Medical Policy

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

Related Policies:	▪ *Postsurgical Home Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis*

Professional / Institutional
Original Effective Date: June 7, 2013 / July 8, 2013
Latest Review Date: April 25, 2023
Current Effective Date: April 25, 2023

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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 (e.g., exercise, compression therapy, elevation) • Manual lymphatic drainage • Complete decongestive therapy	Relevant outcomes include: • Symptoms • Change in disease status • Functional outcomes • Quality of life
Individuals: • With lymphedema who failed to	Interventions of interest are: • Pneumatic compression pumps applied to trunk	Comparators of interest are: • Conservative therapy (e.g., exercise, compression therapy, elevation)	Relevant outcomes include: • Symptoms

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Populations	Interventions	Comparators	Outcomes
respond to conservative therapy	and/or chest as well as limb	• Manual lymphatic drainage • Complete decongestive therapy • Pneumatic compression pump applied to limb only	• Change in disease status • Functional outcomes • Quality of life
Individuals: • With lymphedema who failed to respond to conservative therapy	Interventions of interest are: • Pneumatic compression pumps applied to the head and neck	Comparators of interest are: • Conservative therapy (eg, range of motion exercises, compression therapy) • Manual lymphatic drainage • Complete decongestive therapy	Relevant outcomes include: • Symptoms • Change in disease status • Functional outcomes • Quality of life
Individuals: • With venous ulcers	Interventions of interest are: • Pneumatic compression pumps	Comparators of interest are: • Medication therapy • Continuous compression (e.g., stockings, bandages)	Relevant outcomes include: • Symptoms • Change in disease status • Morbid events • Quality of life

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.

OBJECTIVE

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

BACKGROUND

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. 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. Another 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. Pneumatic compression pumps are proposed as a treatment for patients with lymphedema who have failed conservative measures.

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Pneumatic compression pumps are also proposed to supplement standard care for 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. Standard treatment for venous ulcers includes compression bandages or hosiery supplemented by conservative measures such as leg elevation.

Pneumatic compression pumps may be used in lymphedema or wound care clinics, purchased, or rented for home use; home use is addressed herein. Pneumatic compression pumps consist of pneumatic cuffs connected to a pump. These pumps 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, with varying materials, designs, degrees of pressure, and complexity. There are 3 primary types of pumps. Single chamber nonprogrammable pumps are the simplest pumps, consisting of a single chamber that is inflated at 1 time to apply uniform pressure. Multichamber nonprogrammable pumps 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 multi-chamber programmable pumps 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.

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 (FDA) through the 510(k) process. Examples of devices with these indications intended for home or clinic/hospital use include the Compression Pump, Model GS-128 (MedMark Technologies); the Sequential Circulator® (Bio Compression Systems); the Lympha-Press® and Lympha-Press Optimal (Mego Afek); the Flexitouch® and Flexitouch Plus systems (Tactile Medical, formerly Tactile Systems Technology); the Powerpress Unit Sequential Circulator (Neomedic); and the EzLymph and EzLymph M (EEZCare Medical).

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

FDA product code: JOW.

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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 (e.g., 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 individuals with lymphedema with or without involvement of the upper and/or lower limbs is considered **experimental / investigational**.

F. The use of lymphedema pumps applied to the head and neck to treat lymphedema is considered **experimental / investigational**.

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RATIONALE

The evidence review has been updated regularly with searches of the PubMed database. The most recent literature update was performed through January 30, 2023.

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.

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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 1 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. Randomized controlled trials 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.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

LYMPHEDEMA–PNEUMATIC COMPRESSION PUMPS APPLIED TO THE LIMB ONLY

Clinical Context and Therapy Purpose

The purpose of pneumatic compression pumps applied to the limb only is to provide a treatment option that is an alternative to or an improvement on existing therapies for patients with lymphedema who failed to respond to conservative therapy.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is patients with lymphedema who have failed to respond to conservative therapy.

Interventions

The therapy being considered is the use of pneumatic compression pumps applied to limb only.

Comparators

The following practices are currently being used to treat lymphedema: conservative therapy (eg, exercise, compression therapy, elevation), manual lymphatic drainage, and complete decongestive therapy.

Outcomes

The general outcomes of interest are symptoms, change in disease status, 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 is a chronic condition, and follow-up of at least 6 weeks to 6 months would be desirable to assess outcomes.

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Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

REVIEW OF EVIDENCE

Systematic Reviews

In 2010, the Agency for Healthcare Research and Quality published a technology assessment on the diagnosis and treatment of secondary lymphedema that included a discussion of intermittent pneumatic compression pumps.[1,] Oremus et al identified 12 studies focusing on the treatment of lymphedema with intermittent pneumatic compression pumps. Seven studies were moderate- to high-quality RCTs, 3 were low-quality RCTs, and 2 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, intermittent pneumatic compression 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.[2,] The authors identified 36 English-language studies on a variety of treatments, 30 of which were RCTs and 6 were observational studies. Six RCTs evaluated intermittent pneumatic compression. Study findings were not pooled. According to reviewers, 2 RCTs found that intermittent pneumatic compression was superior to decongestive therapy or self-massage, but 3 other RCTs failed to show that intermittent pneumatic compression was superior to another conservative treatment.

A systematic review by Shao et al (2014) addressed pneumatic compression pumps for the treatment of breast cancer-related lymphedema.[3,] The authors 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 the use of lymphedema pumps (mean difference, 4.51; 95% confidence interval [CI], -7.01 to 16.03).

Randomized Controlled Trials

A 2015 RCT from Japan included 31 women with unilateral upper-extremity lymphedema after mastectomy.[4,] 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 intermittent pneumatic compression (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

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immediate post-treatment 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.

Tastaban et al (2020) conducted an RCT in 76 patients with unilateral arm lymphedema related to breast cancer.[5,] Patients received complex decongestive treatment alone (n=38) or complex decongestive treatment plus intermittent pneumatic compression (n=38). Intermittent pneumatic compression was delivered for 30 minutes. All patients received complex decongestive treatment, which consisted of skin care, manual lymphatic drainage, compression bandaging, and exercise. Patients received 20 sessions of therapy over the course of 4 weeks. Both groups saw decreases in excess volume after 4 weeks, but between-group differences were not significant (percent reduction in excess volume, 54.6% with intermittent pneumatic compression vs. 49.6% without; p=.140). Symptoms of heaviness and tightness were significantly lower among patients who received intermittent pneumatic compression, as assessed by visual analog scale scores (heaviness, 2.0 vs. 3.0; p=.024; tightness, 2.0 vs. 2.5; p=.048).

Section Summary: Lymphedema–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.

LYMPHEDEMA–PNEUMATIC COMPRESSION PUMPS APPLIED TO THE TRUNK AND/OR CHEST AS WELL AS LIMB

Clinical Context and Therapy Purpose
The purpose of pneumatic compression pumps applied to the trunk and/or chest as well as the limb in patients who have lymphedema who failed to respond to conservative therapy is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is patients with lymphedema who failed to respond to conservative therapy.

Interventions
The therapy being considered is the use of pneumatic compression pumps on the trunk and/or chest, as well as the limb.

Comparators
The following practices are currently being used to treat lymphedema: conservative therapy (eg, exercise, compression therapy, elevation), manual lymphatic drainage, complete decongestive therapy, and pneumatic compression pump applied to the limb only.

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Outcomes

The general outcomes of interest are symptoms, change in disease status, 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 is a chronic condition and follow-up of at least 6 weeks to 6 months would be desirable to assess outcomes.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Due to the Food and Drug Administration (FDA) 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.

Randomized Controlled Trials

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 were statistically significant week by group interactions in 2 of these outcomes (edema volume reported as a percent, p=.047; tissue water, p=.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=.141; edema volume reported in milliliters, p=.050). Moreover, had there been statistical adjustments for multiple comparisons (i.e., if p<.0125 had been used instead of p<.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.

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Ridner et al (2012) compared treatment using the Flexitouch system for an arm only versus 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 were 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=.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=.145).

Section Summary: Lymphedema–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.

LYMPHEDEMA–PNEUMATIC COMPRESSION PUMPS APPLIED TO THE HEAD AND NECK

Clinical Context and Therapy Purpose

The purpose of pneumatic compression pumps applied to the head and neck in patients who have lymphedema who failed to respond to conservative therapy is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is patients with lymphedema who failed to respond to conservative therapy.

Interventions

The therapy being considered is the use of pneumatic lymphatic pumps on the head and neck.

Comparators

The following practices are currently being used to treat lymphedema: conservative therapy (eg, range of motion exercises, compression therapy), manual lymphatic drainage, and complete decongestive therapy.

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Outcomes

The general outcomes of interest are symptoms, change in disease status, functional outcomes (eg, range of motion), and quality of life (eg, ability to conduct activities of daily living). The Lymphedema Symptom Intensity and Distress Survey-Head and Neck is a patient-reported tool that captures symptom intensity and distress.

Lymphedema is a chronic condition and follow-up of at least 6 weeks to 6 months would be desirable to assess outcomes.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

This literature review focuses on RCTs evaluating pneumatic compression for patients with head and neck lymphedema. One RCT was identified that evaluated the feasibility and efficacy of an advanced pneumatic compression device, which was industry-sponsored. Additional uncontrolled preliminary observational studies have been published, which have reported improvements in symptoms and function with use of advanced pneumatic compression devices for head and neck lymphedema secondary to head and neck cancer.[8,9,10,11,]

Randomized Controlled Trial

Ridner et al (2021) evaluated the Flexitouch system for head and neck lymphedema in an open-label, randomized, wait-list controlled study.[12,] Patients were randomized to lymphedema self-management or lymphedema self-management plus the use of the Flexitouch system twice daily for 8 weeks. Patients were trained on use of the Flexitouch system and were instructed on time of use, which varied based upon size of garment and ranged from 23 to 45 minutes. Patients who were initially randomized to lymphedema self-management only could opt to continue on after the initial 8-week period to receive the Flexitouch system for a subsequent 8-week treatment period. A summary of the design and key results are included in Tables 1 and 2. Adherence to the device was low; at week 8, only 4 of the 19 patients still enrolled in the intervention group used the Flexitouch system as prescribed for at least 5 days (only 1 patient used it twice a day, every day).

Table 1. Summary of Key RCT Characteristics

Study	Countries	Sites	Dates	Participants	Interventions[a]	
					Active	Comparator
Ridner (2021)[12,]	US	2	NR	N=49 patients who had completed treatment for head and neck cancer with no active disease, had a clinical diagnosis of head and neck	Lymphedema self-management plus the use	Lymphedema self-management (n=25)

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Study	Countries	Sites	Dates	Participants	Interventions[a]	
					Active	Comparator
				lymphedema, and had either already received lymphedema therapy or were unable to access therapy due to barriers (eg, lack of insurance)	of the Flexitouch system twice daily for 8 weeks (n=24)	

NR: not reported; RCT: randomized controlled trial.
[a]All patients were provided with a self-care kit that included a diary, self-care checklist, and calendar of future study appointments.

Table 2. Summary of Key RCT Results

Study	LSIDS-HN, change from baseline (median [IQR])				Swelling, median change from baseline in percentage grids with observable swelling			Adverse events
Ridner (2021)[12,]	Soft tissue	Neurological	Activity	Function	Front view	Right view	Left view	
Lymphedema self-management plus Flexitouch system (n=19)	-2.0 [-2, 0]	0.0 [-2, 0]	0.0 [-3, 0]	0.0 [-1, +1]	-24%	-22%	-17%	4 serious adverse events reported (considered unrelated to device use)
Lymphedema self-management only (n=24)	0.0 [0, +2]	0.0 [0, +2]	0.0 [-3, +1]	0.0 [-1, +2]	+5%	-7%	-4%	-
p-value	.004	.047	.08	.479	<.001	.004	.005	

IQR: interquartile range; LSIDS-HN: Lymphedema Symptom Intensity and Distress Survey-Head and Neck; RCT: randomized controlled trial.

Tables 3 and 4 display notable limitations identified in the study.

Table 3. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-up[e]
Ridner (2021)[12,]		1. Unclear what therapies were included as part of the self-care kit; 3. Low rates of adherence	1. Unclear what therapies were included as part of the self-care kit		1. Longer-term outcomes not evaluated

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4.

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Study population not representative of intended use.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 4. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Ridner (2021)[12,]		1. Blinding not feasible; most measures were patient-reported 3. Assessment of swelling by physician was not blinded		6. Intention to treat analysis not used (5 of 24 patients in intervention group did not complete the trial)	2. Feasibility trial, so no power calculations were performed	2. No adjustment for multiplicity

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Section Summary: Lymphedema–Pneumatic Compression Pumps Applied to Head and Neck

One RCT has evaluated pneumatic compression treatment for head and neck lymphedema. The trial evaluated the feasibility, adherence, and safety of the intervention. Results demonstrated some improvements in patient-reported outcomes and swelling, but adherence was low, with only 1 patient using the pneumatic compression treatment device twice daily as prescribed. Further investigation in larger studies and those that compare against the gold standard comparator of complete decongestive therapy are needed to determine efficacy of this treatment approach.

PNEUMATIC COMPRESSION PUMPS APPLIED TO VENOUS ULCERS

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Clinical Context and Therapy 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 following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is patients with venous ulcers.

Interventions

The therapy being considered is the use of pneumatic lymphatic pumps.

Comparators

The following practices are currently being used to treat venous ulcers: medication therapy and continuous compression (eg, stockings, bandages).

Outcomes

The general outcomes of interest are symptoms, change in disease status, morbid events, and quality of life. 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.

Venous ulcers are a chronic condition, and follow-up of at least 6 weeks to 6 months would be desirable to assess outcomes.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

REVIEW OF EVIDENCE

Systematic Review

A Cochrane review updated by Nelson et al (2014) addressed intermittent pneumatic compression pumps for treating venous leg ulcers.[13,] 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 intermittent pneumatic compression regimens. In a meta-analysis of 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% CI, 1.06 to 1.63). Two of these 3 trials were considered to have a high-

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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 intermittent pneumatic compression with continuous compression plus stockings or bandages found statistically significant between-group differences in healing rates.

Randomized Controlled Trials

An RCT by Dolibog et al (2014) was published after the Cochrane review literature search.[14,] The trial included 147 patients with venous ulcers. It compared 5 types of compression therapy: intermittent pneumatic compression 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. In 2013, a pilot study by Dolibog et al, included in the Cochrane review, had similar findings.[15,]

Alvarez et al (2020) conducted an RCT in 52 patients with large (>20 cm^2) chronic venous leg ulcers that compared intermittent pneumatic compression plus standard compression therapy (n=27) to standard compression therapy alone (n=25).[16,] Standard compression therapy consisted of multilayer compression bandages. Intermittent pneumatic compression therapy was performed for 1 hour twice daily. At 9 months, median time to wound closure was significantly shortened in the group receiving pneumatic compression (141 days vs. 211 days; p=.03). Wound pain relief was greater in the pneumatic compression group for the first 3 weeks of therapy, but pain relief was similar between groups at subsequent time points.

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.

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

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.

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

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

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

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

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

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

U.S. Preventive Services Task Force Recommendations
Not applicable.

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 5.

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Table 5. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT04797390[a]	A Randomized Trial of an Advanced Pneumatic Compression Device vs. Usual Care for Head and Neck Lymphedema	250	Dec 2023
NCT05659394[a]	Intermittent Pneumatic Compression of the Thigh for the Treatment of Lower Limb Wounds: a Randomised Control Trial (IPCOTT)	160	Sep 2024

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

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CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. This may not be a comprehensive list of procedure codes applicable to this policy.

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.

The code(s) listed below are medically necessary ONLY if the procedure is performed according to the "Policy" section of this document.

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
E0670	Segmental pneumatic appliance for use with pneumatic compressor, integrated, 2 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

REVISIONS	
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."

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REVISIONS	
	▪ 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
07-01-2019	Updated Description section
	Updated Rationale section
	Updated References
09-18-2020	Updated Description section
	Updated Rationale section
	Updated References
05-05-2021	Updated Description section
	Updated Rationale section
	Updated References
11-08-2021	Updated Description section
	In Policy section: F. The use of lymphedema pumps applied to the head and neck to treat lymphedema is considered experimental / investigational**.**
	Updated Rationale section
	Updated References
05-04-2022	Updated Description Section
	Updated Rationale Section
	Updated References Section
04-25-2023	Updated Description Section
	Updated Policy Section ▪ Section E: changed "limited to" to read "with or without involvement of"
	Updated Rationale Section
	Updated Coding Section ▪ Removed ICD-10 codes
	Updated References Section

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