August 28, 2023

Division of DMEPOS Policy
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

Re: Calendar Year 2024 Home Health Prospective Payment System Rate Update proposed rule, Lymphedema Compression Coverage (Section VIIB)

Dear Director Kaiser:

On behalf of the 5 million Americans with lymphedema, approximately half of whom are Medicare beneficiaries, the Lymphedema Advocacy Group is grateful for the opportunity to comment on section VIIB of the Calendar Year 2024 Home Health Prospective Payment System Rate Update proposed rule, *Scope of the Benefit and Payment for Lymphedema Compression Treatment Items*.

We applaud the agency's work to institute comprehensive coverage for the prescribed medical compression supplies needed to treat and manage this chronic disease. We strongly support many aspects of the proposed rule, and through these comments hope that the agency will provide clarification on and/or modification to certain aspects of the draft rule before it is finalized, in order to ensure equitable and accessible care for all patients.

We commend the agency's decision to cover a broad spectrum of compression supplies and accessories for all parts of the body, so that the individual needs of each patient can be met. In order to ensure that the final rule fulfills this intent, we recommend that the following clarifications be made:

- Some patients require the use of compression bandaging during the maintenance phase, so it is important that the language does not limit coverage of these supplies to the intensive phase of treatment. Compression bandaging during the maintenance phase is utilized by some patients instead of or in addition to day and/or nighttime garments. It also can be necessary at any point if a patient has extenuating circumstances, such as a sudden increase in swelling due to an infection.
- The proposed codes in the draft rule only encompass pressure ranges up to 50mmHG, however, some patients require the use of compression garments with pressure greater than 50mmHG, so it is important that codes and coverage exist for those garments.

- With regard to proposed codes for individual compression supplies, notably absent is what is commonly referred to as “toe caps.” Just as a hand affected by lymphedema needs a glove to provide compression to each finger, toe caps (essentially a foot glove) provide compression to each individual toe and are available in both standard and custom fit options.
- We understand that further clarification on what requirements must be met in order for a patient to qualify for coverage of custom fit compression garments will be determined by later rulemaking, but would like to urge the agency to ensure that patients who require custom fit supplies do not face undue burdens or delays. Patients who are subject to “try and fail” type policies that require them to use a less costly item first risk a worsening of their condition and other complications, all of which result in added healthcare costs and are detrimental to the patient's overall health. Whether or not a patient’s condition requires custom fit supplies should be based on the medical expertise of the prescribing healthcare provider. Further, once a patient has met the requirement to qualify for custom fit supplies that determination should be precedent setting for that patient, so they do not have to re-qualify each time they need to reorder supplies.

We strongly agree with the agency’s proposal to calculate allowable quantities per affected body part, so that patients with lymphedema in multiple areas of the body have coverage for the number of garments they need. We would like to offer the following feedback regarding allowable quantities and replacement:

- We agree that frequency limitations are important to establish in the rule, as well as exceptions for sooner replacement. Please note that two sets of daytime compression garments every six months and one set of nighttime garments each year is the bare minimum a patient would need, and many will require sooner replacement under these proposed frequency limitations. We believe that three sets of daytime garments every six months and two sets of nighttime garments each year would enable better compliance and disease management, ensuring that a patient is never without a wearable compression garment if one were to suddenly be lost, stolen, irreparably damaged, or simply soiled and another clean and dry garment was not immediately available. If the rule is enacted with the proposed frequency limitation we hope that the agency will closely monitor the number of necessary exceptions, in order to evaluate whether adjustments to these allowable quantities and/or replacement frequencies are needed during future rulemaking.
- Also in regard to exceptions for sooner replacement of day or nighttime garments, we urge the agency to ensure that patients do not face undue burdens or delays when these exceptions are needed. In the proposed rule CMS acknowledges that patients' needs vary, and we hope the agency will give close consideration to the public comments regarding quantity needs. Further, we recommend that qualifying exceptions include not just a significant change in weight, but also any change in size that is significant enough to result in the patient’s compression garment or garments no longer fitting properly.

- The agency has asked for comments on whether two nighttime garments should be allowed, with both garments being replaced once every two years, to allow for more than one day for washing and drying of the garment(s). As noted above, we believe that two nighttime garments each year for the patients who need to utilize nighttime compression would allow for optimal disease management. However, if this is not possible, two nighttime garments every two years is preferable to one each year.
- Lastly, a small minority of patients must layer compression garments in order to effectively treat and manage their condition. This typically occurs when a patient requires a high level of compression, but is unable to don or doff a single garment providing that level of compression. In those instances, the necessary level of compression can only be achieved by layering two garments, and it is important that in this unique situation the patient be afforded coverage for the number of items needed.

We recognize the complex nature of establishing the necessary billing codes and corresponding reimbursement rates for the various supplies and services. We are grateful that the agency is seeking feedback on these matters and would like to offer the following:

- As recognized in the proposed rule, in many cases a therapist may take measurements and provide other fitting services necessary for furnishing a gradient compression garment that is then supplied by a separate DME vendor.
    - We strongly support the proposal from the American Physical Therapy Association (APTA) and American Occupational Therapy Association (AOTA), which is outlined in the addendum, for the following reasons: (1) separate payment is important to ensure that clinicians are paid directly and fairly for the services they provide; (2) DME suppliers should not be administrating payment for these critical services; and (3) DME supplier status for clinicians is neither feasible nor necessary.
    - Creating a reimbursement structure whereby the payments for the measurement and fitting services can be separated when needed enables each patient to utilize the best option for their individual needs and/or circumstances. Some patients do not have the luxury of choice, and only have access to either a therapist or a certified fitter to provide these services. Additionally, patients who have just completed the intensive/reduction phase of treatment are typically wrapped in compression bandaging that must be re-applied immediately after the garment measurements are taken. If the patient is unable to reapply the bandaging themselves, and the therapist is not the individual taking the measurements, the patient is at risk of having a setback in their treatment that could result in the need for additional therapy services and/or the garment that they were just measured for not fitting properly.
    - In instances where non-clinicians are providing fitting and/or measuring services we support phased-in certification requirements for these individuals, in order to ensure that they have received the proper education and training to provide these services.

    - Please note, the proposed rule only makes reference to measurement and fitting services related to custom fit garments, however, standard fit garments also require measurement and fitting services.
- While the large majority of standard fit garments are constructed using a circular knit, and the large majority of custom fit garments are constructed using a flat knit, there are also flat knit standard fit garments and circular knit custom garments. Medicare may wish to consider codes that differentiate between each possible combination, as each variation contains unique therapeutic properties and unique manufacturing costs.
- We have concerns with the proposed method for calculating the reimbursement rates for compression garments. Utilization of Medicaid rates to establish state-by-state Medicare rates will result in geographic discrepancies in pricing. Further, if the Medicare reimbursement rates are unreasonably low, vendors will be unwilling to supply these items and patients may be left without access. And likewise, patients are burdened when reimbursement rates are unnecessarily high, as even with Medicare coverage beneficiaries will be required to pay 20%.

Thank you for your work to ensure that millions of Medicare beneficiaries with lymphedema will have comprehensive, equitable, and accessible coverage for the compression garments and supplies necessary for the treatment and management of this chronic disease. We are grateful for this opportunity to provide feedback as you work to finalize the rule. Please contact me if you have any questions about our comments.

Sincerely,

Heather Ferguson
Founder & Executive Director
Lymphedema Advocacy Group
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ADDENDUM

APTA believes that it is within CMS' authority to establish separate payment for measuring, fitting, and training services without premising such payment on therapists enrolling as DME suppliers. To this end, we provide a recommendation below of an implementable payment structure, closely modeled after the framework CMS provides in the alternative comment solicitation.

Generally, our recommendation would necessitate that CMS: (1) Establish two temporary "G" codes for measuring and fitting services; (2) Establish four modifiers that indicate which entity (the DME supplier or a therapist) provided the associated measuring and fitting services; and (3) **does not** require DME supplier status for clinicians performing and billing these services.

This recommendation would provide an immediate short-term framework that adequately recognizes and directly pays therapists for the services they provide, without enabling DME suppliers to act as administrators of payments for these services. Again, it is neither appropriate nor administratively simple under CMS' proposed structure, which would allow DME suppliers to set rates, and be relied upon to administrate payments for these services without oversight or infrastructure to address non-payments, appeals, and other unforeseen circumstances described in greater detail in the body of this letter. If CMS elects to adopt this framework, the eventual goal would be to pursue two permanent CPT service codes through the AMA/CPT process that mirror the temporary "G" codes.

It is critical that, as CMS works toward its final rule, that associated services are paid separately to providers, and do not require DME supplier status. Again, we direct CMS to the extensive comments above explaining why DME supplier status is neither necessary nor appropriate to require for clinicians. We believe our recommendations below are feasible, and would ensure that only DME suppliers would be paid through DME MACs, while therapists would be able to bill their claims separately through their traditional MACs using these temporary service codes.

Establish Two Temporary "G" Codes

We request CMS establish two temporary "G" codes for therapists to use when they provide measuring and fitting/training services. Below are descriptions of these procedures, as well as recommended sources for establishing associated payment amounts.

Recommended Codes and Descriptions

- *GXXX1*— Lymphedema Compression Garment Measurement
    - **Description of Procedure:** Patient is seen for assessment of lower extremity(ies) and explanation of the measurement process. Measurements are taken in sitting or lying position with additional measurements in standing for thigh length and panty options. All length measurement points are marked on the patient with a skin marker prior to taking measurement for circumferences. Length measurements are taken as needed to follow the contour of the leg. Consideration is taken regarding the patient or caregiver's ability level, functional level, or lifestyle to ensure a clinically effective fit. All measurements are recorded and provided to the manufacturer or fabricator.
- *GXXX2*— Lymphedema Compression Garment Fitting and Education
    - **Description of Procedure:** The patient presents after receiving the ordered/prescribed garment. The Qualified Healthcare Professional (QHP) assists the patient in donning the

garment and checks the fit of the garment. The QHP determines if any adjustments are needed. The QHP provides training and education to the patient and caregiver if applicable on skin inspection, proper donning/doffing of the garment, wearing schedule, and any relevant patient specific considerations.

Recommended Payment Amounts Associated with Temporary "G" Codes

There are two sources that we believe could help CMS establish payment for these temporary "G" codes – pricing that can be crosswalked from similar existing codes, and survey data from the US Medical Compression Alliance.

The temporary G code would allow reimbursement for QHP work until a permanent CPT code could be created through the American Medical Association CPT process. CMS could cross walk the rate from codes within the CPT code set that have similar practice expense, clinical labor and skill level:

CPT Code	Descriptor	Pre/Intra/Post time	Work RVUs	PE Clinical Labor	PE Supplies Equipment	Non-Facility Payment
29505	Application of long leg splint thigh to ankle or toes)	9/22/10	0.69	RN/LPN/MTA	Drape, gloves, underpad, cast cart	$90.14
29520	Strapping; hip	7/9/2	0.39	PT Aide	Gloves, tape (surgical paper 1 in), foam underwrap, rigid strapping tape, skin prep barrier wipes	$35.24
29584	Application of multi-layer compression system; upper arm, forearm, hand, and fingers	4/12/2	0.35	PT Aide, PTA	Pack, bandage system, lotion, exam table	$83.02

There is precedence for this manner of coding methodology within the code set for DME related to orthotics and prosthetic devices and the fitting and training services that occur when the device is issued. With orthotics and prosthetics, a HCPCs code captures the device supply and its initial fitting/training when initial fitting and training is performed by the DMEPOS supplier who has supplied the device, however when a qualified healthcare professional (QHP) such as an occupational or physical therapy practitioner conducts the initial fitting and training for the orthotic, CPT code 97760 *Orthotic management and training, initial orthotics encounter* is billed by the QHP to reimburse the "work" associated with the service.

However, while similar, these codes do not directly reflect the costs associated with providing these services. However, USMCA performed a survey with over 700 respondents to estimate the costs associated with measuring, fitting, and training. Sixty percent of respondents were therapists, and we believe that the results would better reflect appropriate payment for these services as well.

Recommended HCPCS Modifiers

To identify which claims are appropriate for therapists to bill for their services, we would anticipate that appending modifiers that reduce payment for the item would be most administratively simple. Our recommendation would function just as CMS recommends in its own alternate proposal, where the payment for services is backed out of the overall payment for the item.

Through discussions with clinicians and manufacturers, APTA identified four potential situations that need to be delineated. As such we propose that CMS establish a set of four modifiers that can be appended to the HCPCS claim to distinguish when, and how much separate payment is permissible, ensuring payment is appropriately distributed between the DME supplier and clinician.

- **Modifier A** – Lymphedema Compression Garment, Garment Only
    - This modifier would be billed with the associated garment HCPCS code when the DMEPOS supplier supplies the garment but an external qualified healthcare provider such as an occupational or physical therapist performs **both** the measuring service and provides the fitting and training once the garment arrives.
- **Modifier B** – Lymphedema Compression Garment, Includes **Measuring** by DME Supplier
    - This modifier would be billed with the associated garment HCPCS code when the DMEPOS supplier conducts the measuring task and supplies the garment but an external qualified healthcare provider such as an occupational or physical therapist performs the fitting and training once the garment arrives.
- **Modifier C** – Lymphedema Compression Garment, Includes **Fitting** by DME Supplier
    - This modifier would be billed with the associated garment HCPCS code when the DMEPOS supplier supplies the garment following receipt of measurements from an external qualified healthcare provider such as an occupational or physical therapist. The DMEPOS supplier then conducts the garment fitting and patient instruction after the garment is received.

- **Modifier D** – Lymphedema Compression Garment, Includes **Measuring and Fitting** by DME Supplier
    - This modifier would be billed with the associated garment HCPCS code when the DME supplier conducts all aspects of the custom garment process including measuring, supplying, and then assesses fit and provides patient instruction in use when the custom garment is received.

Examples of Recommended Payment Structure

To provide clarity around these recommendations, we have provided below two simplified examples where that use the following numbers. These numbers **do not** reflect actual pricing, but, again, are simplified to illustrate how our recommended payment structure would function in practice.

- Custom-Fit Garment X (represented by HCPCS Code 12345) ($100)
- Measuring/Training Services Only (represented by *GXXX1*) ($20)
- Fitting Services Only (represented by *GXXX1*) ($20)

Example 1: Measuring and Fitting/Training Performed by Therapist

Therapist sees Medicare beneficiary "MB" and takes measurements for Custom-Fit Garment X. Therapist sends measurements to DME supplier to fill order with manufacturer. Garment X is shipped to the therapist, who provides follow-up visit with Medicare beneficiary "MB" and then provides fitting and training services.

- **The claims and payment would be administered as follows:**
    - ***DME Supplier:*** Bills HCPCS Code 12345 appended with Modifier "A"
        - § This indicates that the DME supplier provided only the garment, and that the therapist provided the associated measuring and fitting services. As such, the garment payment of $100 dollars is reduced to **$60** to exclude payment for both the measuring and fitting/training services, which the therapist will bill separately. The DME MAC would pay $60 directly to the DME supplier, while the remaining $20 would be available to be billed separately by the therapist.
    - ***Therapist:*** Bills Temporary "G" Codes *GXXX1 and GXXX2.*
        - § Therapist would be paid $40 — $20 for associated measuring services, and $20 for associated fitting/training services with Custom Garment "X."

Example 2: DME Performs Measuring Services, Therapist Performs Fitting/Training Services

Therapist sees Medicare beneficiary "MB" during decongestive phase, and sends "MB" to DME supplier to be measured for Custom-Fit Garment X. DME supplier measures and submits order to manufacturer.

Garment X is shipped to the therapist, who provides follow-up visit with Medicare beneficiary “MB” and provides fitting and training services with them.

- **The claims and payment would be administered as follows:**
  - ***DME Supplier:*** Bills HCPCS Code 12345 appended with Modifier “B”
    - § This indicates that the DME provided the garment, as well as performed the associated measuring services, while the therapist provided the associated fitting/training services. As such, the garment payment of $100 dollars is reduced to $60 to exclude the measuring and fitting services, which the therapist will bill separately. The DME MAC would pay $60 directly to the DME supplier, while the remaining $40 would be available to be billed separately by the therapist.
  - ***Therapist:*** Bills Temporary “G” Codes *GXXX2.*
    - § Therapist would be paid $20 for associated fitting services with Custom Garment “X.”