BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

FEP 1.01.18 Pneumatic Compression Pumps for Treatment of Lymphedema and Venous Ulcers

Effective Policy Date: July 1, 2023

Original Policy Date: December 2011

Related Policies:

None

Pneumatic Compression Pumps for Treatment of Lymphedema and Venous Ulcers

Description

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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.

OBJECTIVE

The objective of this evidence review is to evaluate whether the use of pneumatic compression pumps improves net health outcomes in patients with lymphedema or venous ulcers.

POLICY STATEMENT

Single-compartment or multichamber *nonprogrammable* lymphedema pumps applied to the limb may be considered **medically necessary** 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 2 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**.

POLICY GUIDELINES

None

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

Compliance may be an issue with lymphedema pumps, due either to lack of effectiveness or to patient dissatisfaction with the pumping process itself. Therefore, Plans may consider requiring that a pump be rented initially for a period of 1 to 2 months before purchase to confirm compliance.

FDA REGULATORY STATUS

Several pneumatic compression pumps, indicated for the primary or adjunctive treatment of primary or secondary (eg, postmastectomy) lymphedema, have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. Examples of devices with these indications intended for home or clinic/hospital use include the Compression Pump, Model GS-128 (MedMark Technologies); the Sequential Circulator (Bio Compression Systems); the Lympha-Press and Lympha-Press Optimal (Mego Afek); the Flexitouch and Flexitouch Plus systems (Tactile Medical, formerly Tactile Systems Technology); the Powerpress Unit Sequential Circulator (Neomedic); and the EzLymph and EzLymph M (EEZCare Medical).

Several pneumatic compression devices have been cleared by the FDA for treatment of venous stasis ulcers. Examples include the Model GS-128, Lympha-Press, Flexitouch, Flexitouch Plus, and Powerpress Unit (listed above) as well as NanoTherm™ (ThermoTek), CTU676 devices (Compression Technologies), and Recovery+™ (Pulsar Scientific).

FDA product code: JOW.

RATIONALE

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 of RCTs. Relevant outcomes are symptoms, change in disease status, functional outcomes, and quality of life. Most RCTs were rated as moderate-to-high quality by an Agency for Healthcare Research and Quality review, and about half reported significant improvements with pumps compared with conservative care. 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 the trunk and/or chest as well as a limb, the evidence includes 2 RCTs comparing treatment with and without truncal involvement. Relevant outcomes are symptoms, change in disease status, functional outcomes, and quality of life. In 1 RCT, 2 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 other 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 1 RCT comparing treatment with a pneumatic compression pump along with lymphedema self-management compared to self-management alone. Relevant outcomes are symptoms, change in disease status, functional outcomes, and quality of life. The trial evaluated the feasibility, adherence, and safety of the intervention. Results demonstrated some improvements in patient-reported outcomes and swelling, but adherence was low, with only 1 patient using the pneumatic compression treatment device twice daily as prescribed. Further investigation in larger studies and those that compare against the gold standard comparator of complete decongestive therapy are needed to determine 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 a systematic review of RCTs. 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. Moreover, the 2 trials comparing lymphedema pumps with continuous compression did not find significant between-group differences in healing rates. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Venous Forum et al

In 2022, the American Venous Forum, American Vein and Lymphatic Society, and the Society for Vascular Medicine published an expert opinion consensus statement on lymphedema diagnosis and treatment.[17,] The following statements were issued regarding use of pneumatic compression:

- "Sequential pneumatic compression should be recommended for lymphedema patients." (92% panel agreement; 32% strongly agree)
- "Sequential pneumatic compression should be used for treatment of early stages of lymphedema." (62% panel agreement - consensus not reached; 38% panel disagreement; 2% strongly disagreed)

International Union of Phlebology

A 2013 consensus statement from the International Union of Phlebology indicated that primary lymphedema could be managed effectively by a sequenced and targeted management program based on a combination of decongestive lymphatic therapy and compression therapy.[18,] Treatment should include compression garments, self-massage, skin care, exercises, and, if desired, pneumatic compression therapy applied in the home.

Society for Vascular Surgery and American Venous Forum

The 2014 joint guidelines from the Society for Vascular Surgery and the American Venous Forum on the management of venous ulcers included the following statement on pneumatic compression[19,]:

"We suggest use of intermittent pneumatic compression when other compression options are not available, cannot be used, or have failed to aid in venous leg ulcer healing after prolonged compression therapy. [GRADE - 2; LEVEL OF EVIDENCE - C]"

Wound Healing Society

A 2015 guideline from the Wound Healing Society states that for patients with venous ulcers, intermittent pneumatic pressure can be used with or without compression dressings and can provide another option in patients who cannot or will not use an adequate compression dressing system.[20,]

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

A 2002 national coverage determination for pneumatic compression devices by the Centers for Medicare & Medicaid Services has stated the following[21,]:

A. "Lymphedema

...Pneumatic compression devices are covered in the home setting for the treatment of lymphedema if the patient has undergone a four-week trial of conservative therapy and the treating physician determines that there has been no significant improvement or if significant symptoms remain after the trial. The trial of conservative therapy must include use of an appropriate compression bandage system or compression garment, exercise, and elevation of the limb. The garment may be prefabricated or custom-fabricated but must provide adequate graduated compression."

B. "Chronic Venous Insufficiency With Venous Stasis Ulcers

Chronic venous insufficiency (CVI) of the lower extremities is a condition caused by abnormalities of the venous wall and valves, leading to obstruction or reflux of blood flow in the veins. Signs of CVI include hyperpigmentation, stasis dermatitis, chronic edema, and venous ulcers."

"Pneumatic compression devices are covered in the home setting for the treatment of CVI of the lower extremities only if the patient has one or more venous stasis ulcer(s) which have failed to heal after a 6 month trial of conservative therapy directed by the treating physician. The trial of conservative therapy must include a compression bandage system or compression garment, appropriate dressings for the wound, exercise, and elevation of the limb."

REFERENCES

1. 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.
2. Oremus M, Dayes I, Walker K, et al. Systematic review: conservative treatments for secondary lymphedema. BMC Cancer. Jan 04 2012; 12: 6. PMID 22216837
3. 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
4. Uzkeser H, Karatay S, Erdemci B, et al. Efficacy of manual lymphatic drainage and intermittent pneumatic compression pump use in the treatment of lymphedema after mastectomy: a randomized controlled trial. Breast Cancer. May 2015; 22(3): 300-7. PMID 23925581
5. Tastaban E, Soyder A, Aydin E, et al. Role of intermittent pneumatic compression in the treatment of breast cancer-related lymphoedema: a randomized controlled trial. Clin Rehabil. Feb 2020; 34(2): 220-228. PMID 31795748
6. 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
7. 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
8. Gutierrez C, Karni RJ, Naqvi S, et al. Head and Neck Lymphedema: Treatment Response to Single and Multiple Sessions of Advanced Pneumatic Compression Therapy. Otolaryngol Head Neck Surg. Apr 2019; 160(4): 622-626. PMID 30694720

9. Gutirrez 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
10. Mayrovitz HN, Ryan S, Hartman JM. Usability of advanced pneumatic compression to treat cancer-related head and neck lymphedema: A feasibility study. Head Neck. Jan 2018; 40(1): 137-143. PMID 29131439
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. 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
13. Nelson EA, Hillman A, Thomas K. Intermittent pneumatic compression for treating venous leg ulcers. Cochrane Database Syst Rev. May 12 2014; (5): CD001899. PMID 24820100
14. 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
15. 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
16. 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
17. 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
18. 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
19. 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
20. 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
21. 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, 2023.

POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
December 2011	New policy	
December 2012	Replace policy	Policy title changed to add "and Venous Ulcers,, Deleted statement on two-phase pumps, statement added that use of lymphedema pumps to treat the trunk or chest in patients with lymphedema limited to upper and/or lower limbs is considered investigational. Use of lymphedema pumps to treat venous ulcers is considered investigational. References updated.
December 2013	Replace policy	Policy reviewed with literature. "Applied to the limb, added to the first 3 policy statements for clarification. References 7, and 11 added; other references renumbered or removed.
December 2014	Replace policy	Policy reviewed with literature search, no change to policy statements. References 4, 11-13 added.
December 2015	Replace policy	Policy updated with literature review through August 10, 2015; references 5 and 11 added. Policy statements unchanged.
March 2017	Replace policy	Policy updated with literature review through January 25, 2017; reference 11 added. Policy statements unchanged.
June 2018	Replace policy	Policy updated with literature review through January 8, 2018; no references added. Policy statements unchanged except "not medically necessary, corrected to "investigational, due to FDA 510k approval in the following statements: lymphedema pumps to treat the trunk or chest in patients with lymphedema limited to the upper and/or lower limbs and the use of lymphedema pumps to treat venous ulcers is considered investigational.
June 2019	Replace policy	Policy updated with literature review through January 6, 2019; no references added. Policy statements unchanged.
June 2020	Replace policy	Policy updated with literature review through January 13, 2020; no references added. Policy statements unchanged.
June 2021	Replace policy	Policy updated with literature review through January 22, 2021; references added and updated. Policy statements unchanged.
December 2021	Replace policy	Policy updated with literature review through June 17, 2021; references added. Policy statement added that use of lymphedema pumps applied to the head and neck to treat lymphedema is considered investigational.
June 2022	Replace policy	Policy updated with literature review through January 27, 2022; no references added. Policy statements unchanged.
June 2023	Replace policy	Policy updated with literature review through January 30, 2023; references added. 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.