition to the coverage of daytime and nighttime garments.

A few commenters shared concerns over terms used in the proposed rule. A commenter recommended that CMS eliminate a reference to "bandaging systems" and replace with language that includes "lymphedema bandages and related supplies such as foam rolls or sheets, lining materials." Several commenters indicated that patients need "sets of garments" as opposed to individual garments.

Many commenters requested CMS ensure inclusion of bandaging for various body parts including stretch bandages, firm bandaging, custom and adjustable wraps, bandage liners, night garments, Kinesio tape, Circaid wraps, Ready wraps, digital bandaging, elastic and non-elastic wraps, rolls of gauze bandaging, wraps for foot, calf, knee, thigh, hand, arm, Velcro bandage/compression systems, all knit type garments, compression socks/ sleeve/ gloves/ gauntlets/ pantyhose /thigh highs, standard fitted compression garments for the chest and back, such as compression bras which are able to hold a breast prosthesis; and toe caps that may be used for long term treatment, nighttime or other phases of treatment.

Response: We appreciate the comments on a variety of different viewpoints on bandaging, bundling payments and how to approach payment for therapists and other skilled professionals. We understand and agree that bandaging may be provided at different phases of the beneficiary's treatment of lymphedema and the use of bandaging can continue at various stages of lymphedema as long as medically necessary. We are clarifying that payment for compression bandaging systems under this benefit category is not limited to Phase 1 (acute or decongestive therapy) but is also available under Phase 2 (maintenance therapy). With regards to payment, we note that currently a therapist who applies compression bandaging supplies during Phase 1 of treatment can bill for the service of applying the bandages using CPT codes 29581 and 29584. It is important to note, however, that if the CPT codes are billed and paid for a particular date of service, then billing for the bandaging supplies used during that date of service using the HCPCS A codes is not allowed and would be denied as it would result in duplicate payment of the supplies since the Medicare payment amounts for codes 29581 and 29584 include payment for the compression bandaging supplies.

We are finalizing the proposal to cover gradient compression wraps with adjustable straps and compression bandages under the new benefit as well as accessories necessary for the effective use of gradient compression garments and wraps with adjustable straps. In response to comments about ensuring inclusion of bandaging for various body parts we are adding more HCPCS codes, in addition to those originally proposed, to be clearer about the inclusion of bandaging and accessories for the various body parts. Detailed discussion on HCPCS coding is included in section 4 "Healthcare Common Procedure Coding System (HCPCS) Codes for Lymphedema Compression Treatment Items" and a list of HCPCS codes being added is included in Table FF-A 2.

With regard to the reference to "compression bandaging systems", we are finalizing the use of the term "compression bandaging systems" in our regulations at 42 CFR 410.36(4)(iii) for lymphedema compression treatment items that are comprised of a combination of individual

lymphedema compression bandages and related supplies as well as kits that can include both lymphedema bandages and related supplies used to create the compression bandaging system.

Comment: Many commenters requested that CMS provide separate payment for the measurement and fitting services to ensure that patients receive the best care for their individual needs and that clinicians, therapists, and certified fitters are paid fairly and directly for the service they provide in all settings where fittings may be provided. Some commenters suggested they had greater trust in therapists than in general DMEPOS suppliers for garment measurement, believing that therapists provided more accurate measurements. Some commenters suggested precedent with orthotics and prosthetics for separate codes specifically for fitting services (with varying recommendations for the specific codes that could be created), and these codes may also assist in reimbursement in the event follow-up visits are needed to assess possible re-fitting as limb size may change significantly over time (for example, HCPCS level 1 code 97760 “Orthotic management and training” when services are not provided by a DMEPOS supplier).

A commenter expressed concern that DMEPOS suppliers may not be prepared for the influx of referrals for lymphedema compression treatment garments, and that only separate payment for fitting services would alleviate wait times or other access issues.

At the same time, many commenters expressed concerns with aspects that would arise from separate payment for fitting services. A commenter expressed concern that the patient receive clear and correct pricing for each garment, regardless of how the fitting services are provided. A commenter stated that therapists may use multiple garment suppliers which may create complications in arranging for separate payment for fitting.

A commenter believed the proposal to implement a separate fitting component where payment is made to a therapist for taking measurements would be difficult for suppliers, particularly those that maintain a physical office where patients can attend a complimentary fitting appointment with a trained fitter.

Several commenters expressed concern with responsibility for replacement of ill-fitting garments if separate payment for fitting services were established. While most commenters believe that separately paid fitters should not bear financial responsibility for garments that do not fit as expected, a commenter recommended that if the garment matches the written fitting order, the fitter should bear responsibility for the cost of replacement in the event of a poor fit. A commenter specifically recommended that since the supplier retains responsibility for replacement or alteration of an ill-fitting garment, their payment should include the cost of fitting. A commenter noted that improperly measured garments could be altered (so full replacement may not be necessary) and that even with accurate measurement there is no guarantee of proper fit since there can be reduction or increase in the patient's condition during the weeks between measuring and receipt of the garment.

A few commenters support the proposal to bundle payment for fitting and garments and that it be coordinated by enrolled DMEPOS suppliers. A commenter indicated that if DMEPOS suppliers are enabled to act as administrator of payments for these services it would allow DMEPOS suppliers to set rates and administer payments without oversight or infrastructure to address non-payments, appeals and other unforeseen billing and reimbursement circumstances. Several commenters shared concerns that DMEPOS suppliers may not be ideal or have adequate training for measuring, assisting in choices or educating patients with certain circumstances such as lymphedema in sensitive areas, compression choices based on sensitivities or personal challenges in doffing and donning, or reach and balance concerns and may lead to delay and regression in treatment. A few commenters believe DMEPOS suppliers will have financial incentives that do not account for patient needs or preference. A few commenters indicated there is a difference between the measuring and fitting services provided by a DMEPOS supplier as compared to a therapist and indicated that when DMEPOS suppliers perform the measuring services the garment is typically sent to the patient's home and the supplier is not required to follow-up with the patient whereas with therapists the garment is sent to the therapist's office.

where they ensure the garment fits properly and the patient's comfort and functional needs are met leading to higher rates of compliance. A commenter indicated that the differences should be acknowledged in the payment.

Response: We appreciate the many concerns commenters expressed both in support and against the idea of separate payment for fitting services. In the proposed rule, we noted that therapists often take measurements of affected body areas and perform other fitting services related to the furnishing of gradient compression garments. These measurements are an integral part of furnishing the custom garments and in some cases, the standard 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, including fitting and measuring services. 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. The supplier receiving payment for the garment may work out an arrangement with the therapist for the fitting component that is an integral part of furnishing the item. Although we solicited comments on the option of paying separately for the fitting component furnished by the therapist and then backing this payment out of the payment for the garment, we did not propose this policy. We did not propose this policy because of the many complexities associated with this policy and the comments reinforced that this is a very complicated alternative that requires careful analysis and consideration. We do not believe we are in a position to implement such a policy in 2024, but it is something we could consider under future rulemaking if we believe it would improve the administration of this new DMEPOS benefit category.

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 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 did not propose 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 specifically solicited 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 sought comment on whether there are best practices in this space that CMS should consider further in the future. We also solicited comments on whether any HCPCS Level I (Current Procedural Terminology or CPT®) codes may describe the services of the therapist in these scenarios. The following is a summary of the comments we received and our responses.

Comment: A commenter recommended a specific proposal where the 20 percent beneficiary copay would be directed to the fitter for these services while the supplier of the garment would receive 80 percent of the allowed payment amount for the garment.

Response: The CAA, 2023 did not modify or exempt lymphedema compression treatment items from the normal copay requirements that apply to Medicare items and services, so we do not intend to direct that beneficiaries make copayments for these items to fitters rather than the DMEPOS suppliers of the items.

Comment: A few commenters are concerned that having DME suppliers administer payment for these services may open a window for abuse of Federal anti-kickback laws in the industry.

Response: With regard to the concerns raised by the commenters about the Federal anti-kickback statute, while all applicable parties must comply with this law, such concerns are outside the scope of this rulemaking.

Comment: A few commenters requested CMS to require non-clinician fitters to complete a training program, while a few other commenters requested CMS to adopt quality standards for

non-clinician fitters of lymphedema compression treatment items. Alternatively, a few commenters recommended CMS provide a separate payment to clinicians for providing DME services and did not support DME suppliers administering payment for these critical services. A commenter requested clarification from CMS on whether private practice physical (PT) and occupational therapists (OT) are exempt from proposed surety bond requirements if the business is solely owned and operated by the PT or OT's. This commenter requested CMS to premise payment on enrolling as a DME supplier. Some commenters expressed concern that CMS may have omitted from the proposal the full range of medical professionals who provide fitting services. Some commenters recommend that CMS support the establishment of an industry-standard licensing or certification process for fitting services to ensure training in garment selection, fabric type, compression class and the necessary options for specific disease states, and presentation, while other commenters expressed concern with limiting fitting services to certain licensed health professionals in a way that may reduce access in areas of the country already struggling with a lack of lymphedema treatment professionals.

Response: Suppliers of lymphedema compression treatment items are required to become enrolled DMEPOS suppliers, which in turn requires the supplier to obtain a surety bond, become accredited, and be in compliance with the DMEPOS supplier standards and quality standards. Medical professionals that currently provide fitting services are able to enroll in Medicare as DMEPOS suppliers and receive such bundled payment for garments and related supply services provided to beneficiaries. We will consider whether specific quality standards for suppliers of lymphedema compression treatment items should be added to the DMEPOS quality standards in the future. With regards to the comment requesting exemption from the surety bond requirements, we note that section 1834(a)(16) of the Act requires DMEPOS suppliers to maintain a surety bond of at least \$50,000 as a condition for the receipt or renewal of a Medicare provider number.

Comment: Several comments noted that fitting may be required not only for patients wearing custom garments, but also ready-to-wear products, although some comments specifically noted that the time required to fit for custom garments is longer. Some commenters stated that patients sometimes require multiple visits to ensure a proper fit, particularly for patients with more complex cases. A few commenters also noted that in certain complex cases it may be necessary for the supplier or manufacturer to interact with the therapist to co-engineer a custom garment, so CMS should ensure appropriate reimbursement for this type of work. A commenter urged CMS to collect and make public data on where beneficiaries are accessing lymphedema products, whether through suppliers or therapists, and to implement an auditing process to ensure that therapists are being adequately reimbursed.

Response: We appreciate these comments. Payment for all services necessary for furnishing a gradient compression garment are included in the rates paid by Medicaid State agencies and we proposed to use the average Medicaid payment rate plus twenty percent as the payment basis for Medicare (when such Medicaid rates are available). Therefore, Medicare payments likewise include payment for all services necessary for furnishing the gradient compression garment, which is consistent with how Medicare payment is made for other DMEPOS items and services. We intend to closely monitor access to lymphedema compression treatment items and related services necessary for the effective use of these items to ensure that the Medicare payments for these items are appropriate.

Comment: A few commenters raised concerns that bundling payment for a lymphedema compression treatment item that is supplied by a DMEPOS supplier where the measuring and fitting of the item is performed by a therapist or other practitioner would require the therapist or practitioner to enter into a financial relationship with the DMEPOS supplier that would implicate the physician self-referral law at section 1877 of the Act. A commenter requested that CMS clarify that a financial relationship between a DMEPOS supplier and a therapist or a practitioner

who performs the fitting component of the service would be permissible under the physician self-referral law.

Response: Section 1877 of the Act, also known as the physician self-referral law: (1) Prohibits a physician from making referrals for certain designated health services payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship, unless an exception applies; and (2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third-party payer) for those referred services. A financial relationship is an ownership or investment interest in the entity or a compensation arrangement with the entity. The statute establishes a number of specific exceptions and grants the Secretary the authority to create regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse.

The physician self-referral law would be implicated only if the therapist or practitioner who provides the fitting component of a service is a physician or the immediate family member of a physician (as defined at § 411.351) and there is a financial relationship between the therapist or practitioner and the DMEPOS supplier. Where the physician self-referral law is implicated, a physician's referrals to the DMEPOS supplier with which the physician (or the immediate family member of the physician) has the financial relationship will not be prohibited if all the requirements of an applicable exception are satisfied. We note that several statutory and regulatory exceptions may be applicable to the type of financial relationship described by the commenters.

We are finalizing the proposal to include payment for fitting services in the overall payment for lymphedema compression treatment garments that CMS will make to Medicare-enrolled DMEPOS suppliers that furnish lymphedema compression treatment items to Medicare beneficiaries.

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 proposed 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 solicited 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. The following is a summary of the comments we received and our responses.

Comment: All commenters supported the addition of accessories to the items and services covered under the Medicare benefit category for lymphedema compression treatment items. Several commenters thanked and supported CMS's proposal to include accessories such as donning and doffing aids that assist patients with putting on compression items. Several commenters indicated that lymphedema treatment items are customizable and vary widely by patient but are especially important for Medicare recipients who are more likely to have multiple co-morbidities that restrain their strength and range of motion. A few commenters indicated the need to account for layering garments as recommended by clinicians. A few commenters described these items as part of a "build" of a garment/solution and suggested they have unique HCPCS codes to support the "build."

Several commenters requested clarification on the term “padding” suggesting this should be itemized for the sake of comprehensiveness and include foam sheets, foam rolls, cotton or synthetic padding, stockinette, customized foam cutouts, and chip pads as well as Swell Spots or similar quilted items to be used under clothing. A commenter suggested padding be listed according to use (that is, skin protection and cushioning, compression, fibrosis). A commenter indicated that the proposed definition in 42 CFR 410.36(a)(4) needs additional language to better describe the wide range of accessories that are necessary for effective use of medically necessary lymphedema compression treatment items.

Many commenters indicated the need for coverage of aids that facilitate use and enhance compliance rates such as: adhesive roll on, fasteners and closures, bandage liners, donning and doffing aids (such as limb butlers, foot slippers, liners, silicone donning lotions, and bandaging supplies), padding, skin barrier stocking, accessories which are attached to and modify the lymphedema treatment garment, and accessories which are separate from the lymphedema garments such as oversleeves and undersleeves. Many commenters made suggestions on the range of accessories for which HCPCS codes are needed. Many commenters identified the following accessories for HCPCS code development: stockinettes, customized foam cutouts, foam pads, foam chips, bandage rollers (manual and motorized), bandaging liners, medium-stretch bandages, under-bandage pads and bandage liners, and short-stretch bandages, securing tape, donning and doffing aids such as wire frame butlers, easy slide sleeves, donning gloves, lubricants and adhesives, garment washing fluid, oversleeves, strap extenders, lobe straps, tape measures, garter belts, zippers, pull loops, silicone bands, comfort/flexion zones, outer jackets, and fitting lotion.

A few commenters indicated that padding is generally durable but only some is washable and that materials break down over time and need replacement every 1 to 2 years. The commenter indicated bandages lose their stretch and need replacing at least every 4 to 6 weeks.

A few commenters requested CMS clarify that lymphedema compression treatment items and pneumatic compression pumps may be covered concurrently if medically necessary. A commenter suggested that supporting the cost of donning and doffing aids would benefit patients who lack the mobility to don and doff the garments themselves.

Response: We appreciate the detailed lists and comments that the commenters have provided to us on the types of accessories as well as suggestions for accessory HCPCS codes. We thank commenters for the support of our proposal to cover accessories necessary for the effective use of gradient compression garments and gradient compression wraps with adjustable straps, including donning and doffing aids, under the new lymphedema compression treatment items benefit. We recognize that the form accessories may take in relation to the garments and wraps is varied with some accessories part of the garment as furnished such as zippers and others separate such as liners worn under garments or wraps. We believe the proposed definition of accessories for lymphedema compression treatment items at 42 CFR 410.36(a)(4) captures the variance in form and range of accessories that are needed for the effective use of garments and wraps with adjustable straps. We also believe that additional specification in terms of type or use on the term “padding” that is provided as an example in the definition is not necessary to clarify the scope of the benefit and are finalizing the definition as proposed. Concerning HCPCS codes to describe these items, as commenters note, there is a wide array of accessories on the market that can be used to facilitate effective use of the garments or wraps. Given the number and types of accessories available, we have initially established a not otherwise specified code for accessories, as shown in Table FF A 2, that will be effective January 1, 2024 for use in identifying accessories used in conjunction with lymphedema garments and wraps. We believe it is important to have a code in place on January 1, 2024 for identifying such items and we refer readers to the public HCPCS process, described at <https://www.cms.gov/medicare/coding/medhcpcsgeninfo/hcpcspublicmeetings>, as a means for modifying the code set in the future. Since Medicare coverage determinations have not been

developed at this time for different types of accessories used in conjunction with lymphedema garments and wraps, the coverage determinations for any claims submitted for these items must be made on an individual, claim-by-claim basis, beginning on January 1, 2024. We note that one code for these accessories is all that will be needed to process claims for these items and services. Should CMS develop an NCD or LCDs with specific medical necessity criteria for different types of accessories in the future, we would add codes for the different types of accessories addressed in these coverage determinations for Medicare claims processing purposes. With respect to concurrent coverage of lymphedema compression treatment items and pneumatic compression pumps, DME MACs will continue to make determinations on the medical necessity of items and services, including items that fall under the new benefit category for lymphedema compression treatment items and existing benefit categories.

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 HCPCS Level II 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

Code	Description
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 did not propose to change this policy with this rule, but we addressed 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 therefore proposed 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 proposed to use existing codes A6530 through A6541, and code A6549 from Table FFA-1. For codes A6530 through A6541, we solicited 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 also solicited 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 proposed 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 proposed to use existing codes A6549 and S8420 through S8428. We proposed renumbering codes S8420 through S8428 as “A” codes rather than S codes. We proposed 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 proposed to add the word “arm” in front of the word “sleeve” for the upper extremity garments. We also proposed to add a code for a custom gauntlet. Finally, we proposed to add the word “each” to the description for each code. We proposed that if no other changes are made, the new codes would be as follows:

- A---- 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 solicited 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 solicited 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 also proposed 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 solicited 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 proposed 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 proposed 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 solicited comments on HCPCS codes needed to describe accessories necessary for the effective use of gradient compression garments or wraps

with adjustable straps. The following is a summary of the comments we received and our responses.

Comment: Several commenters recommended that flat-knit garments have separate codes from circular-knit garments. A commenter supported development of separate HCPCS codes for circular knit vs flat knit garments as they have different costs and are appropriate for different patients.

Response: While some commenters supported having different codes for flat knit and circular knit garments, we do not believe this differentiation is necessary since it is our understanding that the majority of flat knit garments are custom garments, and the majority of circular knit garments are non-custom. We believe that having separate codes for custom and non-custom codes should be sufficient to address this difference in garment material.

Comment: A few commenters expressed general support for existing compression stocking codes (A6530-41 and A6549). A few commenters indicated that changes to these codes would affect existing processes, knowledge, and experience throughout the insurance industry. A few commenters did not support any changes in these codes. A few commenters supported changes to the A6530-41 and A6549 codes to reflect the different kinds of knits, lengths, and other variations in garments, including the addition of modifiers to describe each criterion when billed with a specific HCPCS code. Other commenters favored establishing new codes with additional textile and technology specifications instead of using the existing compression stocking codes. A few commenters indicated that the number of proposed HCPCS codes was inadequate. A few commenters made suggestions on codes on custom versions of Existing Gradient Compression Stocking Codes (A6530-41 and A6549). A commenter recommended custom nighttime compression garments be available at any compression pressure and custom non-elastic gradient compression wrap at any compression pressure.

A commenter suggested expanding and updating the codes for each type of material (circular knit, flat knit, inelastic wraps) and indicating whether it is ready made or custom

made. Many commenters offered suggestions on better ways to describe body areas. Several commenters suggested adding descriptions that would apply to multiple body areas, including toe and individual toes, calf, foot, ankle, below knee, knee, above knee, thigh, pelvis, and pelvis and thigh(s), genital, head, neck, chest, torso, arm, hand, and finger. Several commenters suggested descriptions for items that apply to a range of body areas, including shorts, thigh to waist length compression shorts, ankle to waist length compression capris, full body suit, biker short and adding “knee-high” or “thigh-high” to descriptions, combined gauntlet and arm sleeve, and torso only (bodysuits, bras, axillary compression items, vests, abdominal compression items, short-sleeve shirts, and long-sleeve shirts) and chest/torso compression garments. A few commenters noted the need for descriptions that would cover garment items used for multiple body areas. A commenter suggested “high rise panty” or “high rise panty with leg” or “bicycle short style” to clarify that stocking definitions include the buttocks, the foot, open or closed toe, as well as a partial leg on the non-affected side. A commenter indicated the need for a description that would apply to a standard thigh high compression garment on one leg to a custom panty hose with 2 legs of differing lengths and compression levels. A commenter indicated the need for a description that would apply to a garment item that covers an entire limb/body part or is divided into components to allow ease of donning/doffing and best coverage per patient. The description should also be inclusive of all body parts with appropriate codes for each. A few commenters suggested new HCPCS billing codes for items such as custom flat knit compression waist high pantyhose (with multiple compression levels in different body parts) and a groin compression panel option.

Response: We thank the commenters for providing comments on the use of the existing codes (A6530-41 and A6549) and for support of our proposal. After careful review, we believe that retaining the existing longstanding compression stocking codes will work to identify and describe these items and will be less disruptive across all payer settings than establishing new HCPCS codes that would replace the existing codes. Some commenters suggested separate new

codes or modifications to the existing codes to distinguish custom versions of garments, different types of textiles (flat and custom knit), different pressure designations or different body areas. We thank commenters for supporting our proposal to add a matching code for the custom version of each garment and are adding these new codes for use on January 1, 2024. We also proposed use of existing not otherwise specified code A6549 and are finalizing this along with a change to the code descriptor from “stocking/sleeve” to “garment” to clarify its use as a gradient compression garment code. We thank commenters for the numerous suggestions on ways to describe the various body areas that gradient compression areas can cover, including ranges of body areas and descriptions such as “high rise panty with leg.” After careful review, we have identified in Table FF-A 2 new codes that we will be finalizing as part of this rule with an effective date of January 1, 2024, including gradient compression garment codes for the genital regions, neck/head and toe caps. In addition to the new codes in Table FF-A 2, we are retaining the following existing codes, with revisions to the descriptors where applicable as noted previously, that are also available to describe lymphedema compression treatment items:

Code	Description
A6530	Gradient compression stocking, below knee, 18-30 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 mmhg or greater, 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 mmhg or greater, 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 mmhg or greater, each
A6549	Gradient compression garment, not otherwise specified

We believe it is important to have a set of codes in place on January 1, 2024, that will generally meet the needs of the majority of patients. However, we recognize that additional refinements may be necessary. As such, the public HCPCS process, described at <https://www.cms.gov/medicare/coding/medhcpcsgeninfo/hcpcspublicmeetings> is available as a means for modifying the code set in the future.

Comment: Many commenters offered suggestions on changes to the proposal on differentiating pressure levels for HCPCS codes A6530-41 and A6549. A commenter supported the pressure levels described, while adding language to acknowledge that they do not include all pressure levels available. A few commenters supported including compression levels higher than 50 mmHg. A commenter recommended aligning the pressure level differentiations in codes A6530-A6541 to the compression class designations utilized by providers to ensure that higher levels of compression are captured for reimbursement. A few commenters suggested separate treatment of pressure levels for circular and flat knit garments. A commenter suggested including nighttime compression items at any compression pressure. Another commenter suggested including pressure level differentiations with all items for upper extremity and upper body areas. A few commenters suggested use of Mild Pressure, Moderate Pressure, Maximum Pressure across all codes because some vendors use class levels and some use specific levels. A commenter indicated that ranges of compression be explicitly covered (15-20 mmHg, 20-30 mmHg, 30-40 mmHg, and 40-50 mmHg). A commenter recommended keeping the pressure levels the same for lower and upper extremity garments. A commenter suggested having a standard and custom garment for each pressure level as well as for each garment type. A commenter suggested adding a matching code for the custom version of the garment, dividing custom garments by compression class (18-30 mmHg; 30-40 mmHg; 40-50 mmHg) and custom flat knit garments (15-21 mmHg; 22-32 mmHg; 33-46+ mmHg).

Response: We believe that the existing pressure designations in mmHg generally capture how these items are presented and marketed in the U.S. market. We believe a change to an alternative pressure designation such as mild, moderate or maximum pressure would present more challenges for billing and be more disruptive to the lymphedema market. However, we recognize that the existing pressure ranges that end in 50 mmhg that we proposed may not capture all the pressure levels available, so we are revising the following gradient compression

stocking code pressure ranges by removing “40-50 mmhg” and adding “40 mmhg or greater” to ensure that higher levels of compression are addressed in both the standard and custom versions:

- A----Gradient compression stocking, below knee, 40 mmhg or greater, each
- A----Gradient compression stocking, below knee, 40 mmhg or greater, custom, each
- A6535 Gradient compression stocking, thigh length, 40 mmhg or greater, each
- A----Gradient compression stocking, thigh length, 40 mmhg or greater, custom, each
- A6538 Gradient compression stocking, full length/chap style, 40 mmhg or greater,

each

- A----Gradient compression stocking, full length/chap style, 40 mmhg or greater,

custom, each

- A6541 Gradient compression stocking, waist length, 40 mmhg or greater, each
- A----Gradient compression stocking, waist length, 40 mmhg or greater, custom, each

Table FF-A2 also includes the five new A codes that instead of finalizing as proposed, we are finalizing by adding “40 mmhg or greater” to the stocking code pressure ranges.

Comment: A few commenters expressed general support for the addition of new HCPCS codes for use when billing for A6531, A6532, and A6545 items used as surgical dressings only. Several commenters disagreed with the addition of three new HCPCS codes for use when billing for A6531, A6532, and A6545 items used as surgical dressings. A few commenters suggested that the addition of new codes was unnecessary. Another commenter suggested current HCPCS modifiers are sufficient to differentiate these garments when used for different purposes and was concerned with overcomplicating coding decisions. Several commenters believe it might require a change to existing wound care guidance, affect national and local coverage determinations, and increase administrative burden. A few commenters indicated that the new HCPCS codes would be confused with existing HCPCS codes. A commenter indicated that the addition of new codes would lead to payment errors. A few commenters recommended that existing A6531, A6532,

and A6545 codes not be modified for coverage of lymphedema compression garments and that new codes be developed to describe items under the new benefit to avoid confusion.

Response: We appreciate the comments and agree with commenters that establishing new codes for lymphedema compression garments would be preferable to modifying the existing A6531, A6532, and A6545 surgical dressing codes for use under the new benefit as proposed. To avoid confusion and disruption associated with repurposing the existing A6531, A6532, and A6545 surgical dressing codes, instead of finalizing new A codes for the existing A6531, A6532 and A6545 codes under the surgical dressing benefit and retaining A6531, A6532 and A6545 for use under the lymphedema benefit as proposed, we are instead finalizing new A codes for the following gradient compression garment and wrap codes under the lymphedema compression benefit effective January 1, 2024.

- A----Gradient compression stocking, below knee, 30-40 mmhg, each
- A----Gradient compression stocking, below knee, 40 mmhg or greater, each
- A----Gradient compression wrap with adjustable straps, below knee, 30-50 mmhg,

each

Additionally, we will revise the descriptors of existing A6531, A6532, and A6545 to clarify their use under the surgical dressing benefit. For example, A6531 would read “Gradient compression stocking, below knee, 30-40 mmhg, used as surgical dressing, each.”

Comment: On CMS’s proposal to use existing A6549 and S8428-S8428 codes, a few commenters supported renumbering S8420 through S8428 to A codes. A commenter suggested replacing the terms "medium weight" and "heavy weight" with compression values, or, in the alternative, adding section defining the range of compression values that qualify as "medium weight" and "heavy weight." A few commenters disagreed with renumbering S-8420 through S8428 to A codes and indicated it could lead to problems with claims payment by private and other payers. A few commenters expressed general support for existing codes for upper extremities and body garments (A6549, S8420-28). A few commenters indicated support for the

addition of codes for upper body areas. A commenter supported the addition of codes for non-limb areas of the body. A commenter recommended that existing codes not be changed because they are used across the insurance industry. A few commenters supported differentiating pressure levels for codes for upper extremities and body areas. A commenter agreed with differentiation for upper limb garment, suggesting differentiation by compression ranges (20-30, 30-40, 40-50 mmHg) or compression class level (for example, Class 1, Class 2, Class 3). Another commenter supported the three-pressure level differentiations but indicated the need to distinguish circular-knit and flat-knit compression garments. A commenter suggested the coverage of gradient compression garments such as the compression arm sleeve with shoulder attachment and the compression arm sleeve with gauntlet attachment. A commenter also suggested that the proposed list of arm sleeves needs should include “A---- Gradient compression arm sleeve and gauntlet, custom” as they believe it is frequently prescribed and indicated. A commenter did not support retention of HCPCS codes S8420-S8428, indicating that they could be included with other code changes effective in 2024. Another commenter also supported the removal of the “S” codes due to difficulties obtaining a Medicare denial when other insurers require use of these garment codes for the upper extremities. A commenter supported maintaining HCPCS codes S8420-S8428 because they are used by insurers for diagnoses other than lymphedema. Other commenters noted billing challenges if not all Medicaid and commercial payers adopt the replacement “A” codes for HCPCS codes S8420-S8428.

Response: Thank you for your comments on our proposal to use existing HCPCS code A6549 and to add new “A” codes based on the S8420-S8428 codes for upper extremity gradient compression garments. After careful review, we are finalizing the addition of A codes that align with the codes and descriptors of S8420 through S8428 along with the following changes to the A code descriptors: removing the words “ready-made,” revising “custom made” to “custom,” replacing the word “pressure” with “compression,” adding “each,” and adding the word “arm” in front of the word “sleeve” for the upper extremity garments. We are also finalizing the addition

of a code for a custom gauntlet as proposed. Based on commenter input, we will retain codes S8420 through S8428, in addition to the new A code versions, for use by other payers other than Medicare. The “S” codes will be invalid for Medicare use, but they could be used by other payers in lieu of the new upper extremity garment “A” codes. Similar to the lower extremity gradient compression garments, we did not find a need to further differentiate the proposed upper extremity codes based on circular-knit and flat-knit compression materials. Since the majority of flat-knit garments are custom garments and circular-knit garments are non-custom garments, we do not believe further stratification of the proposed custom and non-custom upper extremity HCPCS codes is necessary for this distinction. While some commenters recommended adding pressure level differentiations such as (20-30, 30-40, 40-50 mmHg) or compression class level (for example, Class 1, Class 2, Class 3) to the upper extremity codes, we believe the long-standing “S” codes that are being established as A codes provide a way to identify upper extremity gradient compression garments without further stratification by pressure level. Our review of the cost of these items also does not generally support a need to stratify by pressure level tiers. We will retain the medium and heavy weight terminology in the new sleeve and arm “A” codes from the predicate S8422, S8423, S8425 and S8426 codes. The new codes we are finalizing in Table FF-A 2 identify the new gradient compression garment codes we are adding for upper limb and non-limb areas of the body such as the neck and head and the genital regions. In addition to the new codes in Table FF-A 2, we are finalizing the addition of the following new A codes that align with the codes and descriptors of S8420 through S8428, as discussed previously, effective January 1, 2024:

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

- A---- Gradient compression glove, custom, medium weight, each

A---- Gradient compression glove, custom, heavy weight, each

- A---- Gradient compression glove, each
- A---- Gradient compression gauntlet, each

Comment: Many commenters made suggestions on codes for mastectomy sleeves. Many commenters supported including mastectomy sleeves in the codes for compression sleeves and not creating separate mastectomy codes. Many commenters did not believe it was necessary to distinguish via separate coding patients with breast cancer from patients with other types of lymphedema. A commenter opposed the inclusion of mastectomy or other procedures in the new codes for lymphedema compression treatment items. Another commenter noted that all sleeves for mastectomy are the same as all compression garments used for lymphedema, so they did not see a need for separate codes. A few commenters suggested not using the L8010 HCPCS code for a compression sleeve. Several commenters suggested deleting code L8010.

Response: We appreciate the recommendations provided related to whether separate codes are needed for mastectomy sleeves and if items can be grouped together under the same codes used for other arm sleeves (S8422 thru S8424). After reviewing the comments, we agree that separate codes are not necessary to distinguish mastectomy sleeves from other arm compression sleeves used for lymphedema. We will also continue to consider what to do with regard to the status of existing code L8010 Breast prosthesis, mastectomy sleeve and may announce our views in advance of a future public meeting related to the HCPCS code set.

Comment: A few commenters supported new HCPCS codes for nighttime garments in general. A commenter supported coverage of a nighttime chipped foam compression garment for the body parts that are affected. A few commenters indicated the need for additional codes. A commenter indicated that there should be fewer HCPCS codes for nighttime garments. Another commenter recommended additional codes to reflect nighttime use of padded head/neck garments for lymphedema management. Concerning gradient compression wraps with adjustable

straps, a commenter indicated the need for codes for gradient compression wraps for below knee and above knee and a code for a full-leg wrap. Another commenter indicated that gradient compression wraps with adjustable straps should include: foot wraps, calf wraps, knee wraps, thigh wraps, hand wraps, and arm wraps. A commenter indicated that additional HCPCS codes need to be established for wraps for different parts of the body. With respect to other comments related to garments or wraps with adjustable straps, a commenter indicated that the term “with adjustable straps” refers to both garments and wraps. The commenter indicated that it might be clearer to eliminate “with adjustable straps,” which would indicate coverage for wraps that are adjustable by straps or by other means.

Response: Thank you for your comments on the HCPCS codes for nighttime garments and gradient compression wraps with adjustable straps. We appreciate the support for our proposal to add the following nighttime garment codes and will be finalizing these codes for use effective January 1, 2024.

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

Table FF-A 2 identifies the new nighttime garment HCPCS codes that we are adding to the HCPCS code set effective January 1, 2024, including a bra garment and custom versions of the glove, arm, lower leg and full leg and foot nighttime garments. Regarding gradient compression wrap coding, we proposed to use existing code A6545 to identify below knee gradient compression wraps with adjustable straps. As discussed in a prior response, to avoid confusion with repurposing the existing A6545 code used for surgical dressings, we will establish a new A code to describe below knee gradient pressure wraps with adjustable straps under the new lymphedema benefit for use effective January 1, 2024. We appreciate the commenters input on additional coding for other areas of the body and descriptor language. We

believe that including adjustable straps in the descriptor for gradient pressure wrap with adjustable straps is necessary to help identify the general type of wrap that supplies gradient pressure and are retaining this terminology. Table FF-A 2 includes the new codes we are adding for gradient pressure wraps with adjustable straps and includes wraps for above knee, full leg, and foot.

Comment: Many commenters provided comments on a range of issues related to HCPCS Codes for lymphedema compression items. A few commenters indicated that the number of proposed HCPCS codes was inadequate. Many expressed support for a range of new codes. A few supported a proposal for 229 new HCPCS codes that differentiate between textiles and technologies (circular knit, flat knit, inelastic adjustable wraps). A commenter supported development of a code for each individual component. A commenter indicated that limiting the number of HCPCS codes would not reflect the large variety of lymphedema compression treatment items. Commenters also provided suggestions on codes for bandaging systems. A commenter indicated a need for more codes than the existing S bandaging codes as lymphedema bandaging systems can include: short-stretch compression bandages, stockinette or tubular gauze sleeves, finger/toe bandages, rolled padding (synthetic or foam), adhesive tape, foam pads, chip pads; chip bags. A commenter recommended that HCPCS codes should be added for lymphedema compression bandaging kits for: a single upper limb; two upper limbs; a single lower limb; and two lower limbs. Some commenters supported new codes for bandages and recommended that the descriptors be based on the width and length. A commenter requested that CMS ensure these garments/bandaging/padding are properly identified via the HCPCS codes. Another commenter submitted a list of recommended new HCPCS codes for bandaging system components that were based on size. A commenter indicated that many of the longer and wider bandages specifically used on large lower extremity legs, hips and buttocks are too long or too wide for existing HCPCS code categories and need to correct the description or add a new code.

A commenter cited concerns using the same codes as traditional bandaging materials will result in reimbursement that is too low.

Response: We thank the commenters for the detailed HCPCS recommendations for lymphedema compression treatment items. We have identified in the chart 57 HCPCS codes that we are finalizing for lymphedema compression treatment items and accessories, as discussed in the previous responses. We recognize that additional refinements to the code set may be necessary, thus we direct readers to the HCPCS Level II coding process, described at <https://www.cms.gov/medicare/coding/medhcpcsgeninfo/hcpcspublicmeetings> , which provides a means for modifying the HCPCS code set for lymphedema compression treatment items in the future. Regarding the commenter's request for 229 new HCPCS codes that differentiate between textiles and technologies (circular knit, flat knit, inelastic adjustable wraps), we do not currently see a Medicare program need to add codes at this level of specificity. If commenters continue to believe that coding for one textile vs. another (for example, circular knit vs. flat knit) would still be useful after January 1, 2024, we direct commenters to the HCPCS Level II coding process described previously. We appreciate the suggestions for HCPCS coding changes needed to describe the various compression bandaging systems used for the treatment of lymphedema. We agree with commenters that more codes are needed beyond existing codes S8430 (Padding for compression bandage, roll) and S8431 (Compression bandage, roll) to describe the bandaging systems.

Therefore, after careful review of the comments, we are establishing new HCPCS codes, effective January 1, 2024, to describe the following bandaging system components: upper and lower extremity bandage liners; high density foam rolls; long, medium and short stretch bandages; high density foam sheets and pads; low density channel and flat foam sheets; padded foam and textile; and tubular protective absorption layers with and without padding. These new codes will allow suppliers to separately identify the supplies that are being furnished to the patient as opposed to establishing bandaging kit HCPCS codes delineated by the extremity body

type. The list of the new HCPCS bandaging codes and descriptors that we are adding to the HCPCS code set effective January 1, 2024 is available in Table FF-A 2. Similar to the disposition of the other existing S codes, we will retain bandaging codes S8430 and S8431 in the HCPCS code set for use by other payers. We are also establishing a new gradient compression bandaging supply not otherwise specified code, effective January 1, 2024, that will be available for use in identifying bandaging supplies that are not identified by a unique HCPCS code. Since this is a new benefit category, payment for lymphedema compression treatment items will be established in accordance with the requirements at section 1834(z) of the Act and will not be based on the surgical dressing payment requirements for traditional Medicare bandaging at 42 CFR 414.220.

TABLE FF-A 2: FINAL NEW HCPCS CODES FOR LYMPHEDEMA COMPRESSION TREATMENT ITEMS

Code	Description
AXXXX	Gradient compression stocking, below knee, 18-30 mmhg, custom, each
AXXXX	Gradient compression stocking, below knee, 30-40 mmhg, each
AXXXX	Gradient compression stocking, below knee, 30-40 mmhg, custom, each
AXXXX	Gradient compression stocking, below knee, 40 mmhg or greater, each
AXXXX	Gradient compression stocking, below knee, 40 mmhg or greater, custom, each
AXXXX	Gradient compression stocking, thigh length, 18-30 mmhg, custom, each
AXXXX	Gradient compression stocking, thigh length, 30-40 mmhg, custom, each
AXXXX	Gradient compression stocking, thigh length, 40 mmhg or greater, custom, each
AXXXX	Gradient compression stocking, full length/chap style, 18-30 mmhg, custom, each
AXXXX	Gradient compression stocking, full length/chap style, 30-40 mmhg, custom, each
AXXXX	Gradient compression stocking, full length/chap style, 40 mmhg or greater, custom, each
AXXXX	Gradient compression stocking, waist length, 18-30 mmhg, custom, each
AXXXX	Gradient compression stocking, waist length, 30-40 mmhg, custom, each
AXXXX	Gradient compression stocking, waist length, 40 mmhg or greater, custom, each
AXXXX	Gradient compression wrap with adjustable straps, below knee, 30-50 mmhg, each
AXXXX	Gradient compression wrap with adjustable straps, not otherwise specified
AXXXX	Gradient compression gauntlet, custom, each
AXXXX	Gradient compression garment, neck/head, each
AXXXX	Gradient compression garment, neck/head, custom, each
AXXXX	Gradient compression garment, torso and shoulder, each
AXXXX	Gradient compression garment, torso/shoulder, custom, each
AXXXX	Gradient compression garment, genital region, each
AXXXX	Gradient compression garment, genital region, custom, each
AXXXX	Gradient compression garment, glove, padded, for nighttime use, each
AXXXX	Gradient compression garment, glove, padded, for nighttime use, custom, each
AXXXX	Gradient compression garment, arm, padded, for nighttime use, each
AXXXX	Gradient compression garment, arm, padded, for nighttime use, custom, each
AXXXX	Gradient compression garment, lower leg and foot, padded, for nighttime use, each
AXXXX	Gradient compression garment, lower leg and foot, padded, for nighttime use, custom, each
AXXXX	Gradient compression garment, full leg and foot, padded, for nighttime use, each
AXXXX	Gradient compression garment, full leg and foot, padded, for nighttime use, custom, each
AXXXX	Gradient compression garment, bra, for nighttime use, each
AXXXX	Gradient compression garment, bra, for nighttime use, custom, each
AXXXX	Gradient compression garment, toe caps, each

Code	Description
AXXXX	Gradient compression garment, toe caps, custom, each
AXXXX	Gradient pressure wrap with adjustable straps, above knee, each
AXXXX	Gradient pressure wrap with adjustable straps, full leg, each
AXXXX	Gradient pressure wrap with adjustable straps, foot, each
AXXXX	Gradient pressure wrap with adjustable straps, arm, each
AXXXX	Gradient pressure wrap with adjustable straps, bra, each
AXXXX	Accessory for gradient compression garment or wrap with adjustable straps, not-otherwise specified
AXXXX	Gradient compression bandaging supply, bandage liner, lower extremity, any size or length, each
AXXXX	Gradient compression bandaging supply, bandage liner, upper extremity, any size or length, each
AXXXX	Gradient compression bandaging supply, conforming gauze, per linear yard, any width, each
AXXXX	Gradient compression bandage roll, elastic long stretch, per linear yard, any width, each
AXXXX	Gradient compression bandage roll, elastic medium stretch, per linear yard, any width, each
AXXXX	Gradient compression bandaging supply, high density foam roll for bandage, per linear yard, any width, each
AXXXX	Gradient compression bandaging supply, high density foam sheet, per 250 square centimeters, each
AXXXX	Gradient compression bandaging supply, high density foam pad, any size or shape, each
AXXXX	Gradient compression bandage roll, inelastic short stretch, per linear yard, any width, each
AXXXX	Gradient compression bandaging supply, low density channel foam sheet, per 250 square centimeters, each
AXXXX	Gradient compression bandaging supply, low density flat foam sheet, per 250 square centimeters, each
AXXXX	Gradient compression bandaging supply, padded foam, per linear yard, any width, each
AXXXX	Gradient compression bandaging supply, padded textile, per linear yard, any width, each
AXXXX	Gradient compression bandaging supply, tubular protective absorption layer, per linear yard, any width, each
AXXXX	Gradient compression bandaging supply, tubular protective absorption padded layer, per linear yard, any width, each
AXXXX	Gradient compression bandaging supply, not otherwise specified

Note: Table FF-A 2 does not include the 9 new A codes that align with the codes and descriptors of S8420 through S8428 discussed previously that we are finalizing effective January 1, 2024.

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

We proposed 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 proposed 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 proposed 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 proposed 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 proposed to revise the DMEPOS regulations to include lymphedema treatment items in the competitive bidding process. We proposed 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. The following is a summary of the comments we received and our responses.

We received approximately 14 comments from suppliers, manufacturers, professional, State and national trade associations, beneficiaries and their caregivers related to the proposal to use the same process for benefit category and payment determination for future lymphedema compression treatment items as for new DMEPOS items and the inclusion of lymphedema compression treatment items in the DMEPOS competitive bidding program mandated by section 1847(a) of the Act.

Comment: Commenters opposed the inclusion of lymphedema compression treatment items in the DMEPOS competitive bidding program due to concerns that competitive bidding could result in reduced access to these items for beneficiaries. Commenters supported the proposed use of the existing process for addressing benefit category and payment determinations for DMEPOS for benefit category and payment determinations for lymphedema compression treatment items in the future.

Response: Section 1847(a)(2)(D) of the Act mandates the inclusion of lymphedema compression treatment items in the DMEPOS competitive bidding program, and the proposed

changes to the regulation were merely conforming changes to reflect this statutory requirement. We note however, that section 1847(a)(3) of the Act provides discretionary authority to exempt certain areas and items from the DMEPOS competitive bidding program, including rural areas and areas with low population density within urban areas that are not competitive, unless there is a significant national market through mail order for a particular item or service, and items and services for which the application of competitive acquisition is not likely to result in significant savings. In addition, section 1847(b)(2) of the Act mandates certain conditions that must be met before contracts can be awarded under the DMEPOS competitive bidding program. A contract may not be awarded to a supplier that does not meet applicable quality and financial standards and State licensure requirements. Contracts may not be awarded in a competitive bidding area unless access to a choice of multiple suppliers in the area is maintained and total amounts to be paid in the area are expected to be less than the total amounts that would otherwise be paid. Section 1847(a)(5) of the Act provides authority for and regulations at 42 CFR 414.420 establish a physician authorization process which requires contract suppliers to furnish specific brands of items the beneficiary's physician or treating practitioner prescribes to avoid an adverse medical outcome for the beneficiary. These requirements and additional terms for contract suppliers that ensure access to quality items and services under the program are spelled out in the regulations at 42 CFR 414.422. CMS closely monitors the DMEPOS competitive bidding program to ensure that all suppliers are in compliance with the terms of their contracts and access to quality items and services is maintained at all times.

We appreciate the comments in support of using the existing DMEPOS process for addressing benefit category and payment determinations for new lymphedema compression treatment items.

After consideration of the public comments, we are finalizing that future items that the public considers to be lymphedema compression items would be addressed by CMS pursuant to the same process as the benefit category and payment determination process for new DMEPOS

items (including the HCPCS public meeting process) at 42 CFR 414.240, as proposed. We are also finalizing the conforming changes to 42 CFR 414.402, 42 CFR 414.408 and 42 CFR 414.412 to incorporate lymphedema compression treatment items in the competitive bidding program as proposed.

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)(E) 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 proposed 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.

Comment: Many commenters disagreed that fitting specialists like therapists should not have an undue burden of having to apply as a DMEPOS supplier and adhere to enrollment, quality standards and accreditation. A commenter agreed that all those who provide and fit garments should be accredited and should adhere to all quality standards.

Response: We appreciate all the comments in regard to Medicare enrollment, quality standards and accreditation. Section 1834(j)(5)(E) of the Act mandates that to receive Medicare payment for lymphedema items and services, suppliers must enroll in Medicare, receive a supplier number, and meet all of the same supplier standards as a DMEPOS supplier.

We are finalizing Medicare enrollment, quality standards, and accreditation requirements for suppliers of lymphedema compression treatment items as proposed.

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.²⁰⁰ For the purpose of this final rule, we took into account the average Medicaid fee schedule payment 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. These fee schedule payment amounts will be finalized based on the average Medicaid fee schedules in effect at the time this rule is finalized.²⁰¹

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

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

201 At the time of writing, this would include fee schedule amounts from up to 38 state Medicaid plans.

schedule amount plus 20 percent. Therefore, we 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 sought 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 the Act, we proposed 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 proposed 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 proposed 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 proposed to base payment amounts based on 100 percent of average internet retail prices for that item. We sought comment on these payment methodologies and whether further adjustments are appropriate.

As previously noted, payment rates established by Medicaid, the VHA, and TRICARE for the supply of these items includes payment for fitting services and any other services necessary for furnishing the item, including training beneficiaries in the proper use of these items. The cost of these services is also reflected in the price suppliers would charge a beneficiary directly. For these reasons, we believe that our payment methodology will implicitly incorporate payment for these services. 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 proposed to be classified under the Medicare Part B benefit category for lymphedema treatment items. This table reflects the application of our methodology to the underlying data sources as they were available in early 2023.

TABLE FF-A 3: 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 mmhg or greater, 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 mmhg or greater, 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 mmhg or greater, 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 mmhg or greater, each	\$128.85
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

Code	Description	Example Payment Amount
Axxxx	Gradient compression glove, custom, heavy weight, each	\$349.33
Axxxx	Gradient compression glove, each	\$92.24
Axxxx	Gradient compression gauntlet, each	\$42.85

Final payment amounts will be determined in accordance with the methodology as previously detailed based on the most recent data available in late 2023 and will most likely be higher than these example payment amounts. Beginning January 1, 2025, and annually thereafter, these final payment amounts will be updated 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.

When 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 proposed 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 received approximately 62 comments related to the proposed payment methodology: eight from organizations of providers, suppliers, or manufacturers; 15 from individual supply businesses or practices; and 39 from individual beneficiaries, caregivers, or providers. A summary of the major issues raised in these comments and our responses are as follows.

Comment: Several commenters, without specifically voicing concern or support for our proposed payment methodology, emphasized the need to balance payment amounts high enough to support beneficiary access and low enough to ensure that copays remain affordable to beneficiaries.

Response: We agree with these comments and believe that our proposed payment methodology meets these goals. We share the commenters' views that beneficiary copayments will affect access to the products and their health outcomes.

Comment: Some commenters expressed concern that the proposed payment amounts appeared low compared to what the commenters pay out of pocket for specific garments, and some of these commenters also requested limits to the copayment amount (either limited to a specific dollar amount or reduced to zero).

Response: Beneficiary copayment amounts under Medicare are determined by statute, and CMS did not propose to or intend to waive or modify beneficiary copayment amounts for lymphedema compression treatment items in the proposed rule. While we appreciate concerns regarding payment amounts for specific items, many of the items mentioned by commenters were custom garments for which we did not provide example pricing. We expect that custom garments will have payment amounts substantially higher than standard garments. For example, based on our payment methodology, the payment amount for a standard gradient compression arm sleeve would be approximately \$58 while the payment amount for a custom gradient compression arm sleeve would be approximately \$175. There will always be situations where specific items cost more or less than the Medicare payment amount but our methodology is sound because we believe that most items described by each code will be adequately covered by the payment amount established. As outlined in the DMEPOS Quality Standards, enrolled DME suppliers are required to provide all items as ordered by the prescribing provider.

Comment: Several commenters expressed concern that the proposed payment methodology would result in payment amounts that are below the supplier's cost for furnishing the items, with one noting specifically that average internet pricing may be skewed by large online retailers selling garments that may not be medical-grade garments. The commenters urged the adoption of a more "real world" method for payment determination, without offering specific suggestions for an alternate model.

Response: We thank the commenters for sharing this concern. Our methodology is designed to approximate what the VHA pays suppliers for veterans to have appropriate access to lymphedema treatment items, and we are not aware of any access concerns that veterans have experienced. We note that the use of internet retail pricing is a long-established method of determining commercial prices for use in the DME payment determination process. 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. Specifically addressing the commenters' concern, we would exclude from consideration any items that are not medical-grade items, and for this reason we often must exclude retail listings from common consumer internet retailers. We continue to believe that prices from online suppliers of medical-grade products offer real-world examples of commercial pricing for use in the Medicare payment determination process when other payers, such as VHA or State Medicaid agencies, do not have established pricing histories.

Comment: A commenter disagreed with our proposed payment methodology, raising a number of specific concerns. These include concerns that many payers, including Medicaid state plans and TRICARE, have not consistently covered lymphedema compression garments and do not represent large shares of the market, and so these sources would not represent appropriate pricing information. The commenter expressed further concerns that Medicaid pricing may not be available for many proposed codes and may not be at a level sufficient to ensure appropriate patient access. The commenter stated that internet prices may not account for costs of compliance and claims filing faced by Medicare DMEPOS suppliers and that cash-pay transactions have reduced administrative burden, but that customers may face charges in addition to the item price upon check out (such as shipping and handling). The commenter proposed an alternate payment methodology based on the average manufacturer's Minimum Advertised Price (MAP) plus 20 percent, together with recommendations to simplify the calculation of payment amounts by using the average ratio of standard to custom garment prices and the ratio of prices

for different compression levels of the same garment type. The commenter separately submitted to CMS confidential commercial MAP amounts to support our analysis of this proposed methodology. Other commenters expressed their support for this commenter's proposal.

Response: We appreciate the comment and the alternative pricing proposal. In developing our payment methodology, we have tried to set payment amounts at a level high enough to ensure beneficiary access, while low enough to ensure that copay amounts do not present a barrier for beneficiaries. As we expressed, we continue to believe that the most appropriate source for Medicare payment determination would be the prices paid by the Veteran's Health Administration (VHA). While the VHA does not publish national fee schedules for these items, we believe that our payment methodology is a good approximation of what the VHA would pay. We recognize that there are gaps in the available data among TRICARE, Medicaid, and other payors. We believe that internet retail prices continue to be the most appropriate source of commercial pricing to fill these gaps, as this has been a longstanding method of pricing used for Medicare DMEPOS items that has not hindered beneficiary access to DMEPOS items. We note that internet retailers often offer free shipping in order to compete with brick-and-mortar businesses. We agree that cash-pay transactions may be administratively simpler than billing insurance. However, suppliers and providers that accept insurance also enjoy a far higher volume; for this reason, it is common practice in healthcare for large insurers to receive a substantial discount off of the cash price, despite the additional administrative burden. We have carefully considered the proposed alternative payment methodology. Our analysis shows that across a representative sample of compression treatment garments, this alternative methodology would result in payment amounts approximately 35 percent higher than our imputed VHA²⁰² or TRICARE payment amounts. There is no evidence that beneficiaries of the VHA or TRICARE programs experience difficulty accessing compression treatment garments,

²⁰² Imputation based on 120 percent of the average of up to 38 Medicaid state plan fee schedules as currently in effect.

so it would be difficult to justify the need for such a significantly higher payment amount – and commensurately higher beneficiary copay – for Medicare, potentially resulting in payment amounts that are too high, which, as noted previously, was a concern of other commenters.

Comment: A commenter recommended that decongestive therapy services and the associated supplies be covered by Part A/B MACs or Home Health Services as they believe there would be problems with implementing decongestive therapy services if they are covered by a non-DME MAC contractor while the DME MACs cover the associated supplies since providers and suppliers have up to one year to submit the claim and DME MACs are unable to verify if decongestive therapies were covered to appropriately allow the related supplies.

Response: We are not finalizing our alternative proposal, but we appreciate the comments concerning the implementation problems that could arise with separate payment for the bandaging and fitting therapy services. As stated earlier, while compression bandaging systems are included in the lymphedema treatment items benefit category when applied during Phase 1 (acute or decongestive therapy) and/or Phase 2 (maintenance therapy), payment for decongestive therapy services would not be covered under this lymphedema treatment items benefit category, and so would not fall within the established remit of the Part B MACs.

Comment: A commenter requested that the payment amounts should be set by the individual DME MACs, or alternatively established as the manufacturer's MAP plus 50 percent.

Response: We are required by statute to establish payment amounts for these items. Contractor pricing is generally reserved for situations where we do not have adequate data to establish payment amounts for newly developed items or where codes represent such a disparate variety of items that a single payment amount would prove impractical (such as for “not otherwise classified” codes). Regarding the proposal to pay MAP plus 50 percent, as noted earlier, we have not seen evidence that beneficiaries experience difficulties accessing lymphedema treatment garments through the VHA or TRICARE at the payment amounts they

set, so we do not believe there is good justification for Medicare to burden beneficiaries with the substantial higher copay implied by the commenter's proposed reimbursement methodology.

Comment: A commenter expressed broad support for the proposed payment methodology, but expressed concern that data may not be available to establish payment amounts for custom garments if it were necessary to use the fallback approach of internet retail pricing.

Response: We appreciate the comment and understand that many common internet suppliers do not offer custom garments or do not make pricing publicly available. However, we believe that a sufficient number of internet suppliers offer public pricing for custom garments to allow for accurate pricing of these items, if this approach were needed.

Comment: A few commenters proposed that, in place of average internet pricing, we use either MAP or average internet pricing plus 30 percent, in order to adequately compensate for suppliers' overhead costs, particularly those with bricks-and-mortar locations.

Response: As noted earlier, 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. Furthermore, we exclude pricing that is not publicly displayed. For this reason, we believe that our methods capture an average internet price that is likely very close to the manufacturers' MAP.

Comment: Several commenters suggested using third party (commercial insurance) payment amounts, as these might avoid possible variation between payment amounts based on the other proposed methods.

Response: We thank the commenters for this suggestion. We believe that as a large government payer, our estimate of what the VHA, another large government payer, pays for these items is the best method for establishing an appropriate Medicare payment basis for these items. Furthermore, use of commercial insurance payment amounts poses a number of practical difficulties. Commercial insurance reimbursement amounts are not freely available, and

procuring and processing the necessary data would have jeopardized our ability to meet the January 1, 2024, start date for this benefit.

Comment: A commenter noted support for the proposed annual adjustment of payment amounts based on the CPI-U.

Response: We appreciate this comment.

Comment: A commenter proposed that instead of adjusting based on the CPI-U, we base adjustment on the average change in online prices from year to year.

Response: We thank the commenter for this proposal, but we believe the CPI-U is an adequate approximation of the price changes these items will experience. While we acknowledge that in any given year this method may over- or under-adjust for price changes observed for specific lymphedema compression treatment items, we do not believe that the gains from an alternative methodology outweigh the costs of introducing a new method of annual adjustment to lymphedema payment amounts that differs from those applied to DMEPOS 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 sought 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 item 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 later in 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 proposed 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 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.

Comment: Commenters expressed appreciation for the new Medicare benefit that covers lymphedema compression items. However, some commenters suggested that Medicare provide coverage for more than two units of daytime garments or wraps and one nighttime garment or wrap as stated in the proposed rule. They explained that patients may have difficulty keeping up with the daily task of washing and drying compression treatment items, which may prevent them from effectively treating and managing their condition. Also, they stated that since some compression items take a day or more to dry completely, this would leave the patient without a compression item to wear on a daily basis. They also described hygiene concerns associated with

the environment, such as sweating from heat in certain regions of the country, that warranted the need to wash garments more frequently.

Response: We appreciate the comments in response to our request for input on our proposal for the frequency limitations for lymphedema compression treatment items and are finalizing changes based on that input. We are making the changes based on the concerns of the commenters related to multiple reasons for needing adequate time to wash and dry compression treatment items, and to be responsive to the needs of Medicare beneficiaries. Specifically, Medicare will cover and pay for three daytime garments or wraps every six months and two nighttime garments or wraps every 2 years. Three units of daytime garments or wraps allows the patient to wear one, wash one, and dry one. Also, Medicare will cover two nighttime garments or wraps every 2 years, allowing the beneficiary to wear one, while a second garment washed during the day is allowed to completely dry and be ready for use the following night.

Comment: Many commenters appreciate and support the provision of the proposed regulation that provides Medicare coverage for compression garments and wraps when these items are lost, stolen, or irreparably damaged, or when there is a change in the patient's medical or physical condition. A commenter believes that the allowance for patients with respect to the number of sets of garments per year should allow for change in style, size, fit and other features to accommodate the patients' clinical progression, as a patient could experience rapid physical changes that require a change in size, style or materials of their compression garments.

Response: We thank the commenters for their support of the proposed rule. If an item is lost, stolen, or irreparably damaged, for example a garment is accidentally ripped by a sharp object, payment can be made for replacement of the garment(s) that has been lost, stolen, or irreparably damaged. Documentation explaining the circumstances of how the garment(s) was lost, stolen, or irreparably damaged should be maintained and may need to be furnished for Medicare claims processing and appeals purposes. If a patient's medical condition has changed enough to warrant the need for a new size or type of garment or wrap, payment can be made for

three new daytime garments or wraps and/or two new nighttime garments. Replacement of both the daytime and nighttime garments used for the same area where lymphedema treatment is needed may be necessary in this situation. Documentation explaining the circumstances of the change in the patient's medical or physical condition and why new garments or wraps are needed should be maintained and may need to be furnished for Medicare claims processing and appeals purposes.

Comment: Some commenters support the replacement of compression garments and wraps sooner if the items wear out due to normal wear before the specified time stated in the proposed rule. Also, some commenters suggest that irreparably damaged items and worn items are the same.

Response: We do not agree. As explained in the proposed rule (88 FR 43776), irreparable damage does not include items that have worn out. 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.

Comment: A few commenters stated that patients should not have to re-qualify each time they need to reorder supplies. A few commenters suggested careful consideration to cover all items a patient may need such as custom stockings or flat knit compression toe caps for the toes and foot and should be limited to only physical items and not services such as therapy, education or treatment. A few commenters indicated that the number and type of bandages covered should be determined by the treating therapist based on the body part, the severity of the lymphedema, and the patient's body shape and size. [A](#) commenter suggested the bandages and garments be separated into two categories and without a cap.

Response: Thank you for sharing your concerns regarding patients' access to lymphedema compression items. The lymphedema benefit includes Medicare coverage of items such as compression garments, wraps, stockings, gauntlets, bandaging and accessories. Once a

patient has been furnished a lymphedema compression item, the patient is eligible to receive a replacement as stated in the frequency limitation section of the rule.

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 did not propose specific replacement frequencies for the compression bandaging systems and supplies. We proposed 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 discussed in section VII.B.3 of this rule, commenters expressed concerns that coverage under the lymphedema benefit category for compression bandaging supplies or systems could continue during the various stages of lymphedema and we clarified that coverage is not limited to Phase 1 (acute or decongestive therapy) but is also available under Phase 2 (maintenance therapy). As a result of this clarification, we are making a conforming change to the regulation text at §414.1680 to remove "during phase one of decongestive therapy" so that determinations regarding the quantity of compression bandaging supplies needed by each beneficiary would be made by the DME MACs regardless of the lymphedema stage.

8. Final Policies

We are finalizing the amendment of 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 finalizing that payment may be made in these circumstances. We are finalizing 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 cover and pay for 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 finalizing the following definitions by adding them 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 definition of “gradient compression” would apply to all lymphedema compression treatment items (garments, wraps, etc.) that utilize gradient compression in treating lymphedema. The 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.

After consideration of the public comments received, we are finalizing §414.1680 with the following modifications to the frequency limitations for lymphedema compression items established in accordance with section 1834(z)(2) of the Act under new subpart Q:

- Three daytime garments or wraps with adjustable straps for each affected limb or area of the body, replaced every 6 months.
- Two nighttime garments for each affected limb or area of the body, replaced once every 2 years.

We are finalizing coverage of replacements of garments or wraps that are lost, stolen, irreparably damaged. If a patient's medical condition has changed enough to warrant the need for a new size or type of garment or wrap, payment can be made for new garments or wraps. We are also finalizing that determinations regarding the quantity of compression bandaging supplies covered for each beneficiary will be made by the DME MAC that processes the claims for the supplies with a modification to remove proposed language referring to "phase one of decongestive therapy."

We are modifying and adding to the existing HCPCS codes for surgical dressings and lymphedema compression treatment items as explained in section VII.B.4. of this rule. 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 adding §414.1670 under new subpart Q to 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 will be posted on CMS.gov in advance of a public meeting. After consideration of public input on the preliminary determinations, CMS will 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 adding 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 adding § 414.1600 to our regulations explaining the purpose and definitions under the new subpart Q. We are adding § 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). Under § 414.1650(b) the payment amounts for lymphedema compression treatment items will be based on the average of state Medicaid fee schedule amounts plus 20 percent. Where Medicaid rates are not available, we will 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). In accordance with § 414.1650(c), 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 adding § 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 are finalizing 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. When the HCPCS codes for several different items are combined into a single code, the payment amounts for the new code will be established using the average (arithmetic mean), weighted by allowed services, of the payment amounts for the formerly separate codes.

We are finalizing the revision to 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 are modifying the list of items that may be included in competitive bidding described in § 414.402 to include lymphedema treatment items and are revising § 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 are adding reference to 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 adding § 414.1690 to indicate 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.