Pneumatic Compression Pumps for Treatment of Lymphedema and Venous Ulcers

**POLICY**

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 that prevent satisfactory pneumatic compression with single-compartment or multichamber nonprogrammable lymphedema pumps (e.g., 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*.

**POLICY GUIDELINES**

**Coding**

Claims for lymphedema pumps are coded with 2 HCPCS codes—one to describe the actual pump and one to describe the appliance (i.e., sleeve) that is put on the affected body part. The various types of pumps may be distinguished by HCPCS codes.

**Single-Compartment Pumps**

E0650 Pneumatic compressor, nonsegmental home model.
Pneumatic Compression Pumps for Treatment of Lymphedema and Venous Ulcers

The above code (E0650) is used in conjunction with any of the following appliances:

- 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.

**Multichamber Pumps**

- E0651 Pneumatic compressor, segmental home model without calibrated gradient pressure
  The above code (E0651) may be used with any of the following appliance codes:
  - E0656 Segmental pneumatic appliance for use with pneumatic compressor, trunk
  - E0657 Segmental pneumatic appliance for use with pneumatic compressor, chest
  - 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.

**Multichamber Programmable Pumps**

- E0652 Pneumatic compressor, segmental home model with calibrated gradient pressure.
  The above code (E0652) may be used with any of the following appliance codes:
  - E0671 Segmental gradient pressure pneumatic appliance, full leg
  - E0672 Segmental gradient pressure pneumatic appliance, full arm
  - E0673 Segmental gradient pressure pneumatic appliance, half leg.

**BENEFIT APPLICATION**

**BlueCard/National Account Issues**

State or federal mandates (e.g., 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 rented initially for a period of one to two months before purchase to confirm compliance.

**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, post radiation fibrosis, scarring of lymphatic channels, or congenital anomalies.

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.

**Regulatory Status**

Several pneumatic compression pumps, indicated for the primary or adjunctive treatment of primary or secondary (e.g., 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.

**RATIONALE**

The evidence review was created in July 1998 and was updated regularly with searches of the MEDLINE database. The most recent literature update was performed through January 6, 2019. 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 technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life (QOL), and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and 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 technology, two domains are examined: the relevance, and 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 (e.g., range of motion), and QOL (e.g., ability to conduct activities of daily living). Limb volume and limb circumference are also commonly reported outcomes.

**Lymphedema**
Clinical Context and Purpose

The purpose of pneumatic compression pumps in patients who have lymphedema is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: does the use of pneumatic compression pumps in patients who have lymphedema improve net health outcomes?

The following PICOTS were used to select literature to inform this review.

Patients

The relevant population(s) of interest are patients with lymphedema. 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 the use of compression garments and compression bandaging. An other conservative treatment is manual lymphatic drainage, a massage-like technique used to move edema fluid from distal to proximal areas. Manual lymphatic drainage is performed by physical therapists with special training. Complete decongestive therapy is a comprehensive program that includes manual lymphatic drainage in conjunction with a range of other conservative treatments. Rarely, surgery is used as a treatment option.

Interventions

The treatment being considered is the use of pneumatic lymphatic pumps. Pneumatic compression pumps consist of pneumatic cuffs 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 three primary types of pumps as follows.

Single chamber nonprogrammable pumps: They are the simplest pumps, consisting of a single chamber that is inflated at one time to apply uniform pressure.

Multichamber nonprogrammable pumps: They 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 multichamber programmable pumps: They 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.

Comparators

The following practices are currently being used to treat lymphedema; physiotherapy and, manual lymphatic drainage.

Outcomes
The general outcomes of interest are symptoms, change in disease status, functional outcomes and QOL.

**Timing**

Lymphedema is a chronic condition and follow-up of at least six weeks to six months would be desirable to assess outcomes.

**Setting**

Pneumatic compression pumps may be used in lymphedema clinics, purchased, or rented for home use; home use is addressed herein. Lymphedema therapists and physiatrists provide care.

Pneumatic Compression Pumps Applied to the Limb Only

The Agency for Healthcare Research and Quality (2010) 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 [2012]) 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 four studies, worse in one study (vs laser), and no different in five 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. 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, two RCTs found that IPC was superior to decongestive therapy or self-massage but three 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. They identified seven 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, -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 one-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 the 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. 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 three 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 2 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. 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 one RCT, two of four 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, QOL). 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**

**Clinical Context and Purpose**

The purpose of pneumatic compression pumps in patients who have venous ulcers is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: does the use of pneumatic compression pumps in patients who have venous ulcers improve net health outcomes?

The following PICOTS were used to select literature to inform this review.

**Patients**

The relevant population(s) of interest are patients with 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.

**Interventions**

The treatment being considered is the use of pneumatic lymphatic pumps. Pneumatic compression pumps consist of pneumatic cuffs 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 three primary types of pumps as follows.

Single chamber nonprogrammable pumps: They are the simplest pumps, consisting of a single chamber that is inflated at one time to apply uniform pressure.

Multichamber nonprogrammable pumps: They 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 multichamber programmable pumps: They 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.

**Comparators**

The following practices are currently being used to treat venous ulcers; local wound care and compression bandages or hosiery supplemented by conservative measures such as leg elevation

**Outcomes**

The general outcomes of interest are symptoms, change in disease status, functional outcomes and QOL.

**Timing**
Venous ulcers are a chronic condition and follow-up of at least six weeks to six months would be desirable to assess outcomes.

**Setting**

Pneumatic compression pumps may be used in wound care clinics, purchased, or rented for home use; home use is addressed herein. Wound care therapists, surgeons and physiatrists provide care.

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. Reviews identified nine RCTs. Five trials compared pneumatic compression pumps plus continuous compression with continuous compression alone, two trials compared compression pumps with continuous compression (stockings or bandages), one trial compared compression pumps with wound dressings only, and one trial compared two 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 three trials were considered to have a high-risk of bias (e.g., 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 two 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 two 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.

**Section Summary: Venous Ulcers**

A Cochrane review of RCTs on pneumatic compression pumps for treating venous leg ulcers conducted a meta-analysis of three trials. This analysis found significantly higher healing rates with lymphedema pumps plus continuous compression than with continuous compression alone; however, two of the three trials were judged to be at high-risk of bias. Moreover, the two 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. The relevant outcomes are symptoms, change in disease status, functional outcomes, and QOL. 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 two RCTs comparing treatment with and without truncal involvement. The relevant outcomes are symptoms, change in disease status, functional outcomes, and QOL. In one RCT, two of four 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, QOL). 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. The relevant outcomes are symptoms, change in disease status, morbid events, and QOL. A meta-analysis of three trials found significantly higher healing rates with lymphedema pumps plus continuous compression than with continuous compression alone; however, two of the three trials were judged to be at high-risk of bias. Moreover, the two 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.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Society for Vascular Surgery and American Venous Forum

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

“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 consensus statement from the International Union of Phlebology (2013) 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. 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 national coverage determination for pneumatic compression devices by the Centers for Medicare & Medicaid Services (2002) has stated the following:

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.”

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

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NCT: national clinical trial.

* Denotes industry-sponsored or cosponsored trial.

REFERENCES


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

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