VHA Office of Integrated Veteran Care
Clinical Determination and Indication
Pneumatic Compression Devices for Lymphedema

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I. Disclaimer

This document is currently in draft and is intended to be used as a reference for non-VA providers and not intended to replace clinical judgment when determining care pathways. These guidelines do not guarantee benefits or constitute medical advice.

II. Clinical Determinations and Indications

a. Indications

i. Indications for Pneumatic Compression Devices

Pneumatic compression devices (PCDs), including use in the home setting, are indicated for the following:

- Primary and secondary lymphedema
- Chronic venous insufficiency with venous stasis ulcers

PCDs will be considered medically necessary when ALL the following clinical criteria are met:

- Documented persistence with presence of symptoms and objective findings consistent with chronic and severe lymphedema
- Failure of a conservative therapy trial with no significant improvement
    - Trial of conservative therapy includes:
        - Regular and compliant use of an appropriate compression bandage system or compression garment to provide adequate graduated compression
        - Regular exercise
        - Elevation of the affected limb
- Lymphedema that is associated with limitations in functional abilities (e.g., impairment of activities of daily living)

- For venous stasis ulcers, PCDs are indicated if other compression interventions are inappropriate

Continued use of PCDs are considered medically necessary and appropriate if there is documented effectiveness to an initial treatment with the device (e.g., decrease in edema, improvement in functional capacity, etc.)

ii. Indications for Programmable Pneumatic Compression Devices (e.g., calibrated gradient pressure)

Programmable PCDs will be considered medically necessary when ALL the following clinical criteria are met:

- Eligible for PCDs as outlined in section II.a.i.
- Presence of unique characteristics that prevent satisfactory pneumatic compression with non-programmable PCDs
  - E.g., significant scarring or contractures

b. Limitations/Exclusions

Pneumatic compression devices for lymphedema are not indicated if any of the following are applicable:

- Serious arterial insufficiency
- Recent skin graft
- Acute cellulitis
- Active skin or limb infection
- Deep venous thrombosis
- Uncontrolled congestive heart failure
- Acute renal failure
- Pregnancy (for trunk garment)
- Uncontrolled hyperthyroidism or hypothyroidism (head and neck garment)
- Carotid sinus hypersensitivity syndrome (head and neck garment)
- Symptomatic bradycardia in absence of a pacemaker (head and neck garment)
- Internal jugular thrombosis within three months (head and neck garment)
- Increased intracranial pressure (vest garment)
- Acute radiation dermatitis, unhealed surgical scar, unhealed or open wound(s), surgical flap less than 6-8 weeks post-operative (head and neck garment)
- Facial or head and neck dermal metastasis (head and neck garment)
- Acute facial infection (head and neck garment)

Conditions/indications for which PCDs are not medically necessary include, but are not limited to, the following:

- Edema from causes other than lymphedema

For all conditions/indications not listed in section II.a. of this document, pneumatic compression devices are considered not medically necessary due to insufficient evidence of efficacy and safety.

c. Request for Durable Medical Equipment

Community providers will utilize the Request for Service Form 10-10172 to submit DME and/or Prosthetic requests to their local VA Facility Community Care office.

All fields in the DME sections of the Request for Service Form 10-10172 must be filled out with accurate information to ensure proper processing and facilitation of the DME request. To facilitate timely review of the DME request, the most recent office notes and plan of care must accompany the request. Incomplete forms with missing information and/or supplementary documents will result in processing delays and prevent the local VA Facility Community Care office from fulfilling the DME request, delaying care for the Veteran.

d. Description of Treatment

Pneumatic compression devices (PCDs) apply intermittent pneumatic pressure, using air to create pressure, to the affected body part, treating the lymphedema. The device consists of an inflatable garment that is connected to a programmable pump that applies sequential gradients of pressure to the body part through inflation and deflation of the garment. The PCD enhances lymphatic and venous circulation by creating a pumping effect to aid in the movement of lymphatic fluid, reducing swelling of the affected area.

Types of PCDs

- **Non-programmable** – also known as fixed or standard pumps. These devices have pre-set compression settings that cannot be adjusted by the user. Non-programmable PCDs are appropriate for Veterans who do not require customized compression therapy. These pumps are typically used where consistent compression is sufficient for therapeutic benefits.
    - Single-Chamber – simplest pumps, consisting of a single chamber that is inflated at one time to apply pressure
    - Multi-Chamber – multiple chambers that are inflated sequentially with fixed pressures in each compartment. Pressures in each chamber may be the same or in a gradient

        - No ability to manually adjust pressure in individual compartments
- **Programmable** – PCDs with advanced features that allow users to customize the compression pressures according to the Veteran needs. These devices offer multiple levels of pressure, different compression patterns, and have adjustable inflation and deflation times. Parameters are set based on the Veteran's condition and preferences which providing a tailored treatment experience.
    - Single- or Multi-Chamber – similar to programmable pumps described above, but have the ability to manually adjust pressure in individual compartments, including the length and frequency of the inflation cycles
    - These devices are generally preferred for individuals with scarring, contractures, or highly sensitive skin

III. Background and Supporting Information

The following information is for reference purposes only in accordance with the medical benefits package outlined in 38 C.F.R. § 17.38 (b). Each subsection supports VA's determinations for medical necessity and alignment with generally accepted standards of medical practice.

a. Background of Lymphedema

Lymphedema is defined as localized swelling caused by isolated accumulation of lymphatic fluid, typically in the arms or legs, but can affect other parts of the body (e.g., abdomen, genital region, face, or neck). Lymphedema occurs when the lymphatic system is impaired or damaged. Common causes are lymph node removal or damage due to cancer treatment. Lymphedema can be categorized as either primary or secondary. Primary lymphedema is a hereditary or congenital condition characterized by an abnormal development of the lymphatic system leading to mechanical insufficiency and the inability to manage the normal transport capacity. Secondary lymphedema is defined as issues or disturbances within the lymphatic system that most commonly affect functionality and movement. Common causes of secondary lymphedema are infection, filariasis injury, cancer, cancer treatment, surgery, inflammation of the limb, or lack of limb movement.

Staging and Management

The International Society of Lymphology (ISL) established a staging system for identifying the severity of disease ranging from I-III.

- For individuals experiencing mild lymphedema stage I, ISL recommends physiotherapy and utilizing compression garments as an initial treatment option, rather than pursuing more intensive therapies
- For individuals with moderate to severe lymphedema ISL stage II to III and no contraindications, ISL recommends intensive physiotherapy, utilizing a form of complete decongestive therapy instead of a less intensive therapy
- For individuals with severe lymphedema (ISL stage III), benefits have been shown with the use of intermittent pneumatic compression in addition to complete decongestive therapy

Conservative and multimodal therapy for the treatment of lymphedema encompass a range of general self-care measures. These include monitoring, skin care, weight reduction, and varying extents of compression treatment. Compression treatment consists of compression bandaging, compression garments, intermittent pneumatic compression, and physiotherapy. Physiotherapy includes manual lymphatic drainage and complete decongestive therapy, which combines manual lymphatic drainage and other conservative treatments like exercise and skin care.

Pneumatic Compression Devices

Pneumatic compression devices (PCDs) are typically the recommended treatment for individuals as a part of their long-term management or maintenance of symptoms. They are often prescribed for home use, allowing patients to conveniently incorporate treatment into their daily routines.

Pneumatic compression devices are categorized as single-chambered or multi-chambered with fixed sequential inflation or manually calibrated gradient chamber pressure. Older models consist of intermittent single-chamber non-segmented pumps, which apply pressure throughout the body part but may permit the backflow of lymphatic fluid. Newer devices have multiple segmented chambers that can provide successive compression. These devices can inflate from distal to proximal and/or proximal to distal, generating a pressure wave that travels along the body part, ensuring consistent pressure is delivered across each section of the garment.

Segmental pumps with calibrated gradient pressure functionality are commonly used in patients that require minimal pressure to a specific area (e.g., significant scars, pain or contracture caused by the clinical condition).

b. Research, Clinical Trials, and Evidence Summaries

The scientific literature on the use of compression devices for lymphedema treatment has predominantly concentrated on PCDs to address affected limbs. These devices have shown to be beneficial in aiding the management

of lymphedema and promoting fluid movement. Several key findings include reduction in limb volume, improved quality of life and enhanced lymphatic drainage.

Zaleska et al. (2014) conducted a three-year study to verify the effectiveness of intermittent pneumatic compression in long-term therapy of lymphedema in the lower limbs. Intermittent pneumatic compression (IPC) assumes the role of the obliterated lymphatics by applying pressure to the edema tissue fluid, redirecting it towards regions with intact lymphatic drainage. Over a span of three years, 18 patients with moderate to advanced staged lymphedema received treatment utilizing an eight-chamber sleeve with sequential inflation. Outcome measurements included limb circumference and tissue tonicity at monthly intervals. Results showed decreased limb circumference and increased elasticity. The authors concluded that long-term intermittent pneumatic compression can be safely recommended for lower extremity lymphedema.

Dunn et al. (2022) conducted a study to assess the effectiveness of LymphAssist, a patented IPC device that mimics manual lymphatic drainage (MLD), compared to a standard sequential IPC regimen. The three-phased study consisted of 40 patients diagnosed with lower limb ISL stage II or III lymphedema. Bilateral leg volume assessment and quality of life assessment were completed over four clinic visits throughout the study. As a result, the LymphAssist IPC treatment was shown to be more effective in minimizing distal leg volume than the sequential mode. The authors concluded that both methods of IPC are effective in reducing lower limb volume and enhancing the quality of life for patients with lower limb lymphedema.

Devitt et al. (2022) conducted a preliminary assessment of the usability of a novel, compact pneumatic compression device in patients with lymphedema. The assessment was completed in two phases, the first phase included fitting the pneumatic compression device (Aria Free, Aria Health, San Diego CA) while the second phase assessed the comfort of the entire system for a 45-minute period. The study included 15 patients over 18 years old, diagnosed with lower limb lymphedema and utilized a pneumatic compression device for at least three months. Study results showed a decrease in limb volume by 1.85% with no safety issues identified. Authors concluded this pneumatic compression device was successful in reducing leg edema.

Gutierrez et al. (2019) studied the effects of pneumatic compression on head and neck cancer survivors diagnosed with head and neck lymphedema. The team found some benefit with lymphatic drainage in the head and neck, but more high-quality studies are needed to determine the long-term treatment benefits of pneumatic compression on head and neck lymphedema.

Nelson et al. (2022) conducted a systematic review to determine whether IPC increased the healing of venous leg ulcers. The team reviewed randomized controlled trials (RCTs) that compared the effects of IPC with the control (no IPC) and RCTs that compared IPC treatment regiments in venous ulcer management. The authors found that IPC may increase healing when compared to treatment with no compression. Limited evidence has shown that IPC may improve healing when used in conjunction with compression. Further trials are needed to validate findings.

Ridner et al. (2021) conducted an open-label, multi-site, stratified randomized, wait list control study to evaluate the feasibility and efficacy regarding the use of an advanced pneumatic compression device (APCD) in patients with head and neck cancer with lymphedema. Eligible patients had completed treatment for head and neck cancer (disease free) and had a lymphedema diagnosis. Forty-nine patients were enrolled in the study, while 43 patients completed the study. Participants were randomized to receive either self-management of lymphedema alone (control group) or self-management plus the use of an APCD for eight weeks. The device was found to be safe with good adherence to a once-daily treatment regimen. Significant improvements were observed in patient-reported measures of swelling, pain, and perceived control of lymphedema with use of the APCD. While results support the feasibility of the advanced compression device for head and neck lymphedema and provide preliminary evidence that the APCD may provide additional benefits over self-management alone, larger trials may be needed to confirm efficacy and safety.

c. U.S. Food & Drug Administration (FDA) Information

VA generally only approves use of medical devices that have received at least FDA clearance for 510(k) Premarket Notification. The FDA has determined these Class II devices are substantially equivalent (SE) to legally marketed predicate devices and may be marketed in the U.S.

To search for devices that have received FDA 510(k) clearance or Premarket Approval (PMA), please visit the FDA Devices database.

d. Medicare Coverage Determinations

Available Medicare coverage determinations are listed below as a resource. VA and Medicare are governed by separate laws and regulations; thus, VA coverage determinations may be different.

NCD Number	Name	Revision Effective Date
280.6	Pneumatic Compression Devices	01/14/2022

LCD Number	Contractor	Revision Effective Date
L33829	CGS Administrators, LLC Noridian Healthcare Solutions, LLC	10/22/2023

- NCD: National Coverage Determination
- LCD: Local Coverage Determination

IV. Definitions

Term	Definition
Arterial Insufficiency	Condition that slows or stops the flow of blood through the arteries
Blood Thinners	Medications that prevent blood clots from forming
Edema	A non-specific term for the accumulation of fluid in tissue, most often in the extremities
Filariasis	An infectious tropical disease caused by any one of several thread-like parasitic round worms
Lymph Node	Small structures that work as filters for foreign substances, such as infections or cancer cells
Lymphedema	Accumulation of protein rich fluid in the interstitial space of tissue that the circulatory system is unable to pick up
Physiotherapy	Treatment of disease, injury, or deformity by physical methods such as massage, heat treatment, and exercise rather than by drugs or surgery; physical therapy
Tonicity	The normal presence of tone or tension in a muscle or organ

V. References

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VI. CDI History/Revision Information

- Explanation of changes to the CDI

Revision Type	Date of Revision	Update(s) Made to CDI
	MM/DD/YYYY	
	MM/DD/YYYY	