



August 16, 2023

Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Submitted electronically via www.regulations.gov

RE: Calendar Year 2024 Home Health Prospective Payment System Rate Update; Certain Requirements for Durable Medical Equipment Prosthetics and Orthotics Supplies (CMS- 1780-P)

Dear Administrator Brooks-LaSure:

On behalf of the American Society of Breast Surgeons (ASBrS), I am providing comments in response to the calendar year (CY) 2024 home health prospective payment system proposed rule, which also includes new policies directed at durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) coverage and reimbursement that affect the breast cancer patients that our members treat. The American Society of Breast Surgeons (ASBrS) is the primary leadership organization for surgeons who treat patients with breast cancer and benign breast diseases. ASBrS is committed to continually improving the practice of breast surgery by serving as an advocate for those who seek excellence in the care of breast patients. Founded in 1995, the Society now has more than 3,100 members throughout the United States and in 35 countries around the world. Active membership is open to surgeons with a special interest in breast disease.

Our comments are focused on the lymphedema compression treatment items proposal.

Proposed Changes Regarding DMEPOS: *Scope of the Benefit and Payment for Lymphedema Compression Treatment Items*

The *Consolidated Appropriations Act, 2023 (CAA, 2023)* added a new benefit category and payment under Medicare Part B for lymphedema compression treatment items, along with standards for suppliers, which CMS proposes to implement through this rulemaking. Per the *CAA, 2023*, these policies will be effective January 1, 2024.

The new benefit applies according to the following parameters:

- 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 defined in current statute and to the extent authorized under State law.

In addition to gradient compression¹ garments, CMS proposes that any other items covered under this new benefit must also use “compression” in treating lymphedema since the specific category of medical items referenced in the Act are “lymphedema compression treatment items.” CMS proposes 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 (e.g., items described by HCPCS code A6545 (*Gradient compression wrap, non-elastic, below knee, 30-50 mmhg, each*))
- Compression bandaging systems applied in a clinical setting as part of phase one decongestive therapy

CMS proposes that these would be standard and custom items. CMS also proposes 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.²

CMS proposes to cover two daytime garments or wraps with adjustable straps for each affected limb or area of the body, replaced every 6 months. CMS proposes 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.³ However, CMS requests input on whether it should increase the frequency limitation for nighttime compression garments from 1 to 2 (for replacement every two years) in order to allow more than one day for washing

¹ “Gradient compression” is defined as “*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*”; The proposed definition of “gradient compression” would apply to all lymphedema compression treatment items (garments, wraps, etc.) that utilize gradient compression in treating lymphedema.

² CMS notes that these provisions do not include professional lymphedema treatment services or other services not directly related to the furnishing of the lymphedema compression treatment items given that these professional services are already reimbursed under the Medicare Physician Fee Schedule.

³ CMS states that changes due to medical necessity will not be subject to the frequency limitations. In addition, as with other DMEPOS items, payment could be made for replacement of garments and other items when they are lost, stolen, or irreparably damaged.

and drying. **ASBrS encourages CMS to increase the nighttime garment frequency limitation to 2, which would match the daytime garment frequency limitation.**

Generally, **ASBrS is extremely supportive of the CAA, 2023 creation of the benefit category and the CMS implementation of this benefit.** Expanding access to lymphedema treatment items should be an important goal of the Agency. As a society, this is an important part of the continuum of treatment for breast cancer patients. As has been observed in literature, breast cancer-related lymphedema is a common, underreported complication of breast cancer treatment, and lymphedema has a demonstrative negative impact on quality of life and increases financial stress for patients, caregivers, and society.⁴ As cited in the *Annals of Surgical Oncology*, “With the National Cancer Institute (NCI) predicting more than 4 million breast cancer survivors in the United States by 2024 and nearly 2 million women with a diagnosis of breast cancer annually worldwide, lymphedema represents a significant burden to global public health.”⁵

In order to effectuate the new policies, CMS is proposing to use several existing HCPCS codes, revise the descriptors of others, and add new additional codes where necessary.⁶ However, CMS specifically seeks 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.⁷ CMS also seeks input on whether any of the S-codes should be retained, noting that S-codes are invalid for Medicare use, but could be used by other payers in lieu of the updated and new A codes.

Patient Education

ASBrS is extremely supportive of the efforts to expand access for Medicare beneficiaries to lymphedema treatment options. However, the options available to cancer patients are often undermined by lack of patient awareness and education surrounding lymphedema. As published by our expert panel, “The current lack of patient educational standards as well as patient and clinician low awareness of risks and treatments makes lymphedema a critical concern for patients and patient advocates.”⁸ To ensure that the provisions of the CAA, 2023 and CMS’ implementing regulations reach their full potential, **ASBrS urges CMS to provide patient education⁹ materials and assistance to help patients and caregivers better understand lymphedema, treatments, and the expanded Medicare benefit.** In designing and developing these materials, please do not hesitate to use ASBrS as a resource.

ASBrS appreciates the opportunity to provide comments on these expanded Medicare benefits, which we believe will be particularly valuable for breast cancer patients. We share the goal of ensuring that all

⁴ McLaughlin, S. et al., *Considerations for Clinicians in the Diagnosis, Prevention, and Treatment of Breast Cancer-Related Lymphedema: Recommendations from a Multidisciplinary Expert ASBrS Panel, Part 1: Definitions, Assessments, Education, and Future Directions*, *Annals of Surgical Oncology*, 24:2818 (2017).

⁵ *Id.*

⁶ See, [Table FF-A1](#) for a list of existing related HCPCS codes, 88 *Fed. Reg.* 43772 (July 10, 2023); See, [Table FF-A2](#) for the list of proposed codes and proposed payment rates, 88 *Fed. Reg.* 43774 (July 10, 2023).

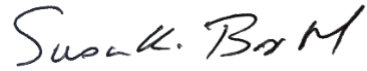
⁷ S8422 (*Gradient pressure aid (sleeve), custom made, medium weight*); S8423 (*Gradient pressure aid (sleeve), custom made, heavy weight*); S8424 (*Gradient pressure aid (sleeve), ready made*)

⁸ McLaughlin, et al., *Supra* note 3 at 2821.

⁹ “The goals of patient education are threefold. First, clinicians must raise awareness of the lifetime risk for lymphedema, especially in the 3–5 years after surgery. They should inform patients of concerning early signs and symptoms (unilateral/ipsilateral aching, heaviness, tightness, fullness, or stiffness) that often precede visible swelling and should ask about clothing or jewelry becoming tighter or patient-perceived swelling. Second, clinicians should educate patients on critical risk-reducing strategies that are practical and evidence based. Finally, clinicians should provide patients with a reliable specialist as a point of contact should they experience symptoms.” (footnotes omitted), McLaughlin, et al., *Supra* note 3 at 2822.

women can access excellent breast cancer prevention and treatment, including addressing breast cancer-related lymphedema. If you have questions or if ASBrS can ever be of assistance, particularly on any patient education efforts, please do not hesitate to reach out to Sharon Grutman, Director of Advocacy, Communications, and Quality Initiatives, at sgrutman@breastsurgeons.org.

Sincerely,

A handwritten signature in black ink that reads "Susan K. Boolbol". The signature is written in a cursive, flowing style.

Susan K. Boolbol, MD, FACS
President
The American Society of Breast Surgeons