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## **Medical Policy**

# Pneumatic Compression Pumps for Treatment of Lymphedema and Venous Ulcers

## **Table of Contents**

- Policy: Commercial
- Policy: Medicare
- Authorization Information
- Coding Information
- Description
- Policy History
- Information Pertaining to All Policies
- References

**Policy Number: 354** 

BCBSA Reference Number: 1.01.18 (For Plan internal use only)

### **Related Policies**

- Bioimpedance Devices for the Detection of Lymphedema, #261
- Noncontact Ultrasound Treatment for Wounds, #657

## **Policy**

## Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Single compartment or multichamber *nonprogrammable* lymphedema pumps applied to the limb may be considered <u>MEDICALLY NECESSARY</u> for the treatment of lymphedema that has failed to respond to conservative measures, such as elevation of the limb and use of compression garments.

Single-compartment or multichamber *programmable* lymphedema pumps applied to the limb may be considered **MEDICALLY NECESSARY** for the treatment of lymphedema when:

- 1. The individual is otherwise eligible for nonprogrammable pumps; AND
- 2. There is documentation that the individual has unique characteristics (eg, significant scarring) that prevent satisfactory pneumatic compression with single-compartment or multichamber nonprogrammable lymphedema pumps.

Single-compartment or multichamber lymphedema pumps applied to the limb are considered **INVESTIGATIONAL** in all situations other than those specified above in the first two policy statements.

The use of lymphedema pumps to treat the trunk or chest in patients with lymphedema with or without involvement of the upper and/or lower limbs is considered **INVESTIGATIONAL**.

The use of lymphedema pumps applied to the head and neck to treat lymphedema is considered **INVESTIGATIONAL**.

The use of pneumatic compression pumps to treat venous ulcers is considered **INVESTIGATIONAL**.

## **Prior Authorization Information**

## Inpatient

 For services described in this policy, precertification/preauthorization <u>IS REQUIRED</u> for all products if the procedure is performed <u>inpatient</u>.

#### Outpatient

• For services described in this policy, see below for products where prior authorization <u>might be</u> required if the procedure is performed outpatient.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is <b>not required</b> .
Commercial PPO and Indemnity	Prior authorization is <b>not required</b> .

## **CPT Codes / HCPCS Codes / ICD Codes**

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above <u>medical necessity criteria MUST</u> be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:

### **HCPCS Codes**

HCPCS	Code Description
codes:	
E0650	Pneumatic compressor, nonsegmental home model
E0651	Pneumatic compressor, segmental home model without calibrated gradient pressure
E0652	Pneumatic compressor, segmental home model with calibrated gradient pressure
E0655	Nonsegmental pneumatic appliance for use with pneumatic compressor, half arm
E0660	Nonsegmental pneumatic appliance for use with pneumatic compressor, full leg
E0665	Nonsegmental pneumatic appliance for use with pneumatic compressor, full arm
E0666	Nonsegmental pneumatic appliance for use with pneumatic compressor, half leg
E0651	Pneumatic compressor, segmental home model without calibrated gradient pressure
E0667	Segmental pneumatic appliance for use with pneumatic compressor, full leg
E0668	Segmental pneumatic appliance for use with pneumatic compressor, full arm
E0669	Segmental pneumatic appliance for use with pneumatic compressor, half leg
E0652	Pneumatic compressor, segmental home model with calibrated gradient pressure
E0670	Segmental pneumatic appliance for use with pneumatic compressor, integrated, 2
	full legs and trunk
E0671	Segmental gradient pressure pneumatic appliance, full leg
E0672	Segmental gradient pressure pneumatic appliance, full arm
E0673	Segmental gradient pressure pneumatic appliance, half leg

The following ICD Diagnosis Codes are considered medically necessary when submitted with the HCPCS codes above if <u>medical necessity criteria</u> are met:

**ICD-10-CM Diagnosis Coding** 

ICD-10-CM diagnosis codes:	Code Description
189.0	Lymphedema, not elsewhere classified
197.2	Postmastectomy lymphedema syndrome

Q82.0	Hereditary lymphedema

## The following HCPCS codes are considered investigational for <u>Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:</u>

## **HCPCS Codes**

HCPCS codes:	Code Description
E0656	Segmental pneumatic appliance for use with pneumatic compressor, trunk
E0657	Segmental pneumatic appliance for use with pneumatic compressor, chest

## **Description**

## Lymphedema

Lymphedema is an accumulation of fluid due to disruption of lymphatic drainage. It is characterized by nonpitting swelling of an extremity or trunk, and is associated with wound healing impairment, recurrent skin infections, pain, and decreased quality of life. Lymphedema can be caused by congenital or inherited abnormalities in the lymphatic system (primary lymphedema) but is most often caused by acquired damage to the lymphatic system (secondary lymphedema). Breast cancer treatment (surgical removal of lymph nodes and radiotherapy) is one of the most common causes of secondary lymphedema. In a systematic review of 72 studies (N=29,612 women), DiSipio et al (2013) reported that nearly 20% of breast cancer survivors will develop arm lymphedema. The risk factors with robust evidence for the development of lymphedema included extensive surgical procedures (such as axillary lymph node dissection, a higher number of lymph nodes removed, and mastectomy) as well as being overweight or obese.

## **Diagnosis and Staging**

A diagnosis of secondary lymphedema is based on history (e.g., cancer treatment, trauma) and physical examination (localized, progressive edema and asymmetric limb measurements) when other causes of edema can be excluded. Imaging, such as MRI, computed tomography, ultrasound, or lymphoscintigraphy, may be used to differentiate lymphedema from other causes of edema in diagnostically challenging cases. Table 1 lists International Society of Lymphology guidance for staging lymphedema (2023) based on "softness" or "firmness" of the limb and the changes with an elevation of the limb.<sup>2</sup>

Table 1. Recommendations for Staging Lymphedema

Stage	Description
Stage 0 (latent or subclinical)	Swelling is not yet evident despite impaired lymph transport, subtle alterations in tissue fluid/composition, and changes in subjective symptoms. It can be transitory and may exist months or years before overt edema occurs (Stages 1-III).
Stage I (mild)	Early accumulation of fluid relatively high in protein content (e.g., in comparison with "venous" edema) which subsides with limb elevation. Pitting may occur. An increase in various types of proliferating cells may also be seen.
Stage II (moderate)	Involves the permanent accumulation of pathologic solids such as fat and proteins and limb elevation alone rarely reduces tissue swelling, and pitting is manifest. Later in this stage, the limb may not pit as excess subcutaneous fat and fibrosis develop.
Stage III (severe)	Encompasses lymphostatic elephantiasis where pitting can be absent and trophic skin changes such as acanthosis, alterations in skin character and thickness, further deposition of fat and fibrosis, and warty overgrowths have developed. It should be noted that a limb may exhibit more than one stage, which may reflect alterations in different lymphatic territories.

## **Management and Treatment**

Lymphedema is treated using elevation, compression, and exercise. Conservative therapy may consist of several features depending on the severity of the lymphedema. Individuals are educated on the importance of self-care including hygiene practices to prevent infection, maintaining ideal body weight through diet and exercise, and limb elevation. Compression therapy consists of repeatedly applying padding and bandages or compression garments. Manual lymphatic drainage is a light pressure massage performed by trained physical therapists or by affected individuals designed to move fluid from obstructed areas into functioning lymph vessels and lymph nodes. Complete decongestive therapy is a multiphase treatment program involving all of the previously mentioned conservative treatment components at different intensities. Pneumatic compression pumps may also be considered as an adjunct to conservative therapy or as an alternative to self-manual lymphatic drainage in individuals who have difficulty performing self-manual lymphatic drainage. In individuals with more advanced lymphedema after fat deposition and tissue fibrosis has occurred, palliative surgery using reductive techniques such as liposuction may be performed.

#### **Venous Ulcers**

Venous ulcers, which occur most commonly on the medial distal leg, can develop in patients with chronic venous insufficiency when leg veins become blocked. Standard treatment for venous ulcers includes compression bandages or hosiery supplemented by conservative measures such as leg elevation.

#### **Pneumatic Compression Pumps**

Pneumatic compression pumps (PCPs) may be used in lymphedema or wound care clinics, purchased, or rented for home use; home use is addressed herein. PCPs consist of pneumatic cuffs connected to a pump. These pumps use compressed air to apply pressure to the affected limb. The intention is to force excess lymph fluid out of the limb and into central body compartments in which lymphatic drainage should be preserved. Many PCPs are available, with varying materials, designs, degrees of pressure, and complexity. There are 3 primary types of pumps. Single chamber nonprogrammable pumps are the simplest pumps, consisting of a single chamber that is inflated at 1 time to apply uniform pressure. Multichamber nonprogrammable pumps have multiple chambers ranging from 2 to 12 or more. The chambers are inflated sequentially and have a fixed pressure in each compartment. They can either have the same pressure in each compartment or a pressure gradient, but they do not include the ability to adjust the pressure manually in individual compartments. Single- or multi-chamber programmable pumps are similar to the pumps described above except that it is possible to adjust the pressure manually in the individual compartments and/or the length and frequency of the inflation cycles. In some situations, including patients with scarring, contractures, or highly sensitive skin, programmable pumps are generally considered the preferred option. PCPs are also proposed to supplement standard care for patients with venous ulcers.

## Summary

Pneumatic compression pumps are proposed as a treatment for patients with lymphedema who have failed conservative measures. They are also proposed to supplement standard care for patients with venous ulcers. A variety of pumps are available; they can be single chamber (nonsegmented) or multichamber (segmented) and have varying designs and complexity.

#### **Summary of Evidence**

For individuals who have lymphedema who failed to respond to conservative therapy who receive pneumatic compression pumps applied to limb only, the evidence includes randomized controlled trials (RCTs) and systematic reviews primarily focusing on upper-limb lymphedema secondary to breast cancer. Relevant outcomes are symptoms, change in disease status, functional outcomes, and quality of life. Most of these RCTs were deemed moderate-to-high quality by the Agency for Healthcare Research and Quality, and about half reported significant improvements with the use of pumps compared to conservative care. Recent meta-analyses indicate that incorporating intermittent pneumatic compression (IPC) with complete decongestive therapy can further enhance lymphedema management within four weeks post-treatment. Similar findings are observed when IPC is combined with decongestive lymphatic therapy compared to decongestive lymphatic therapy alone in managing upper limb lymphedema after breast cancer surgery, with the former combined regimen showing improved external rotation joint mobility. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have lymphedema who failed to respond to conservative therapy who receive pneumatic compression pumps applied to limb and chest and/or trunk, the evidence includes two RCTs of the Flexitouch system (Tactile Medical), published in 2012, comparing treatment with and without truncal involvement. Relevant outcomes are symptoms, change in disease status, functional outcomes, and quality of life. In one RCT, two (of 4) key outcomes were significantly better with truncal involvement than without. This trial was limited by small sample size, failure to adjust statistically for multiple primary outcomes, and use of intermediate outcomes (eg, amount of fluid removed) rather than health outcomes (eg, functional status, quality of life). The second RCT did not find statistically significant differences between groups for any of the efficacy outcomes. The available evidence does not demonstrate that pumps treating the trunk or chest provide incremental improvement beyond that provided by pumps treating the affected limb only. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have lymphedema who failed to respond to conservative therapy who receive pneumatic compression pumps applied to the head and neck, the evidence includes one RCT and a systematic review to assess the use of pneumatic compression treatment for head and neck lymphedema. Relevant outcomes are symptoms, change in disease status, functional outcomes, and quality of life. The RCT, comparing treatment with a pneumatic compression pump along with lymphedema self-management compared to self-management alone, examined the feasibility, adherence, and safety of the Flexitouch advanced pneumatic compression device (APCD) by Tactile Medical. The findings showed some improvements in patient-reported outcomes and swelling, although adherence was low, with only one patient using the device twice daily as prescribed. The systematic review also suggested benefits from using the APCD, and it was considered safe and feasible according to the observational studies that reported adverse events. Most studies included participants who had completed or were concurrently undergoing complete decongestive therapy. Out of the 5 observational studies included in the systematic review, four (80%) had potential conflicts of interest related to the funding source. The only study not sponsored by the industry highlighted difficulties in obtaining the APCD, with fewer than half of the patients receiving the device as prescribed. Further research with larger sample sizes and comparisons against the criterion standard of complete decongestive therapy is necessary to establish the efficacy of this treatment approach. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have venous ulcers who receive pneumatic compression pumps, the evidence includes RCTs and one systematic review. Relevant outcomes are symptoms, change in disease status, morbid events, and quality of life. A meta-analysis of 3 trials found significantly higher healing rates with lymphedema pumps plus continuous compression than with continuous compression alone; however, 2 of the 3 trials were judged to be at high risk of bias. A 2020 RCT compared lymphedema pumps with continuous compression did not find significant between-group differences in healing rates or durability of pain relief. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

## **Policy History**

Date	Action
3/2025	Annual policy review. Policy updated with literature review through November 25,
	2024; references added. Policy statements unchanged.
5/2024	Annual policy review. Description, summary, and references updated. Policy
	statements unchanged.
5/2023	Annual policy review. Policy clarified. Investigational policy statement regarding the use of lymphedema pumps to treat the trunk or chest in patients with lymphedema was clarified to apply regardless of the involvement of the upper and/or lower limbs; intent unchanged. Coding information clarified.
4/2022	Annual policy review. Policy statements unchanged.
1/2022	Annual policy review. New investigational indications described for use of lymphedema pumps applied to the head and neck to treat lymphedema. Effective 1/1/2022. Clarified coding information.

10/2021	Coding information clarified.
4/2021	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
1/2021	Medicare information removed. See MP #132 Medicare Advantage Management for local coverage determination and national coverage determination reference.
5/2020	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
4/2019	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
4/2017	Annual policy review. New references added.
12/2015	National Coverage Determination (NCD) for Pneumatic Compression Devices (280.6) added.
11/2015	Annual policy review. New references added.
4/2014	Medicare Local Coverage Determination L11503 added.
3/2014	Annual policy review. "Applied to the limb" added to the first 3 policy statements for clarification. In the statement on venous ulcers, "lymphedema pumps" changed to "pneumatic compression pumps." Effective 3/1/2014.
6/2013	Annual policy review. New investigational indications described. Effective 6/1/2013.
6/1/2012	New policy describing ongoing coverage and non-coverage.

## Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

Medical Policy Terms of Use

Managed Care Guidelines

Indemnity/PPO Guidelines

Clinical Exception Process

Medical Technology Assessment Guidelines

### References

- 1. DiSipio T, Rye S, Newman B, et al. Incidence of unilateral arm lymphoedema after breast cancer: a systematic review and meta-analysis. Lancet Oncol. May 2013; 14(6): 500-15. PMID 23540561
- 2. International Society of Lymphology Executive Committee. The Diagnosis and Treatment of Peripheral Lymphedema: 2023 Consensus Document of the International Society of Lymphology. 2023; https://journals.librarypublishing.arizona.edu/lymph/article/id/6372/. Accessed November 25, 2024.
- 3. Oremus M, Walker K, Dayes I, et al. Technology Assessment: Diagnosis and Treatment of Secondary Lymphedema (Project ID: LYMT0908). Rockville, MD: Agency for Healthcare Research and Quality; 2010.
- 4. Oremus M, Dayes I, Walker K, et al. Systematic review: conservative treatments for secondary lymphedema. BMC Cancer. Jan 04 2012; 12: 6. PMID 22216837
- 5. Shao Y, Qi K, Zhou QH, et al. Intermittent pneumatic compression pump for breast cancer-related lymphedema: a systematic review and meta-analysis of randomized controlled trials. Oncol Res Treat. 2014; 37(4): 170-4. PMID 24732640
- 6. Hou S, Li Y, Lu W, et al. Efficacy of intermittent pneumatic compression on breast cancer-related upper limb lymphedema: a systematic review and meta-analysis in clinical studies. Gland Surg. Aug 31 2024; 13(8): 1358-1369. PMID 39282029
- 7. Yao M, Peng P, Ding X, et al. Comparison of Intermittent Pneumatic Compression Pump as Adjunct to Decongestive Lymphatic Therapy against Decongestive Therapy Alone for Upper Limb Lymphedema after Breast Cancer Surgery: A Systematic Review and Meta-Analysis. Breast Care (Basel). Jun 2024; 19(3): 155-164. PMID 38894955
- 8. Fife CE, Davey S, Maus EA, et al. A randomized controlled trial comparing two types of pneumatic compression for breast cancer-related lymphedema treatment in the home. Support Care Cancer. Dec 2012; 20(12): 3279-86. PMID 22549506
- 9. Ridner SH, Murphy B, Deng J, et al. A randomized clinical trial comparing advanced pneumatic truncal, chest, and arm treatment to arm treatment only in self-care of arm lymphedema. Breast Cancer Res Treat. Jan 2012; 131(1): 147-58. PMID 21960113

- Cheng JT, Leite VF, Tennison JM, et al. Rehabilitation Interventions for Head and Neck Cancer-Associated Lymphedema: A Systematic Review. JAMA Otolaryngol Head Neck Surg. Aug 01 2023; 149(8): 743-753. PMID 37382963
- 11. Shires CB, Harris P, Dewan K. Feasibility of machine-delivered sequential massage for the management of lymphedema in the head and neck cancer survivor. Laryngoscope Investig Otolaryngol. Jun 2022; 7(3): 774-778. PMID 35734055
- 12. Gutiérrez C, Mayrovitz HN, Naqvi SHS, et al. Longitudinal effects of a novel advanced pneumatic compression device on patient-reported outcomes in the management of cancer-related head and neck lymphedema: A preliminary report. Head Neck. Aug 2020; 42(8): 1791-1799. PMID 32187788
- 13. Ridner SH, Dietrich MS, Deng J, et al. Advanced pneumatic compression for treatment of lymphedema of the head and neck: a randomized wait-list controlled trial. Support Care Cancer. Feb 2021; 29(2): 795-803. PMID 32488435
- 14. Nelson EA, Hillman A, Thomas K. Intermittent pneumatic compression for treating venous leg ulcers. Cochrane Database Syst Rev. May 12 2014; 2014(5): CD001899. PMID 24820100
- 15. Dolibog P, Franek A, Taradaj J, et al. A comparative clinical study on five types of compression therapy in patients with venous leg ulcers. Int J Med Sci. 2014; 11(1): 34-43. PMID 24396284
- 16. Dolibog P, Franek A, Taradaj J, et al. A randomized, controlled clinical pilot study comparing three types of compression therapy to treat venous leg ulcers in patients with superficial and/or segmental deep venous reflux. Ostomy Wound Manage. Aug 2013; 59(8): 22-30. PMID 23934375
- 17. Alvarez OM, Markowitz L, Parker R, et al. Faster Healing and a Lower Rate of Recurrence of Venous Ulcers Treated With Intermittent Pneumatic Compression: Results of a Randomized Controlled Trial. Eplasty. 2020; 20: e6. PMID 32636985
- 18. Bonkemeyer Millan S, Gan R, Townsend PE. Venous Ulcers: Diagnosis and Treatment. Am Fam Physician. Sep 01 2019; 100(5): 298-305. PMID 31478635
- 19. Lurie F, Malgor RD, Carman T, et al. The American Venous Forum, American Vein and Lymphatic Society and the Society for Vascular Medicine expert opinion consensus on lymphedema diagnosis and treatment. Phlebology. May 2022; 37(4): 252-266. PMID 35258350
- 20. Lee BB, Andrade M, Antignani PL, et al. Diagnosis and treatment of primary lymphedema. Consensus document of the International Union of Phlebology (IUP)-2013. Int Angiol. Dec 2013; 32(6): 541-74. PMID 24212289
- 21. O'Donnell TF, Passman MA, Marston WA, et al. Management of venous leg ulcers: clinical practice guidelines of the Society for Vascular Surgery ® and the American Venous Forum. J Vasc Surg. Aug 2014; 60(2 Suppl): 3S-59S. PMID 24974070
- 22. Marston W, Tang J, Kirsner RS, et al. Wound Healing Society 2015 update on guidelines for venous ulcers. Wound Repair Regen. 2016; 24(1): 136-44. PMID 26663616
- 23. Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD) for Pneumatic Compression Devices (280.6). 2002; https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=225. Accessed January 30, 2024.