

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

**Effective Date:** July 15, 2018

**Related Policies:**

2.01.79 Noncontact Ultrasound Treatment for Wounds  
2.01.82 Bioimpedance Devices for Detection and Management of Lymphedema

## Pneumatic Compression Pumps for Treatment of Lymphedema and Venous Ulcers

### Description

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.

### 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 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™ system (Tactile Medical, formerly Tactile Systems Technology); and the Powerpress Unit Sequential Circulator (Neomedic).

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

Food and Drug Administration product code: JOW.

### 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

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

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 limited to the upper and/or lower limbs is considered **investigational**.

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

### BENEFIT APPLICATION

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

### 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 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 a meaningful 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 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 the effects of the technology on health outcomes.

For individuals who have venous ulcers who receive pneumatic compression pumps, the evidence includes several 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 the effects of the technology on health outcomes.

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### SUPPLEMENTAL INFORMATION

#### Practice Guidelines and Position Statements

##### 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<sup>11</sup>:

“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]”

##### 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.<sup>12</sup> Treatment should include compression garments, self-massage, skin care, exercises, and, if desired, pneumatic compression therapy applied in the home.

#### 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<sup>13</sup>:

##### 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. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Special Report: Comparative Efficacy of Different Types of Pneumatic Compression Pumps for the Treatment of Lymphedema. *TEC Assessments* 1998;Volume 13:Tab 2.
2. 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.

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3. Oremus M, Dayes I, Walker K, et al. Systematic review: conservative treatments for secondary lymphedema. *BMC Cancer*. Jan 4 2012;12:6. PMID 22216837
4. 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*. Apr 2014;37(4):170-174. PMID 24732640
5. 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):300-307. PMID 23925581
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*. May 2 2012;20(12):3279-3286. 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):147-158. PMID 21960113
8. Nelson EA, Hillman A, Thomas K. Intermittent pneumatic compression for treating venous leg ulcers. *Cochrane Database Syst Rev*. May 12 2014;5(5):CD001899. PMID 24820100
9. 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*. Jan 2014;11(1):34-43. PMID 24396284
10. 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
11. O'Donnell TF, Jr., Passman MA, Marston WA, et al. Management of venous leg ulcers: clinical practice guidelines of the Society for Vascular Surgery (R) and the American Venous Forum. *J Vasc Surg*. Aug 2014;60(2 Suppl):3s-59s. PMID 24974070
12. 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):541-574. PMID 24212289
13. Centers for Medicare and Medicaid Services. National Coverage Determination (NCD) for Pneumatic Compression Devices (280.6). 2002; <http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=225&ncdver=1&NCAId=50&NcaName=Lymphedema+Pumps&CoverageSelection=National&Keyword=lymphedema+pumps&KeywordLookup=Title&KeywordSearchType=And&clickon=search&bc=gAA AABAAEAAA&>. Accessed February 6, 2018.

### POLICY HISTORY

Date	Action	Description
December 2011	New Policy	
December 2012	Update 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	Update 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	Update Policy	Policy reviewed with literature search, no change to policy statements. References 4, 11-13 added.
December 2015	Update Policy	Policy updated with literature review through August 10, 2015; references 5 and 11 added. Policy statements unchanged.
March 2017	Update Policy	Policy updated with literature review through January 25, 2017; reference 11 added. Policy statements unchanged.
June 2018	Update 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

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the use of lymphedema pumps to treat venous ulcers is considered investigational.