BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

FEP 1.01.18 Compression Pumps for Treatment of Lymphedema and Venous Ulcers

Annual Effective Policy Date: April 1, 2026

Original Policy Date: December 2011

Related Policies:

None

Compression Pumps for Treatment of Lymphedema and Venous Ulcers

Description

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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. Non-pneumatic, programmable, wearable devices, are also available.

OBJECTIVE

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

POLICY STATEMENT

Single-compartment or multichamber *nonprogrammable*pneumatic compression pumps applied to the limbs 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*pneumatic compression pumps applied to the limbs may be considered **medically necessary** for the treatment of lymphedema when:

1. The individual is otherwise eligible for nonprogrammable pneumatic pumps; and
2. There is documentation that the individual has unique characteristics (eg, significant scarring, recent surgery) that prevent satisfactory pneumatic compression with single-compartment or multichamber nonprogrammable compression pumps; or
3. The individual has had an inadequate response to an initial course of treatment with a nonprogrammable pneumatic compression pump applied to the limbs (see Policy Guidelines).

Single-compartment or multichamber *nonprogrammable* pneumatic compression pumps applied to the chest or trunk in addition to the limbs may be considered **medically necessary** for the treatment of lymphedema that has failed to adequately respond to both conservative measures and nonprogrammable pneumatic compression to the limbs only.

Single-compartment or multichamber *programmable* pneumatic compression pumps applied to the chest or trunk in addition to the limbs may be considered **medically necessary** for the treatment of lymphedema when:

1. The individual is otherwise eligible for nonprogrammable pneumatic pumps applied to the chest or trunk in addition to the limbs; and
2. There is documentation that the individual has unique characteristics (eg, significant scarring, recent surgery) that prevent satisfactory pneumatic compression with single-compartment or multichamber nonprogrammable compression pumps; or
3. The individual has had an inadequate response to an initial course of treatment with a nonprogrammable pneumatic compression pump applied to the chest or trunk in addition to the limbs (see Policy Guidelines).

Single-compartment or multichamber compression pumps are considered **investigational** in all situations other than those specified above, including when applied to the head or neck.

Programmable, wearable non-pneumatic compression pumps (eg, Koya Dayspring) applied to the limbs may be considered **medically necessary** for the treatment of lymphedema when:

1. The individual is otherwise eligible for a programmable pneumatic compression pump; and
2. There is documentation that the individual has lifestyle considerations or mobility requirements where treatment compliance with a traditional programmable, pneumatic compression system is expected to be insufficient.

Programmable, wearable non-pneumatic compression pumps are considered **investigational** in all other situations not specified above.

The use of pneumatic or non-pneumatic compression pumps to treat venous ulcers is considered **investigational**.

POLICY GUIDELINES

Medically necessary positions for treatment of lymphedema at body sites other than the limbs are based on clinical input. Additional details from clinical input are detailed in the Appendix. Individuals who fail to respond to an initial trial of a nonprogrammable pump may benefit from programmable pumps with pulsatile features that can be tailored to address individual lymphatic flow dysfunction patterns. Clinical input supports the use of non-pneumatic compression pumps on the basis of the evidence and clinical experience, emphasizing the importance of compliance with treatment. Clinical input was mixed on the use of compression pumps for the treatment of head and neck lymphedema. Ongoing evidence generation in head and neck cancer populations is expected to elucidate clinical benefit.

BENEFIT APPLICATION

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

State or federal mandates (eg, Federal Employee Program) may dictate that certain U.S. Food and Drug Administration approved devices, drugs, or biologics may not be considered investigational, and thus these devices may be assessed only by their medical necessity.

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).

In 2024, the FDA cleared the Dayspring (Koya Medical, Inc.) non-pneumatic, wearable limb compression system. The device is intended for use in a clinic or home setting by medical professionals and patients who are under medical supervision to increase lymphatic flow in the treatment of various conditions, including lymphedema and venous insufficiency.

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 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 lymphedema who failed to respond to conservative therapy who receive non-pneumatic compression pumps applied to limb only, the evidence includes randomized crossover trials. Relevant outcomes are symptoms, change in disease status, functional outcomes, and quality of life. Randomized crossover trials have compared use of non-pneumatic, wearable, compression devices to traditional, pneumatic compression devices in both upper and lower extremity lymphedema. These studies have consistently supported noninferior reductions in limb edema volume, higher rates of patient compliance, and improvements on quality of life assessments with use in the short-term (28 to 90 days). Additionally, clinical input supports the use of non-pneumatic, wearable compression devices on the basis of this research and clinical experience. These devices may be particularly suitable for individuals who have an active lifestyle or mobility requirements where traditional pneumatic compression devices are expected to impede sufficient compliance with treatment. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have venous ulcers who receive pneumatic or non-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. No prospective, comparative studies assessing the use of non-pneumatic compression devices for the treatment of venous ulcers were identified. 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 Academy of Family Physicians

In 2019, the American Academy of Family Physicians published recommendations for diagnosis and treatment of venous ulcers.[20,] The following statements were issued regarding use of intermittent pneumatic compression.

- "Intermittent pneumatic compression may be considered when there is generalized, refractory edema from venous insufficiency; lymphatic obstruction; and significant ulceration of the lower extremity. Although intermittent pneumatic compression is more effective than no compression, its effectiveness compared with other forms of compression is unclear. Intermittent pneumatic compression may improve ulcer healing when added to layered compression."

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.[21,] 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.[22,] Treatment should include compression garments, self-massage, skin care, exercises, and, if desired, pneumatic compression therapy applied in the home.

National Comprehensive Cancer Network

The National Comprehensive Cancer Network (NCCN) guidelines on survivorship (v.2.2025) recommend that survivors at risk for lymphedema be referred to a certified lymphedema specialist for consideration of the following compression treatments: "fit for compression garments, review use of garments, pneumatic compression for ongoing home management, and review use of multilayered bandage wrapping."[23,]

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[24,]:

"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.[25,]

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[26,]:

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.”

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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.
June 2024	Replace policy	Policy updated with literature review through January 30, 2024; reference added. Policy statements unchanged.
March 2025	Replace policy	Policy updated with literature review through November 25, 2024; references added. The second PICO (pneumatic compression pumps for lymphedema unresponsive to conservative therapy) has been refined to more accurately frame the intervention under review. Policy statements unchanged.
September 2025	Replace policy	Policy updated with literature review through June 16, 2025; references added. Policy statements for use of pneumatic compression pumps for lymphedema were revised to medically necessary chest and trunk use with criteria. Evidence review and medically necessary policy statement added for non-pneumatic compression pumps with criteria. Use of compression pumps for head and neck lymphedema was maintained as investigational in light of ongoing evidence generation.

Date	Action	Description
March 2026	Replace policy €“ coding update	Removed Pneumatic compression device range and added individual codes. Add new codes E0658 and E0659