

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 for Pneumatic Compression Devices

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

Pneumatic compression devices will be considered **medically necessary** when **ALL** the following clinical criteria are met:

- Documented persistence of symptoms and objective findings consistent with chronic and severe lymphedema
- Completion of a four-week trial of conservative therapy with documented failure, inadequate response, or no significant improvement of underlying condition
 - 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

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.
- Documentation of unique characteristics that prevent satisfactory pneumatic compression with non-programmable PCDs
 - E.g., significant scarring or contractures

iii. Continuation of the use of Pneumatic Compression Devices

Continuation of the use of PCDs may be considered **medically necessary** for the indications in section II.a., provided **ALL** applicable clinical criteria are met and documented by the treating provider and/or referring clinician:

- Confirmed ongoing diagnosis of the medical condition for which treatment was initiated
- Clinical reassessment showing therapeutic response or clinical benefit from use of PCDs (e.g., decrease in edema, improvement in functional capacity, etc.)
- Veteran adherence to the use of the equipment as ordered by the healthcare professional

b. Limitations/Exclusions

Pneumatic compression devices for lymphedema are **not indicated** and therefore considered **not medically necessary** for lymphedema 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
- Acute radiation dermatitis

Pneumatic compression devices using a trunk or vest garment are **not indicated** for lymphedema and therefore considered **not medically necessary** if any of the following are applicable:

- Pregnancy
- Increased intracranial pressure

Pneumatic compression devices using a head and neck garment are **not indicated** for lymphedema and therefore considered **not medically necessary** if any of the following are applicable:

- Uncontrolled hyperthyroidism or hypothyroidism
- Carotid sinus hypersensitivity syndrome
- Symptomatic bradycardia in absence of a pacemaker
- Internal jugular thrombosis within three months of diagnosis
- Increased intracranial pressure
- Unhealed surgical scar, unhealed or open wound(s), surgical flap less than six to eight weeks post-operation
- Facial or head and neck dermal metastasis
- Acute facial infection

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, PCDs 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 durable medical equipment (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 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 segments of the garment. The PCD enhances lymphatic and venous circulation by creating a pumping effect to aid in the movement of lymphatic fluid, directing fluid movement to a less congested area, reducing swelling of the affected area.

Types of Pneumatic Compression Devices

- **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** – Pneumatic compression devices 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 provide 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 Information

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 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, 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. The LymphAssist IPC treatment was 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 PCD in patients with lymphedema. The first assessment phase included fitting the PCD (Aria Free, Aria Health, San Diego CA). The second assessment phase examined 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, who utilized a PCD for at least three months. Study results showed a decrease in limb volume by 1.85% with no safety issues identified. Authors concluded this PCD was successful in reducing leg edema.

Gutierrez et al. (2019) investigated the effects of advanced PCD therapy on head and neck lymphedema in ten cancer survivors. Lymphatic drainage and swelling were assessed before and after a single PCD treatment, then reassessed after two weeks of daily home use. Near-infrared fluorescence lymphatic imaging, facial and neck measurements, and patient surveys were used to assess the outcome measures. Results showed that a single PCD session enhanced lymphatic uptake and drainage in all subjects, while two weeks of daily treatment reduced or eliminated dermal backflow in most cases and improved patient-reported symptoms such as swelling, tightness, and swallowing. No adverse events were observed. The study concluded that advanced pneumatic compression therapy can stimulate lymphatic function and reduce external lymphedema, with potential to improve persistent backflow, though longer-term studies are needed to confirm durability and broader efficacy.

Nelson et al. (2014) conducted a Cochrane systematic review evaluating the effectiveness of IPC for treating venous leg ulcers and limb swelling due to lymphedema by analyzing nine randomized controlled trials (RCTs) with a total of 489 participants. The review included studies comparing IPC alone, IPC plus compression, and different IPC regimens, with outcomes measured as ulcer

healing rates, pain, and quality of life. Results showed that IPC alone increased healing compared to dressings alone, and adding IPC to standard compression therapy may further improve healing rates, though findings were inconsistent across studies. Rapid IPC regimens were more effective than slower ones in one trial. The study showed that IPC was associated with modest reductions in pain compared to compression alone. However, the authors noted that most studies were small and at risk of bias, and there is insufficient evidence to determine the optimal IPC regimen or its effectiveness as a replacement for standard compression. The review concludes that IPC may be a beneficial adjunct to compression therapy for some patients with venous leg ulcers and lymphedema, but larger, high-quality trials are needed to clarify its role and best use.

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 provide preliminary evidence that the APCD may have additional benefits over self-management alone, larger trials may be needed to confirm efficacy and safety.

c. U.S. Food & Drug Administration Information

VA generally only approves use of medical devices that have received at least Food & Drug Administration (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 national and local 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	Effective Date
280.6	Pneumatic Compression Devices	01/14/2002

LCD Number	Contractor	Original/Revision Effective Date
None	N/A	N/A

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

e. Health Care Procedural Coding Information

The following CPT[®]/HCPCS codes listed in this section are provided for informational purposes only. Inclusion or exclusion of a code does not constitute or imply VA coverage or provider reimbursement. The list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare & Medicaid Services (CMS) code updates may occur more frequently than CDI updates. Please refer to section II.a. in this document to review indications and clinical criteria for medical necessity.

The following CPT codes are considered **medically necessary/covered** if the indications and clinical criteria outlined in section II.a. are met. Additional codes may also apply.

CPT Code	Description
E0650	Pneumatic compressor, non-segmental home model
E0651	Pneumatic compressor, segmental home model without calibrated gradient pressure
E0652	Pneumatic compressor, segmental home model with calibrated gradient pressure

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IV. Definitions

Term	Definition
Arterial insufficiency	A condition that slows or stops the flow of blood through the arteries
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	Tissue swelling caused by an accumulation of protein rich fluid that's usually drained through the body's lymphatic system
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

Date	Summary of Update(s)
01/07/2026	<ul style="list-style-type: none"> • Added section “Health Care Procedural Coding Information” • Added clinical criteria for “Continuation of Pneumatic Compression Devices” • Removed LCD 33829 due to retirement on 11/14/2024 • Updated “Lymphedema” in Definition section
09/01/2024	<ul style="list-style-type: none"> • New CDI created describing medically necessary indications