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Compression Pumps for Treatment of Lymphedema and Venous Ulcers

Table of Contents
Coverage
Policy Guidelines
Description
Rationale
Coding
References
Policy History

Related Policies (if applicable)
DME101.000: DME Introduction
MED202.073: Postsurgical Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

ALERT: Refer to Medical Policy DME101.000 (DME Introduction) for important information about DME coverage.

NOTE 1: Coverage of DME items is for home/place of residence use only. DME items utilized in a facility setting (hospital, outpatient surgery, physician office, other) are not separately billable and are considered part of the facility/office charge.

Treatment of Lymphedema
Use of *nonprogrammable* compression pumps **may be considered medically necessary** for the treatment of lymphedema that has failed to respond to a four-week trial of conservative measures. (See **NOTE 2**)

Use of *programmable* compression pumps **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 compression with nonprogrammable lymphedema pumps (e.g., significant scarring). (See **NOTE 3**)

Treatment of Venous Ulcers

Use of pneumatic compression pumps to treat venous ulcers caused by chronic venous insufficiency which have failed to heal after a six-month trial of conservative physician-directed medical therapy **may be considered medically necessary.** (See **NOTE 2**)

Use of compression pumps **is considered experimental, investigational and/or unproven** for all other indications, including but not limited to:

1. Treatment of the trunk or chest in individuals with lymphedema with or without involvement of the upper and/or lower limbs;
2. Treatment applied to the head and neck to treat lymphedema;
3. Diabetic neuropathic ulcers;
4. Arterial ischemic lesions/ulcers;
5. Peripheral artery disease/arterial insufficiency;
6. Restless leg syndrome;
7. Upper extremity vascular ulcers.

NOTE 2: Conservative therapy must include the use of a compression bandage system or garment (garment must provide adequate graduated compression), exercise and elevation of the limb. The garment may be prefabricated or custom-fabricated but must provide adequate graduated compression.

Documentation Requirements

The following documentation must be submitted to establish medical necessity of compression devices.

1. Documentation of appropriate physician oversight (i.e., physician evaluation of the individual's condition to determine medical necessity of the device, assuring suitable instruction in the operation of the machine), and
2. A treatment plan defining the pressure to be used, frequency and duration of use, and ongoing monitoring of use and response to treatment.

Physician evaluation documentation must include:

1. Diagnosis and prognosis;
2. Symptoms and objective findings, including measurements which establish the severity of the condition;
3. Reason the device is required, including the treatments which have been tried and failed.

NOTE 3: A segmented, calibrated gradient compression device is allowed only when the individual has unique characteristics (as defined below), that prevent them from receiving satisfactory compression treatment using a non-segmented device in conjunction with a segmented appliance or a segmented compression device without manual control of pressure in each chamber.

Unique characteristics may be defined as:

1. A need to reduce pressure over sensitive areas such as wound sites, ulcers, and painful areas, and
2. That the individual is unable to tolerate use of a non-calibrated nonprogrammable device, and
3. That the calibrated pressure and programmability of the segmental compressor with calibrated gradient pressure is required to address these sensitive areas.

Use of compression pumps **is considered not medically necessary** for the temporary relief of minor muscle aches and pains, and temporary increase in blood circulation in individuals who are in good health (e.g., Recovery Pump Systems).

Policy Guidelines

None.

Description

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 of varying designs and complexity.

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, 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. Compression pumps are proposed as a treatment for patients with lymphedema who have failed conservative measures.

Chronic Venous Stasis Ulcers

Compression therapy is an important part of treatment for chronic venous insufficiency (CVI). 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. CVI is distinguished from lymphedema in that lymphedema is when the lymphatic system is not able to clear fluid from the interstitial tissues of the body and return it to the bloodstream via a system of lymphatic vessels and lymph nodes. (1)

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 CVI when leg veins become blocked. Standard treatment for venous ulcers includes compression bandages or hosiery supplemented by conservative measures such as leg elevation.

Compression Pumps

Compression pumps may be used in lymphedema or wound care clinics, purchased, or rented for home use; home use is addressed herein.

Pneumatic Compression

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. In some situations, including patients with scarring, contractures, or highly sensitive skin, programmable pumps are generally considered the preferred option.

Non-Pneumatic Compression

Non-pneumatic compression pumps have recently been developed that do not utilize pneumatics in the compression mechanism. The Koya Dayspring® (Koya Medical, Oakland, CA.) is a wearable advanced compression device that consists of a programmable, segmental controller with a sleeve garment that can be sized to fit the individual. The garment contains a shape memory alloy made with nickel/titanium (Ni-Ti) that is programmed by a rechargeable controller to shrink in a cyclic manner, applying active gradient pressure from the distal to proximal end of the limb. This mechanistic action is similar to the motion of advanced

pneumatic compression devices. Up to 14 independently controlled segments can be programmed to deliver 0–100 mmHg of compression pressure, with typical initial settings in a range of 30–40 mmHg. A mobile phone application can be used to program and individualize pressures; to start, stop, and pause therapy; and to track device usage. (2)

Regulatory

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:

- Compression Pump, Model GS-128 (Medmark Technologies);
- Sequential Circulator® (Bio Compression Systems);
- Lympha-Press® and Lympha-Press Optimal (Mego Afek);
- Flexitouch® and Flexitouch Plus systems (Tactile Medical, formerly Tactile Systems Technology);
- PowerPress Unit Sequential Circulator (Neomedic); and
- EzLymph and EzLymph M (EEZCare Medical).

Several pneumatic compression devices are cleared by the FDA for treatment of venous stasis ulcers. Examples include:

1. Model GS-128;
2. Lympha-Press;
3. Flexitouch and Flexitouch Plus;
4. Powerpress Recovery Unit (listed above);
5. NanoTherm™ (ThermoTek);
6. CTU676 devices (Compression Technologies); and
7. Recovery+™ (Pulsar Scientific).

FDA product code: JOW.

Several pneumatic compression pumps have also been FDA-approved for the temporary relief of minor muscle aches and pains, and for the temporary increase in blood circulation to the treated areas in people who are in good health. (3) Examples of devices with these indications include:

1. Rp Lite 760R (Mego Afek);
2. Recovery Pump, 737R (Rpx) (Mego Afek);
3. Rapid Reboot (Rapid Reboot Recovery Products);
4. NeoWave Pain Relief and Recovery System, Model# T16-2020 (Eva Medtec); and
5. Powerpress Recovery Unit (Hanuri Distribution).

FDA product code: IRP.

A list of current FDA-cleared pneumatic compression pumps is available at: <https://www.fda.gov>.

In April 2021, the Koya Dayspring system obtained FDA approval through the 510(k) premarket notification process as a compressible limb sleeve. The FDA indications for use were as follows: "The Koya Dayspring system is a prescription only wearable compression system that is intended for use in a clinic or home setting by medical professionals and patients who are under medical supervision to increase lymphatic flow in the treatment of many conditions such as:

- Lymphedema
- Primary lymphedema
- Post mastectomy edema
- Edema following trauma and sports injuries
- Post immobilization edema
- Venous insufficiency
- Reducing wound healing time
- Treatment and assistance in healing stasis dermatitis, venous stasis ulcers, or arterial and diabetic leg ulcers
- Lipedema
- Phlebolymphedema

The Dayspring system is developed on a wearable compression technology platform, which is designed to provide mobility for patients." (2)

In September 2021, the Dayspring Lite device obtained FDA approval via the 510(k) approval process as a compressible limb sleeve. The FDA indications for use were as follows: "Dayspring Lite is a prescription only wearable compression system that is intended for use in a clinic or home setting by medical professionals and patients who are under medical supervision, for the treatment of the following conditions:

- Chronic edema
- Lymphedema
- Venous insufficiency
- Wound healing

Dayspring Lite is developed on a wearable compression technology platform, which is designed to provide mobility for patients." (4)

FDA product code: JOW.

Rationale

Medical policies 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 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. 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.

PNEUMATIC COMPRESSION

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 policy.

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 (e.g., 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 (e.g., range of motion) and quality of life (e.g., 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.

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. (5) In 2012, 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 (e.g., 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. (6) 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. (7) 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 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. (8) 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 compressions (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 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. (9) 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 policy.

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 (e.g., exercise, compression therapy, elevation), manual lymphatic drainage, complete decongestive therapy, and pneumatic compression pump applied to the limb only.

Outcomes
The general outcomes of interest are symptoms, change in disease status, functional outcomes (e.g., range of motion) and quality of life (e.g., 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.

Due to the U.S. 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 medical policy 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. (10) 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 (e.g., 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.

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. (11) 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 (e.g., amount of fluid removed) rather than health outcomes (e.g., 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 policy.

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 (e.g., range of motion exercises, compression therapy), manual lymphatic drainage, and complete decongestive therapy.

Outcomes
The general outcomes of interest are symptoms, change in disease status, functional outcomes (e.g., range of motion), and quality of life (e.g., 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.

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. (12-15)

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. (16) 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	
					Active	**Comparator**
Ridner et al. (2021) (16)	U.S.	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, and had either already received lymphedema therapy or were unable to access therapy due to barriers (e.g., lack of insurance)	Lymphedema self-management plus the use of the Flexitouch system twice daily for 8 weeks (n=24)	Lymphedema self-management (n=25)

NR: not reported; RCT: randomized controlled trial; U.S.: United States.

[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 et al. (2021) (16)	**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 et al. (2021) (16)		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 literature 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. 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. Clinically significant difference not prespecified; 6. Clinically 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 et al. (2021) (16)		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 literature 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

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 policy.

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 (e.g., 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.

Systematic Reviews
A Cochrane review updated by Nelson et al. (2014) addressed intermittent pneumatic compression pumps for treating venous leg ulcers. (17) 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% confidence interval, 1.06 to 1.63).

Randomized Controlled Trials

A RCT by Dolibog et al. (2014) was published after the Cochrane review literature search. (18) 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. (19)

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). (20) 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.

Other Indications

Peripheral Arterial Disease/Ulcers

Montori and colleagues conducted a retrospective analysis of intermittent compression pump therapy for critical limb ischemia at the Mayo wound clinic. (21) Of the 107 patients, 101 had lower extremity ulcers. Of all the wounds, 64% were multifactorial in etiology, and 60% had associated transcutaneous oxygen tension TcPO(2) levels below 20 mmHg. Median follow-up after initiation of treatment was six months. Complete wound healing with limb preservation was achieved by 40% of patients with TcPO(2) levels below 20mmHg; by 48% with osteomyelitis or active wound infection; by 46% with diabetes treated with insulin; and by 28% with a previous amputation. Conclusions from this analysis found that patients with critical limb ischemia and nonhealing wounds at high risk of amputation can achieve complete wound healing and limb preservation by using an intermittent pneumatic compression device.

Filp and Dillon authored a report of a series of 27 patients (41 legs) with cholesterol-embolization syndrome (CES) treated between 1997 and 2005. (22) The alternate therapy offered to most patients at the time of referral was limb amputation. After a median interval of 11 months (range, 3-32 months) after initiation of therapy, 33 legs were totally healed, 6

improved, and 2 amputated. One patient died of causes unrelated to CES or use of the circulator boot. Another improved and discontinued treatment before he was totally healed. The authors concluded that the circulator boot seems to be the only effective therapy for CES. No comparison to alternative interventions at the time of treatment is possible, and treatment, particularly for cutaneous ulcers associated with vascular insufficiency, has continued to evolve since the patients in this study were treated. Large studies are lacking in the case of the Circulator Boot and unfortunately, due to the lack of patient protection are likely never to be done.

Moran et al. (2015) conducted on a systematic review of intermittent pneumatic compression for critical limb ischemia (CLI). (23) Two controlled before-and-after (CBA) studies and six case series were identified. No RCTs or non-randomized controlled trials (NRCTs) were identified. One retrospective CBA study involving compression of the calf reported improved limb salvage and wound healing and one prospective CBA study involving sequential compression of the foot and calf reported statistically significant improvements in claudication distances and SF-36 quality of life scores. There was no difference in all-cause mortality found. Complications included pain associated with compression, as well as skin abrasion and contact rash as a result of the cuff rubbing against the skin. It was noted that all studies had a high risk of bias. The authors concluded that the limited available results suggest that intermittent pneumatic compression (IPC) may be associated with improved limb salvage, wound healing and pain management; however, in the absence of additional well-designed analytical studies examining the effect of IPC in critical limb ischemia, the treatment remains unproven.

Abu Dabrh et al. (2015) reported on a systematic review that examined evidence about various nonrevascularization-based therapies used to treat patients with severe or CLI who are not candidates for surgical revascularization. (24) The review included 19 studies (2779 patients) of controlled randomized and nonrandomized studies that compared the effect of medical therapies (prostaglandin E1 and angiogenic growth factors) and devices (pumps and spinal cord stimulators). None of the nonrevascularization-based treatments were associated with a significant effect on mortality. Intermittent pneumatic compression use was associated with statistically significant improvements in ulcer healing and amputation, but these results were derived from a single small nonrandomized study. The authors note that replication of such results is needed, and the effect needs to be verified in larger RCTs.

Zaki et al. (2016) performed a retrospective analysis of 187 patients (262 limbs) prescribed the Artassist sequential pneumatic compression (SPC) device, comparing outcomes between the group of patients who acquired the device and those who did not. The primary end point was limb salvage; secondary end points were amputation-free survival and improvement in toe pressures. (25) The mean age was 74.78 years, the median follow-up was 16 months, and the median duration of usage was 4 months. 81.72% of the patient acquired the device and 18.28% did not. The mean toe pressure was 61.4 mmHg pre-application, and 65 mmHg after application ($p = .071$). Amputation-free survival was 98% and 96% for those who acquired the device and 90% and 84% for those who did not at 6 and 12 months, respectively. There was a non-significant association between limb salvage and device acquisition ($p = .714$); however, there

was a significant improvement in rest pain ($p < .0001$), reduction in minor amputation ($p = .023$), and amputation-free survival associated with using the device ($p = .01$). The authors concluded that even though limb salvage is the paramount ambition for patients referred to vascular services, some patients with CLI are better served with primary amputation. Although the mechanism of SPC action is still ambiguous, there is evidence to support its role in preventing minor amputation, prolonging amputation-free survival, and improving rest pain in patients with non-reconstructable CLI; nevertheless, its role in prevention of major amputation lacks statistical significance.

Restless Legs Syndrome

In a prospective, randomized, double-blinded, sham-controlled trial, Lettieri and Eliasson (2009) evaluated the effectiveness of pneumatic compression devices (PCDs) as a non-pharmacologic treatment for restless legs syndrome (RLS). (26) Subjects wore a therapeutic or sham device prior to the usual onset of symptoms for a minimum of 1 hour daily. Measures of severity of illness, quality of life, daytime sleepiness, and fatigue were compared at baseline and after 1 month of therapy. A total of 35 subjects were enrolled. Groups were similar at baseline. Therapeutic PCDs significantly improved all measured variables more than shams. Restless legs severity score improved from 14.1 +/- 3.9 to 8.4 +/- 3.4 ($p = 0.006$) and Johns Hopkins restless legs scale improved from 2.2 +/- 0.5 to 1.2 +/- 0.7 ($p = 0.01$). All quality of life domains improved more with therapeutic than sham devices (social function 14 % versus 1 %, respectively; $p = 0.03$; daytime function 21 % versus 6 %, respectively, $p = 0.02$; sleep quality 16 % versus 8 %, respectively, $p = 0.05$; emotional well-being 17 % versus 10 %, respectively, $p = 0.15$). Both Epworth sleepiness scale (6.5 +/- 4.0 versus 11.3 +/- 3.9, respectively, $p = 0.04$) and fatigue (4.1 +/- 2.1 versus 6.9 +/- 2.0, respectively, $p = 0.01$) improved more with therapeutic devices than sham devices. Complete relief occurred in 1/3 of subjects using therapeutic and in no subjects using sham devices. The authors concluded that PCDs resulted in clinically significant improvements in symptoms of RLS in comparison to the use of sham devices and may be an effective adjunctive or alternative therapy for RLS. Moreover, the authors stated that before PCD therapy is ready for more wide-spread use, it will be important to see validating studies in various populations of RLS patients.

Upper Extremity Vascular Ulcers

Pfizenmaier et al. (2005) noted that ischemic vascular ulcerations of the upper extremities are an uncommon and frequently painful condition most often associated with scleroderma and small vessel inflammatory diseases. (27) Digital amputation has been advocated as primary therapy because of the poor outcome with medical care. Intermittent pneumatic compression pump therapy can improve ulcer healing in lower extremity ischemic ulcerations; however, the value of this treatment in upper extremity ischemic ulcerations is not known. This observational pilot study consisted of a consecutive series of 26 patients with 27 upper extremity ischemic vascular ulcers seen at the Mayo Gonda Vascular Center from 1996 to 2003. Inclusion criteria were documented index of ulcer size and follow-up ulcer size and use of the IPC pump as adjunctive wound treatment. Twenty-six of 27 ulcers (96 %) healed with the use of the IPC pump. Mean baseline ulcer size was 1.0 cm2 (SD = 0.3 cm^2) and scleroderma was the underlying disease in 65 % (17/26) of cases. Laser Doppler blood flow in the affected digit was 7 flux units

(normal greater than 100). The mean ulcer duration before IPC treatment was 31 weeks. The average pump use was 5 hours per day. The mean time to wound healing was 25 weeks. Twenty-five of 26 patients reported an improvement in wound pain with pump use. The authors concluded that intensive IPC pump use is feasible and associated with a high rate of healing in upper extremity ischemic ulcers. Furthermore, they stated that prospective, RCTs of IPC is needed to determine whether IPC treatment improves wound healing compared to standard medical care.

NON-PNEUMATIC COMPRESSION

In an open -label pilot study, Rockson et al. (2022a) evaluated the quality of life (QoL) and limb volume maintenance efficacy of a novel wearable compression system (Dayspring™). (28) After 28 days of use, subjects had a statistically significant 18% ($p < 0.001$) improvement in overall QoL as measured by the Lymphedema Quality-of-Life Questionnaire (LYMQOL) compared with baseline. Individual QoL domains, and limb volume improved with therapy. Adherence was 98% over the course of the study. Results of the clinical evaluation suggest the Dayspring wearable compression device is safe and effective and improves QoL and limb volume. The novel, low-profile device is easy to use and allows for mobility during treatment, addressing a potential barrier to adherence with pneumatic compression devices.

Rockson et al. (2022b) conducted a non-randomized, open-label, 12-week pilot study of adult patients with primary or secondary unilateral lower extremity lymphedema, and measured changes in limb edema and QoL using the LYMQOL. (29) Twenty-four subjects were enrolled; the majority were female (n=17) with secondary lymphedema (n=21). Eighteen completed the study. Statistically significant improvements were observed in overall QoL, aggregated LYMQOL total score, and three of four LYMQOL subscales (Function, Appearance, Mood). The fourth (Symptoms) trended toward significant improvement (p=0.06). The average reduction in affected limb edema was 39.4%. The novel non-pneumatic compression device (NPCD) produced statistically significant improvements in QoL, functioning, and edema volume of patients with lower extremity lymphedema. Innovations in devices to manage lower extremity lymphedema can be effective while allowing patients to maintain mobility and physical activity during treatment.

Rockson et al. (2022c) evaluated the safety and efficacy of a novel NPCD for treating lymphedema versus an advanced pneumatic compression device (APCD) in a randomized, crossover head-to-head trial. (30) The patients had been randomized to either the NPCD or a commercially available APCD. The patients used the randomly assigned initial device for 28 days with a 4-week washout period before a comparable 28-day use of the second device. Data from 50 adult women with unilateral breast cancer-related lymphedema were analyzed. Compared with the APCD, the NPCD was associated with a greater mean reduction in the limb edema volume (64.6% vs 27.7%; P < .001), significantly greater mean improvements in QoL scores, greater adherence (95.6% vs 49.8%; P < .001), and greater satisfaction with the device (90% vs 14%; P < .001). The patients indicated that use of the NPCD facilitated exercise and was convenient for travel. No adverse events were reported. Investigators concluded that the novel NPCD is an effective maintenance treatment for reducing the limb volume in patients with

breast cancer-related lymphedema. The NPCD device was more effective than an APCD and resulted in greater adherence to self-care interventions and greater patient satisfaction.

Summary of Evidence

For individuals who have lymphedema who failed to respond to conservative therapy who receive pneumatic compression pumps applied to limb only, the evidence includes randomized controlled trials (RCTs) and systematic reviews 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 an improvement in the net health outcome.

For individuals who have lymphedema who failed to respond to conservative therapy who receive pneumatic compression pumps applied to the 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 (e.g., amount of fluid removed) rather than health outcomes (e.g., 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 that the technology results in an improvement in the net health outcome.

For individuals who have lymphedema who failed to respond to conservative therapy who receive pneumatic compression pumps applied to the head and neck, the evidence includes 1 RCT comparing treatment with a pneumatic compression pump along with lymphedema self-management compared to self-management alone. Relevant outcomes are symptoms, change in disease status, functional outcomes, and quality of life. 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 the efficacy of this treatment approach. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have venous ulcers caused by chronic venous insufficiency who failed to respond to conservative therapy 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. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals using pneumatic compression pumps for peripheral arterial disease/ulcers, the evidence includes retrospective analyses, case studies and systematic reviews. Relevant outcomes are symptoms, change in disease status, morbid events, and quality of life. In one of the more recent systematic reviews, no RCTs or non-randomized controlled trials were identified, with only limited results in two controlled before-and-after studies and six case series. In a second more recent systematic review, intermittent pneumatic compression use was associated with statistically significant improvement in ulcer healing and amputation, but the results were derived from a single small nonrandomized study. Large randomized controlled studies are lacking. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals using pneumatic compression pumps for the treatment of restless legs syndrome (RLS), the evidence includes a prospective, randomized, double-blinded, sham-controlled trial. Relevant outcomes are symptoms, change in disease status, morbid events, and quality of life. Pneumatic compression devices (PCDs) resulted in clinically significant improvements in symptoms of RLS in comparison to the use of sham devices and may be an effective adjunctive or alternative therapy for RLS. However, before PCD therapy is ready for more wide-spread use, it will be important to see validating studies in various populations of patients. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals using pneumatic compression pumps for the treatment of upper extremity vascular ulcers, the evidence includes an observational pilot study. Relevant outcomes are symptoms, change in disease status, morbid events, and quality of life. While intensive intermittent pneumatic compression pump use is feasible and associated with healing in upper extremity ischemic ulcers, additional prospective, RCTs of intermittent pneumatic compression are needed to determine whether intermittent pneumatic compression treatment improves wound healing compared to standard medical care. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have lymphedema who failed to respond to conservative therapy who receive non-pneumatic compression pumps applied to limb only, the evidence includes two nonrandomized open-label pilot studies, as well as a randomized crossover noninferiority trial. Relevant outcomes are symptoms, change in disease status, functional outcomes, and quality of life. Results suggest that non-pneumatic compression devices are safe, effective, and improve quality of life. Additionally, these devices allow for mobility during treatment, addressing a potential barrier to adherence with traditional pneumatic compression devices. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements

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. (31) 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. (32) 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 (33): “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. (34)

Medicare National Coverage

A 2002 national coverage determination for pneumatic compression devices by the Centers for Medicare & Medicaid Services has stated the following (35):

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
Some currently ongoing and/or unpublished trials that might influence this policy are listed in Table 5.

Table 5. Summary of Key Trials

NCT Number	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
NCT05507346[a]	A Multi-center Randomized Control Cross-over Study to Evaluate the Effectiveness of a Novel Portable Non-Pneumatic Active Compression Device vs. an Advanced Pneumatic Compression Device for Treating Lower Extremity Lymphedema (TEAYS)	50	Mar 2023

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

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member’s benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	None
HCPCS Codes	A4600, E0650, E0651, E0652, E0655, E0656, E0657, E0660, E0665, E0666, E0667, E0668, E0669, E0670, E0671, E0672, E0673, E0675, E0676, E0677, E0678, E0679, E0680, E0681, E0682, [Deleted 1/2024: K1024, K1025, K1031, K1032, K1033]

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been changed since this medical policy document was written. See Medicare's National Coverage at <http://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change

02/01/2025	Reviewed. No changes.
07/01/2023	Document updated with literature review. The following changes were made to Coverage: Removed “pneumatic” specificity for compression pumps from: 1) Section on treatment of lymphedema, 2) Experimental, investigational and/or unproven statement, 3) Documentation requirements, 4) NOTE 3, and 5) Not medically necessary statement on use for temporary relief of minor muscle aches, pains, etc.… Add/updated the following references: 2, 4, 15, 23-25, and 28-31. Title changed from “Pneumatic Compression Pumps for Treatment of Lymphedema and Venous Ulcers.”
03/01/2023	Document updated with literature review. The following change was made to the Coverage section: Treatment of the head and neck with lymphedema was added to the experimental, investigational and/or unproven list for pneumatic compression pumps. Added references 1 and 10-13; others updated.
01/15/2023	Reviewed. No changes.
12/01/2021	Document updated with literature review. The following changes were made to the Coverage section: 1) NOTE 1 was added and the other notes renumbered; 2) Outpatient was removed from all the coverage statements; 3) A four-week trial was added to the use of nonprogrammable pneumatic compression pumps medically necessary statement; 4) A not medically necessary statement was added for the use of pneumatic compression pumps for the temporary relief of minor muscle aches and pains, and temporary increase in blood circulation in individuals who are in good health. References 1, 6, 12-13, 20, and 23 were added.
01/15/2021	Document updated with literature review. Coverage revised to include peripheral artery disease/arterial insufficiency, treatment of restless leg syndrome, and treatment of upper extremity vascular ulcers as experimental, investigational and/or unproven. References 15-18 added. Coverage for venous thromboembolism prophylaxis now addressed on MED202.073 Postsurgical Outpatient Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis.
07/01/2019	Reviewed. No changes.
08/15/2017	Document updated with literature review. Coverage unchanged.
02/15/2016	Reviewed. No changes.
07/15/2015	Document updated with literature review. The following medically necessary coverage criteria for use of pneumatic compression devices for venous thromboembolism (VTE) prophylaxis, was removed: “Venous thromboembolism (VTE) prophylaxis for patients at high risk* for VTE (deep venous thrombosis [DVT] and pulmonary embolism [PE]), AND who cannot fully ambulate due to major trauma, major surgery or other circumstances preventing ambulation. Coverage on VTE prophylaxis replaced to note “…for patients with a contraindication to pharmacological agents (i.e., at high risk for bleeding) and after 1) Major orthopedic surgery (includes total hip

	arthroplasty (THA), total knee arthroplasty (TKA), or hip fracture surgery [HFS]), OR 2) Major non-orthopedic surgery (e.g. general gynecologic, urologic, thoracic, or neurosurgical procedures), and are at moderate or high risk of VTE (See Note 2), OR 3) Nonmajor orthopedic surgery (other than THA, TKA or HFS), and are at moderate or high risk of VTE (See Note 2). See coverage section for risk factors. In addition, the following coverage statement was added: "Outpatient use of pneumatic compression devices for VTE prophylaxis (when meeting medically necessary criteria noted above) is considered not medically necessary for periods longer than 30 days postsurgery". The following 3 indications were added to experimental, investigational and/or unproven listing 1) VTE prophylaxis after major orthopedic surgery in patients without a contraindication to pharmacological prophylaxis, 2) VTE prophylaxis after major non-orthopedic surgery or nonmajor orthopedic surgery in patients who are at moderate or high risk of VTE (see note 2) without a contraindication to pharmacological prophylaxis and in patients who are at low risk of VTE, and 3) VTE prophylaxis after all other surgeries not outlined above. The following statement was added: "Outpatient use of pneumatic compression devices for VTE prophylaxis (when meeting medically necessary criteria noted above) is considered not medically necessary for periods longer than 30 days postsurgery. Title changed from: Pneumatic Compression Devices.
02/15/2012	Document updated with literature review. Coverage unchanged.
04/01/2010	CPT/HCPCS code(s) updated
04/15/2009	Coverage and description revised (editorial)
07/01/2008	Revised/updated entire document
02/01/2006	New medical document