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FOLLOW UP DOCUMENT ON LYMPHEDEMA ISSUES FROM ALLIANCE MARCH 15TH MEETING WITH CMS

- **Treatment of Lymphedema from Initiation to Maintenance**

Lymphedema is a complex condition with many causative factors affecting patients of all ages. It may present with relatively rapid onset after trauma or surgical intervention or have a more insidious onset with chronic venous disease. Patients with lymphedema may be identified and treated in a variety of clinical settings and at various stages in the progression of the disease including: acute hospital, hospital or private outpatient centers, wound care centers, vascular clinics, cancer centers, nursing homes, home health care, and hospice care. There is no commonly used diagnostic test for lymphedema. Often, the treating physician or advanced practice provider (APP) such as the NP, PA, and/or APRN rules out a variety of other medical conditions to come to the diagnosis of lymphedema. The patient may have a positive Stemmer sign[1] which is a highly sensitive, yet simple test for lymphedema of the upper or lower extremity.

Lymphedema can also affect the genitalia, head and neck, trunk, chest, and upper extremities. Many of these patients have mixed disease—venous or arterial disease complicated by lymphedema, with or without wounds. The treating provider (Physician or APP) may initiate lymphedema treatment with a referral to a lymphedema specialist, depending on the stage and extent of disease. It is most beneficial to recognize lymphedema and start treating early before tissue becomes fibrotic and before other complicating factors such as cellulitis and wounds develop. The referral will include a diagnosis of lymphedema as well as any other exacerbating conditions as may patients have mixed disease. This highly specialized therapy is not always available and therefore the treating practitioner may prescribe the initial treatment based on the clinical scenario.

There are two phases of lymphedema treatment:

- **Acute/decongestion phase**— typically 4-8 weeks for a stage 2 lymphedema patient but can vary depending upon the stage. Physicians will refer to a skilled medical provider with advanced lymphedema training (if available) to treat the patient. This phase is ideally treated with Complete Decongestive Therapy (CDT) which includes: manual lymphatic drainage, multi-layer short stretch bandaging (reusable or disposable), exercise, skin care, measuring and fitting for compression garments and patient education. The bandaging requires very specific application with close follow up to reduce the area impacted by lymphedema. The acute decongestive phase is completed with measuring and fitting of the compression garments.

[1] Goss, Jeremy A. Sensitivity and Specificity of the Stemmer Sign for Lymphedema: A Clinical Lymphoscintigraphic Study, PRS Global Open. April 2019

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- **Maintenance phase:** During this phase, the patient requires ongoing assessment and treatment with custom and/or standard compression garments (day and night-time garments). The type(s) of compression garment is dependent on the patient's habitus, tissue texture, refill rate, functional level and complexity of lymphedema.[2] Ongoing maintenance can include any or all of the following: skin care, consistent exercise, and pneumatic compression pumps or self-manual lymphatic drainage.

    - It is important to note that these patients will require lifelong maintenance with both daytime and nighttime compression garments.
    - These garments need to be remeasured and fit at minimum annually to ensure proper fit.
    - There will be times that the garments will need to be remeasured and fit due to changes in medical condition and reduction or exacerbation of lymphedema.
    - It should be recognized that there may be occasional complications such as a new wound or an unrelated illness or surgery that moves "maintenance" back to "acute/decongestive" phase.

Lymphedema can result in severe debilitation. Surgical treatment is sometimes indicated with surgical reduction of the tissue with or without lymph node transplant or bypass. Patients continue to require life-long compression garments even after surgical treatment.

• Other Diagnostic Considerations[3]

- Phlebolymphedema is a condition often associated with wounds/ulcerations in combination with lymphedema caused by venous insufficiency. These patients require not only lymphedema treatment but also wound management and care from a vascular surgeon. These patients' wounds heal exceptionally well with addition of compression. Types of compression can include: multi-layer short stretch bandaging, disposable bandaging systems, and inelastic wraps. These patients, just like those with other types of lymphedema, will require lifelong compression garments to maintain swelling reduction and improve vascular functioning.
- Cellulitis---treatment of the co-existing lymphatic impairment and establishing a compression regimen after treatment has been shown to reduce the incidence of cellulitis.[4]

[2] Kankariya, N., R.M. Laing, and C.A. Wilson, *Textile-based compression therapy in managing chronic oedema: Complex interactions.* Phlebology, 2021. **36**(2): p. 100-113.

[3] Ratliff et al, Compression for Lower Extremity Venous Disease and Lymphedema, JWOCN July/August 2022

[4] Webb, E., et al., *Compression Therapy to Prevent Recurrent Cellulitis of the Leg.* N Engl J Med, 2020. **383**(7): p. 630-639.

- **Measurement and Fitting of the Compression Items[5] [6]**

  - Fitting a patient with lymphedema for a compression garment should be done by a trained individual. This can include an allied health provider who has been treating the patient and is trained in fitting for compression garments, or certified fitters licensed in orthotics and prosthetics who have been appropriately trained/accredited to measure and fit for compression garments.

- **What is involved with the measure, fit, and application of bandages and compression items**

  - The treating practitioner will be responsible for obtaining prescriptions related to treatment of lymphedema including: the provision of bandages and compression items, the measuring and fitting of garments, and patient education pertaining to these bandages and compression items.

  - The compression garment should be fitted once the volume of the limb has been stabilized to optimize the fit/utilization of the garment. Most patients with lymphedema will require CDT and healing of wounds prior to fitting for compression garments.

  - The time and physical effort to measure and fit compression garments will vary greatly depending again on the patient complexity of the presentation, type of garment(s).

  - Measurement is only the first step in the 'fitting' journey. Once the garment is available, then the patient's family has be instructed with the use/care, how to don and doff the garment(s). There may be modifications that need to be made that require re-measuring, communication with manufacturers, additional fitting sessions to ensure the garment fits and is functioning properly.

  - Selection of compression garments

    - "Fitting" a compression garment is more than just picking a box off a shelf with a particular dosage.
    - There are many clinical and anatomical factors that need to be considered when choosing the appropriate compression garment as referenced in the STRIDE[7] document including: limb shape/size, tissue texture, edema type, patient functional level and underlying etiology.

[5] Aviles, Frank A, McKeown Brandy, The Lymphedema Treatment Act: A Huge Win for Patients Today's Wound Clinic. P.2-3.

[6] Hettrick, H., et al., *Selecting appropriate compression for lymphedema patients: American Vein and Lymphatic Society position statement.* Phlebology, 2023. **38**(2): p. 115-118.

[7] Bjork, Robyn, Ehmann Suzie, STRIDE- Professional guide to compression garment selection for the lower extremity. Journal of Wound Care 2019

- The decision to select a ready to wear vs. custom compression garment is more than just matching a circumference with a size chart. The choice of flat knit versus circular knit versus velcro wrap is related to function and effective containment of lymphedema.[8]
- Compression has not only a vascular impact, but also a cellular impact. Clinical evidence has shown us that textured compression textiles, such as the flat knit garments, or nighttime garments with an alternating profile produce a physical softening of the tissue and have afforded better edema management. Evidence shows us that patients equipped with these nighttime garments not only have better edema management but have a better quality of life.[9]
- Patient example[10]:

  Patient with fatty tissue consistency and lymphedema. She is at the extremes of the size category for an OTC garment however the circular knit product will have a tendency to roll/cord, potentially producing a counterproductive effect/making the lymphedema worse. However, a flat knit product will contain the tissue and will not roll. Furthermore, because a flat knit garment is stiffer, the patient can be in a lower compression class but still get the same hemodynamic response.

  Therefore, CMS might consider using the statement: a custom garment may be considered reasonable and necessary for patients when their anatomical features or clinical characteristics are not appropriate for ready-to-wear / circle knit garments (e.g., due to size, fatty tissue consistency, etc.).

- **<u>Input on types of items necessary to treat lymphedema, in addition to compression garments.</u>**

  In addition to the standard bandages and day and nighttime garments themselves, there are accessory items that are needed for the patient to successfully use the garments which need new HCPCS codes, coverage, and payment. These are also known as "efficacy aids". They are medically necessary since the patient must be able to don or apply and doff or remove the garments ideally independently. These compression garments are a tight fit and older patients often have trouble with balance or strength in their hands.

  There are a variety of don/doffing devices that reduce the physical strain and reduce the shearing /friction of applying a compression garment over a limb such as [11]:
  - metal frame type products that position the stocking to make it easier to slide the foot into.
  - Anti shear/friction donning devices
  - pull-on straps, loops, T-heels and silicone bands.

[8] Bock, K.J., J. Muldoon, *The 24-hour interval compression plan for managing chronic oedema: part 1- the science and theory behind the concept*. J Wound Care, 2022. **31** (2): p. 2-6.

[9] Bock, K.J., J.S. Ehmann, and J. Muldoon, *The 24-hour interval compression plan: part 2-lifestyle and therapeutic regimens to manage chronic oedema case series.* J Wound Care, 2022. **31**(3): p. 218-223.

[10] Ehmann, S., *Case report to demonstrate the need for selection criteria for optimal adjustable Velcro wrap prescription.* J Wound Care, 2018. **27**(1): p. S10-17.

[11] Ratliff et al, Compression for Lower Extremity Venous Disease and Lymphedema, JWOCN July/August 2022

Additionally, very specialized compression products that address swelling and fibrosis in specific regions of the body parts known as "swell spots or pads" or foam chip bags are needed in addition to their compression bandages and garments.

Therefore, we request that CMS issue new HCPCS codes, cover and provide payment for the following medically necessary efficacy aids:

- "Swell spot" type products, as well as chest, trunk, head, neck, genitalia products, as needed.
- "Donning devices" to help the patient apply or remove the garments for effective utilization.

- **Expected timeframes these items last and how often they should be replaced**
  - Compression garments/devices - replace every 6 months, need 4 sets of garments per period (divided between nighttime and daytime, wash and wear – at practitioner discretion)
    - Whether glove, toe, sleeve, lower extremity, etc. – one "set" equals all garments needed by the patient
  - Extenuating medical circumstances: Skilled practitioner ability to adjust ordered garments or bandages if pt has medical issues/changes or significant fluctuations in lymphedema.

- **Recommendations**
  - We recommend that CMS establish HCPCS or CPT codes along with coverage and payment for the following:
    - CPT procedure codes specific for measuring, fitting and education related to compression garments. Currently there are not skill specific CPT codes for medical providers, allied health and/or fitters to account for the time and expertise required to fit/measure/provide these compression items.
    - HCPCS codes for efficacy aids named above as well as custom compression garments for all body parts.