



Title: Pneumatic Compression Pumps for Treatment of Lymphedema and Venous Ulcers (for Home Use)

See Also: Postsurgical Home Use of Limb Compression Devices for Venous

Thromboembolism Prophylaxis

Professional Institutional

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Populations	Interventions	Comparators	Outcomes
Individuals: • With lymphedema who failed to respond to conservative therapy	Interventions of interest are: • Pneumatic compression pumps applied to limb only	Comparators of interest are: Conservative therapy (eg, exercise, compression therapy, elevation) Manual lymphatic drainage Complete decongestive therapy	Relevant outcomes include:

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Individuals: • With lymphedema who failed to respond to conservative therapy	Interventions of interest are: • Pneumatic compression pumps applied to trunk and/or chest as well as limb	Comparators of interest are: Conservative therapy (eg, exercise, compression therapy, elevation) Manual lymphatic drainage Complete decongestive therapy Pneumatic compression pump applied to limb only	Relevant outcomes include:
Individuals: • With venous ulcers	Interventions of interest are: • Pneumatic compression pumps	Comparators of interest are: • Medication therapy • Continuous compression (eg, stockings, bandages)	Relevant outcomes include:

DESCRIPTION

Pneumatic compression pumps are proposed as a treatment option 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 design and complexity.

Objective

The objective of this evidence review is to evaluate the impact of pneumatic compression pumps on health outcomes in patients with lymphedema or venous ulcers.

Background

LYMPHEDEMA AND VENOUS ULCERS

Lymphedema is an abnormal accumulation of lymph fluid in subcutaneous tissues or body cavities resulting from obstruction of lymphatic flow. Lymphedema can be subdivided into primary and secondary categories. Primary lymphedema has no recognizable etiology, while secondary lymphedema is related to a variety of causes including surgical removal of lymph nodes, postradiation fibrosis, scarring of lymphatic channels, or congenital anomalies. Conservative therapy is the initial treatment for lymphedema and includes general measures such as limb elevation and exercise as well as use of compression garments and compression bandaging. Another conservative treatment is manual lymphatic drainage (MLD), a massage-like technique used to move edema fluid from distal to proximal areas. MLD is performed by physical therapists with special training. Complete decongestive therapy is a comprehensive program that

includes MLD in conjunction with a range of other conservative treatments. Rarely, surgery is used as a treatment option.

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 are proposed as a treatment for venous ulcers, especially for patients who do not respond to these standard therapies.

Treatment

Pneumatic compression pumps consist of pneumatic cuffs that are connected to a pump. They 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 pneumatic compression pumps are available for treating lymphedema, with varying materials, designs, degrees of pressure, and complexity. There are 3 primary types of pumps as follows:

- 1. Single-chamber nonprogrammable pumps: These are the simplest pumps, consisting of a single chamber that is inflated at 1 time to apply uniform pressure.
- 2. Multichamber nonprogrammable pumps: These 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 manually adjust the pressure in individual compartments.
- 3. Single- or multichamber programmable pumps: These 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 to be the preferred option.

Pneumatic compression pumps may be used in lymphedema clinics, purchased, or rented for home use; this policy addresses the home use of these pumps.

Regulatory Status

Several pneumatic compression pumps, indicated for 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™ 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 NanoThermTM (ThermoTek), CTU676 devices (Compression Technologies), and Recovery+TM (Pulsar Scientific). FDA product code: JOW.

POLICY

- A. 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.
- B. 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 that prevent satisfactory pneumatic compression with single-compartment or multichamber nonprogrammable lymphedema pumps (eg, significant scarring).
- C. The use of lymphedema pumps is considered **medically necessary** for the treatment of leg venous stasis ulcers which have failed to heal after 6 months of conservative therapy (compression bandages or garments, appropriate dressings, exercise and leg elevation).
- D. Single-compartment or multichamber lymphedema pumps applied to the limb are considered **experimental / investigational** in all situations other than those specified above.
- E. 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 **experimental / investigational**.

RATIONALE

The evidence review was updated with searches of the MEDLINE database. The most recent literature update was performed through January 8, 2018. A 1998 TEC Assessment, which informed the original review, concluded that pneumatic compression devices are efficacious to some degree but that it was not possible to estimate precisely the magnitude of this effect.¹

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of

life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

In the case of lymphedema, clinically relevant outcomes include symptoms, functional outcomes (eg, range of motion), and quality of life (eg, ability to conduct activities of daily living). Limb volume and limb circumference are also commonly reported outcomes.

LYMPHEDEMA

Pneumatic Compression Pumps Applied to the Limb Only

In 2010, the Agency for Healthcare Research and Quality published a technology assessment on the diagnosis and treatment of secondary lymphedema that included discussion of intermittent pneumatic compression (IPC) pumps. Reviewers (Oremus et al) identified 12 studies focusing on treatment of lymphedema with IPC pumps. Seven studies were moderate- to high-quality RCTs, three were low-quality RCTs, and two were observational studies. There was a high degree of heterogeneity between studies regarding types of lymphedema pumps used, comparison interventions (eg compression bandages, laser, massage), and intervention protocols. Statistically, IPC was significantly better than the comparison treatment in 4 studies, worse in 1 study (vs laser), and no different in 5 studies. Most studies assessed change in arm volume or arm circumference.

Oremus et al (2012) published an updated systematic review of conservative treatments for secondary lymphedema.³ They identified 36 English-language studies on a variety of treatments, 30 of which were RCTs and 6 were observational studies. Six RCTs evaluated IPC. Study findings were not pooled. According to reviewers, 2 RCTs found that IPC was superior to decongestive therapy or self-massage, but 3 other RCTs failed to show that IPC was superior to another conservative treatment.

A systematic review by Shao et al (2014) addressed pneumatic compression pumps for treatment of breast cancer—related lymphedema.⁴ They identified 7 RCTs; most compared decongestive lymphatic therapy alone with decongestive lymphatic therapy plus lymphedema pump therapy. A pooled analysis of data from the 3 RCTs suitable for meta-analysis did not find a statistically significant difference in the percentage of volume reduction with and without use of lymphedema pumps (mean difference, 4.51; 95% confidence interval [CI], -7.01 to 16.03).

A 2015 RCT from Japan included 31 women with unilateral upper-extremity lymphedema after mastectomy. To be eligible; patients had to have experienced at least a 10% increased volume in the affected limb or more than 2 cm difference in circumference between limbs. Patients were randomized to decongestive physical therapy alone (n=15) or decongestive physical therapy plus IPC (n=16). Pneumatic compression was delivered using a pump marketed in Japan (Mark II Plus) and was applied for 45 minutes after manual lymphatic drainage. Both groups underwent 5 weekly sessions for 3 weeks (a total of 15 sessions). At the immediate posttreatment and 1-month follow-up points, there were no statistically significant differences in groups for any outcomes, including arm circumference and dermal thickness of the arm and forearm.

Section Summary: Pneumatic Compression Pumps Applied to the Limb Only
A number of RCTs have been published. Most published 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.

Pneumatic Compression Pumps Applied to the Trunk and/or Chest as Well as Limb Due to U.S. Food and Drug Administration approval of lymphedema pumps that treat the truncal area as well as the affected limb, researchers have assessed truncal clearance as part of lymphedema treatment. This literature review focuses on RCTs comparing pneumatic compression for patients who had lymphedema with and without treatment of the trunk or chest. Two RCTs were identified; both were industry-sponsored, published in 2012, and included women with breast cancer who had documented postsurgical upper-extremity lymphedema.

Fife et al (2012) compared treatment using the Flexitouch system with treatment using the Bio Compression Systems Sequential Circulator.⁶ Participants had to have at least 5% edema volume in the upper-extremity at trial enrollment. A total of 36 women from 3 centers were included, 18 in each group. Participants used the devices for home treatment for 1 hour daily for 12 weeks in addition to standard care (eg, wearing compression garments). The Bio Compression Systems device used an arm garment only, whereas the Flexitouch device used 3 garments and treated the full upper-extremity (arm, chest, truncal quadrant). Outcome assessment was conducted by experienced lymphedema therapists; blinding was not reported. Edema outcomes were available for all participants and local tissue water analysis for 28 (78%) of 36 participants. The authors reported on 4 key outcomes at 12 weeks. There was statistically significant week by group interactions in two of these outcomes (edema volume reported as a percent, p=0.047; tissue water, p=0.049), both favoring treatment with the Flexitouch system. Groups did not differ significantly on the other 2 outcomes (affected arm volume at 12 weeks, p=0.141; edema volume reported in milliliters, p=0.050). Moreover, had there been statistical adjustments for multiple comparisons (ie, if p<0.0125 had been used instead of p<0.05 to adjust for the 4 comparisons), none of the differences would have been statistically significant. The trial was limited by its small sample size, missing data on the local tissue water outcome, and unclear blinding of outcome assessment. Also, the volume of tissue reported (a primary outcome) is of less clinical significance than outcomes such as symptoms or functional status.

Ridner et al (2012) compared treatment using the Flexitouch system for an arm only vs arm, chest, and trunk therapy in women with breast cancer who had arm lymphedema.⁷ To be eligible, patients had to have a 2-cm difference in girth on the affected arm compared with the unaffected arm. Forty-seven patients were enrolled; 5 patients withdrew during the study, leaving 21 in each

treatment group. Participants completed training in using the device and were observed in the laboratory to ensure they used proper technique; the remainder of the sessions was conducted at home. Patients in the experimental group (arm, chest, trunk treatment) were told to perform a 1-hour session daily for 30 days; patients in the control group (arm only) were told to perform a 36-minute session daily for 30 days. The final outcome assessment took place at the end of the 30-day treatment period. The trialists did not report whether the staff members who assessed objective outcomes were blinded to the patient treatment groups. There were no statistically significant differences between groups in efficacy outcomes. For example, change in the volume of the affected arm was -2.66 mL in the experimental group and -0.38 mL in the control group (p=0.609). In addition, the mean number of symptoms reported at 30 days was 10.0 in the experimental group and 6.0 in the control group (p=0.145).

Section Summary: Pneumatic Compression Pumps Applied to the Trunk and/or Chest as Well as Limb

Two published RCTs have compared pneumatic compression treatment with and without truncal involvement. 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.

VENOUS ULCERS

The analysis of venous ulcers focused on RCTs evaluating preferred outcomes for wound healing. Complete healing is generally considered the most clinically relevant outcome; a 50% reduction in wound area over time and time to heal are also considered acceptable outcomes.

A Cochrane review updated by Nelson et al (2014), addressed IPC pumps for treating venous leg ulcers. Reviewers identified 9 RCTs. Five trials compared pneumatic compression pumps plus continuous compression with continuous compression alone, 2 trials compared compression pumps with continuous compression (stockings or bandages), 1 trial compared compression pumps with wound dressings only, and 1 trial compared 2 IPC regimens. In a meta-analysis, 3 of the 5 trials evaluating the incremental benefit of pneumatic compression pumps over continuous compression alone, there was a significantly higher rate of healing with combined treatment (relative risk, 1.31; 95% confidence interval, 1.06 to 1.63). Two of these 3 trials were considered to have a high risk of bias (eg, not blinded, unclear allocation or concealment). There was a high degree of heterogeneity among trials, and findings from other RCTs were not pooled. Neither of the 2 trials comparing IPC with continuous compression plus stockings or bandages found statistically significant between-group differences in healing rates.

An RCT by Dolibog et al (2014) was published after the Cochrane review literature search. The trial included 147 patients with venous ulcers. It compared 5 types of compression therapy: IPC using a 12-chamber Flowtron device, stockings, multilayer bandages, 2-layer bandages, and Unna boots. All patients received standard drug therapy; the compression interventions lasted 2 months. Rates of complete healing at the end of treatment were similar in 3 of the treatment groups: 16 (57%) of 28 patients in the pneumatic compression group, 17 (57%) of 30 in the stockings group, and 17 (59%) of 29 in the multilayer bandage group. On the other hand, rates

of healing were much lower in the other 2 groups: 5 (17%) of 30 in the 2-layer bandage group and 6 (20%) of 30 in the Unna boot group. A pilot study by Dolibog et al (2013), included in the Cochrane review, had similar findings.¹⁰

Section Summary: Venous Ulcers

A Cochrane review of RCTs on pneumatic compression pumps for treating venous leg ulcers conducted a meta-analysis of 3 trials. This analysis 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.

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.

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 compression¹¹:

"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.¹² 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.

ONGOING AND UNPUBLISHED CLINICAL TRIALS

A currently unpublished trial that might influence this review is listed in Table 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT01239160 ^a	Two Pneumatic Compression Devices in the Treatment of	262	Jul 2018
	Lower Extremity Lymphedema (ACE)		

NCT: national clinical trial.

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) 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 of these services as it applies to an individual member.

CPT/HCPCS

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
E0656	Segmental pneumatic appliance for use with pneumatic compressor, trunk
E0657	Segmental pneumatic appliance for use with pneumatic compressor, chest
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
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

^a Denotes industry-sponsored or cosponsored trial.

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E0670	Segmental pneumatic appliance for use with pneumatic compressor, integrated,
	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
E0676	Intermittent limb compression device (includes all accessories), not otherwise
	specified

- Claims for lymphedema pumps are coded with 2 HCPCS codes: one to describe the actual pump (E0650, E0651, E0652) and one to describe the appliance (ie, sleeve) that is put on the affected body part. The various types of pumps may be distinguished by HCPCS codes.
 - Single-compartment pumps (E0650)
 E0650 is used in conjunction with any of the following appliances: E0655, E0660, E0665, E0666.
 - Multichamber pumps (E0651)
 E0651 may be used with any of the following appliance codes: E0656, E0657, E0667, E0668, E0669.
 - Multichamber programmable pumps (E0652)
 E0652 may be used with any of the following appliance codes: E0671, E0672, E0673.

ICD-10 Diagnoses (Effective October 1, 2015)

189.0	Lymphedema, not elsewhere classified
197.2	Postmastectomy lymphedema syndrome
Q82.0	Hereditary lymphedema

REVISIONS

KEVI3IUN3	
06-07-2013	Policy added to the bcbsks.com web site.
	Effective for Institutional providers 30 days after the Revision Date, 07-08-2013.
05-13-2015	In Coding section:
	■ Added HCPCS codes: E0670, E0676
	Updated Coding notations.
04-28-2017	Updated Description section
	In Policy section:
	 In Item A removed "exercise" to read "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."
	■ In Items A, B, C, and D added "applied to the limb" to read " lymphedema pumps
	applied to the limb"
	In Item D removed "in the first two policy statements".
	Updated Rationale section
	In Coding section:
	 Updated coding notations
	Updated References
04-28-2018	Updated Description section
	Updated Rationale section
	In Coding section:
	 Updated coding notations

	Updated References
05-09-2018	Updated Description section
	Updated Rationale section
	Updated References

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