1.01.18	Compression Pumps for Treatment of Lymphedema and Venous Ulcers		
Original Policy Date:	October 15, 2007	**Effective Date:**	September 1, 2025
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Policy Statement

I. Single-compartment or multichamber *nonprogrammable* pneumatic compression pumps applied to the affected body sites (e.g., limb, trunk, chest, head, neck) may be considered **medically necessary** when **either** of the following criteria is met:
   A. Treatment of lymphedema post mastectomy (in accordance with the "Women's Health and Cancer Rights Act of 1998")
   B. Treatment of lymphedema that has failed to respond to conservative measures, including, but not limited to, elevation of the limb and use of compression garments, or manual lymph drainage

II. Single-compartment or multichamber *programmable* pneumatic compression pumps applied to the affected body sites (e.g., limb, trunk, chest, head, neck) may be considered **medically necessary** when **either** of the following criteria is met:
   A. Treatment of lymphedema post mastectomy (in accordance with the "Women's Health and Cancer Rights Act of 1998")
   B. Treatment of lymphedema when the following criteria are met:
      1. The individual is otherwise eligible for nonprogrammable pneumatic pumps
      2. There is documentation that the individual has unique characteristics (e.g., significant scarring, recent surgery) that prevent satisfactory pneumatic compression with single-compartment or multichamber nonprogrammable lymphedema pumps
      3. The individual has had an adequate response to an initial course of treatment with a nonprogrammable pneumatic compression pump (see Policy Guidelines)

III. Single-compartment or multichamber lymphedema pumps are considered **investigational** in all situations not specified above in the first 2 policy statements.

IV. Programmable, wearable non-pneumatic compression pumps (e.g., Koya Dayspring) applied to the limbs may be considered **medically necessary** for the treatment of lymphedema:
   A. The individual is otherwise eligible for a programmable pneumatic compression pump
   B. There is documentation that the individual has lifestyle considerations or mobility requirements where treatment compliance with a traditional programmable, pneumatic compression system is expected to be insufficient

V. Programmable, wearable non-pneumatic compression pumps are considered **investigational** in all other situations not specified above.

VI. The use of pneumatic or non-pneumatic compression pumps to treat venous ulcers is considered **investigational**.

VII. Continued use of a pneumatic and non-pneumatic compression pump may be considered **medically necessary** when documentation supports **both** of the following:
   A. Individual tolerance and compliance to the prescribed treatment plan

B. Effectiveness of the pump as evidenced by decreased edema with pre- and post-treatment measurements and/or documented improvement in functional capacity

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

Note: Equipment may be rented for a period of 2 to 3 months before a request for continued use is made by the provider to establish effectiveness of device and individual compliance and tolerance to the prescribed treatment plan.

Medically necessary positions for treatment of lymphedema at body sites other than the limbs are based on clinical input. Additional details from clinical input are detailed in the Appendix. Individuals who fail to respond to an initial trial of a nonprogrammable pump may benefit from programmable pumps with pulsatile features that can be tailored to address individual lymphatic flow dysfunction patterns. Clinical input supports the use of non-pneumatic compression pumps on the basis of the evidence and clinical experience, emphasizing the importance of compliance with treatment.

Coding

See the Codes table for details.

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; they can be single chamber (nonsegmented) or multichamber (segmented) and have varying designs and complexity. Non-pneumatic, programmable, wearable devices, are also available.

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 primarily focusing on upper-limb lymphedema secondary to breast cancer. Relevant outcomes are symptoms, change in disease status, functional outcomes, and quality of life. Most of these RCTs were deemed moderate-to-high quality by the Agency for Healthcare Research and Quality, and about half reported significant improvements with the use of pumps compared to conservative care. Recent meta-analyses indicate that incorporating intermittent pneumatic compression (IPC) with complete decongestive therapy can further enhance lymphedema management within four weeks post-treatment. Similar findings are observed when IPC is combined with decongestive lymphatic therapy compared to decongestive lymphatic therapy alone in managing upper limb lymphedema after breast cancer surgery, with the former combined regimen showing improved external rotation joint mobility. 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 limb and chest and/or trunk, the evidence includes two RCTs of the Flexitouch system (Tactile Medical), published in 2012, comparing treatment with and without truncal involvement. Relevant outcomes are symptoms, change in disease status, functional outcomes, and quality of life. In one RCT, two (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 second 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 one RCT and a systematic review to assess the use of pneumatic compression treatment for head and neck lymphedema. Relevant outcomes are symptoms, change in disease status, functional outcomes, and quality of life. The RCT, comparing treatment with a pneumatic compression pump along with lymphedema self-management compared to self-management alone, examined the feasibility, adherence, and safety of the Flexitouch advanced pneumatic compression device (APCD) by Tactile Medical. The findings showed some improvements in patient-reported outcomes and swelling, although adherence was low, with only one patient using the device twice daily as prescribed. The systematic review also suggested benefits from using the APCD, and it was considered safe and feasible according to the observational studies that reported adverse events. Most studies included participants who had completed or were concurrently undergoing complete decongestive therapy. Out of the 5 observational studies included in the systematic review, four (80%) had potential conflicts of interest related to the funding source. The only study not sponsored by the industry highlighted difficulties in obtaining the APCD, with fewer than half of the patients receiving the device as prescribed. Further research with larger sample sizes and comparisons against the criterion standard of complete decongestive therapy is necessary to establish 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 lymphedema who failed to respond to conservative therapy who receive non-pneumatic compression pumps applied to limb only, the evidence includes randomized crossover trials. Relevant outcomes are symptoms, change in disease status, functional outcomes, and quality of life. Randomized crossover trials have compared use of non-pneumatic, wearable, compression devices to traditional, pneumatic compression devices in both upper and lower extremity lymphedema. These studies have consistently supported noninferior reductions in limb edema volume, higher rates of patient compliance, and improvements on quality of life assessments with use in the short-term (28 to 90 days). Additionally, clinical input supports the use of non-pneumatic, wearable compression devices on the basis of this research and clinical experience. These devices may be particularly suitable for individuals who have an active lifestyle or mobility requirements where traditional pneumatic compression devices are expected to impede sufficient compliance with treatment. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have venous ulcers who receive pneumatic or non-pneumatic compression pumps, the evidence includes RCTs and one systematic review. Relevant outcomes are symptoms, change in disease status, morbid events, and quality of life. A meta-analysis of 3 trials found significantly higher healing rates with lymphedema pumps plus continuous compression than with continuous compression alone; however, 2 of the 3 trials were judged to be at high risk of bias. A 2020 RCT compared lymphedema pumps with continuous compression did not find significant between-group differences in healing rates or durability of pain relief. No prospective, comparative studies assessing the use of non-pneumatic compression devices for the treatment of venous ulcers were identified. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Additional Information

2025 Input

Clinical input was sought to help determine whether the use of pneumatic compression pumps for individuals with lymphedema would provide a clinically meaningful improvement in net health outcome and represents generally accepted medical practice in selected patients. In response to requests, clinical input was received from 3 respondents identified by the National Commission on

Lymphatic Diseases (NCLD) or an academic medical center. In addition to this request, a plastic surgeon specializing in lymphedema research and reconstruction at a major academic medical center was interviewed.

For individuals with lymphedema who failed to respond to conservative therapy, clinical input supports that use of pneumatic compression pumps applied to the chest and/or trunk in addition to the limbs is consistent with generally accepted medical practice and its use is expected to provide a clinically meaningful improvement in the net health outcome in individuals who do not respond to limb compression alone. For individuals with lymphedema who failed to respond to conservative therapy, use of pneumatic compression pumps applied to the head or neck was mixed, with respondents citing limited direct experience. Ongoing evidence generation in patients treated for head and neck cancers is expected to elucidate clinical benefit. Respondents also supported the use of novel non-pneumatic compression pumps, noting that the evidence supports their noninferiority compared to traditional, pneumatic devices - and helps to support patient compliance with treatment.

Further details from clinical input are included in the Appendix.

Related Policies

- Bioimpedance Devices for Detection and Management of Lymphedema

Benefit Application

Benefit determinations should be based in all cases on the applicable member health services contract language. To the extent there are conflicts between this Medical Policy and the member health services contract language, the contract language will control. 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.

Some state or federal law may prohibit health plans from denying FDA-approved Healthcare Services as investigational or experimental. In these instances, Blue Shield of California may be obligated to determine if these FDA-approved Healthcare Services are Medically Necessary.

Regulatory Status

The Women's Health and Cancer Rights Act of 1998 mandates that a group health plan or group health insurance policy that provides medical and surgical benefits with respect to a mastectomy shall provide coverage for “prostheses and physical complications of all stages of mastectomy, including lymphedemas; in a manner determined in consultation with the attending physician and the patient.”

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).

In 2024, the FDA cleared the Dayspring (Koya Medical, Inc.) non-pneumatic, wearable limb compression system. The device 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 various conditions, including lymphedema and venous insufficiency.

FDA product code: JOW.

Rationale

Background

Lymphedema

Lymphedema is an accumulation of fluid due to disruption of lymphatic drainage. It is characterized by nonpitting swelling of an extremity or trunk, and is associated with wound healing impairment, recurrent skin infections, pain, and decreased quality of life. Lymphedema can be caused by congenital or inherited abnormalities in the lymphatic system (primary lymphedema) but is most often caused by acquired damage to the lymphatic system (secondary lymphedema). Breast cancer treatment (surgical removal of lymph nodes and radiotherapy) is one of the most common causes of secondary lymphedema. In a systematic review of 72 studies (N=29,612 women), DiSipio et al (2013) reported that nearly 20% of breast cancer survivors will develop arm lymphedema.[1,] The risk factors with robust evidence for the development of lymphedema included extensive surgical procedures (such as axillary lymph node dissection, a higher number of lymph nodes removed, and mastectomy) as well as being overweight or obese.

Diagnosis and Staging

A diagnosis of secondary lymphedema is based on history (e.g., cancer treatment, trauma) and physical examination (localized, progressive edema and asymmetric limb measurements) when other causes of edema can be excluded. Imaging, such as MRI, computed tomography, ultrasound, or lymphoscintigraphy, may be used to differentiate lymphedema from other causes of edema in diagnostically challenging cases.

Table 1 lists International Society of Lymphology guidance for staging lymphedema (2023) based on "softness" or "firmness" of the limb and the changes with an elevation of the limb.[2,]

Table 1. Recommendations for Staging Lymphedema

Stage	Description
Stage 0 (latent or subclinical)	Swelling is not yet evident despite impaired lymph transport, subtle alterations in tissue fluid/composition, and changes in subjective symptoms. It can be transitory and may exist months or years before overt edema occurs (Stages 1-III).
Stage I (mild)	Early accumulation of fluid relatively high in protein content (e.g., in comparison with "venous" edema) which subsides with limb elevation. Pitting may occur. An increase in various types of proliferating cells may also be seen.
Stage II (moderate)	Involves the permanent accumulation of pathologic solids such as fat and proteins and limb elevation alone rarely reduces tissue swelling, and pitting is manifest. Later in this stage, the limb may not pit as excess subcutaneous fat and fibrosis develop.
Stage III (severe)	Encompasses lymphostatic elephantiasis where pitting can be absent and trophic skin changes such as acanthosis, alterations in skin character and thickness, further deposition of fat and fibrosis, and warty overgrowths have developed. It should be noted that a limb may exhibit more than one stage, which may reflect alterations in different lymphatic territories.

Management and Treatment

Lymphedema is treated using elevation, compression, and exercise. Conservative therapy may consist of several features depending on the severity of the lymphedema. Individuals are educated on the importance of self-care including hygiene practices to prevent infection, maintaining ideal body weight through diet and exercise, and limb elevation. Compression therapy consists of repeatedly applying padding and bandages or compression garments. Manual lymphatic drainage is a light pressure massage performed by trained physical therapists or by affected individuals designed to move fluid from obstructed areas into functioning lymph vessels and lymph nodes. Complete decongestive therapy is a multiphase treatment program involving all of the previously mentioned conservative treatment components at different intensities. Pneumatic compression pumps may also be considered as an adjunct to conservative therapy or as an alternative to self-manual lymphatic drainage in individuals who have difficulty performing self-manual lymphatic drainage. In individuals with more advanced lymphedema after fat deposition and tissue fibrosis has occurred, palliative surgery using reductive techniques such as liposuction may be performed.

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.

Compression Pumps

Pneumatic compression pumps (PCPs) may be used in lymphedema or wound care clinics, purchased, or rented for home use; home use is addressed herein. PCPs 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 PCPs 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. PCPs are also proposed to supplement standard care for patients with venous ulcers. Recently, non-pneumatic, wearable compression pumps have become available. These garments can be programmed to provide graduated sequential compression therapy while providing patients with a functional range of motion and mobility.

Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent 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.

Lymphedema–Pneumatic Compression Pumps Applied to the Limb Only

Clinical Context and Therapy Purpose

The purpose of pneumatic compression pumps (PCPs) 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 (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 (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

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 (IPC) pumps.[3,] Oremus et al identified 12 studies focusing on the treatment of lymphedema with IPC 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.[4,] 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 IPC. Study findings were not pooled. According to reviewers, 2 RCTs found that IPC was superior to decongestive therapy or self-massage, but 3 other RCTs failed to show that IPC was superior to another conservative treatment.

A systematic review by Shao et al (2014) addressed pneumatic compression pumps for the treatment of breast cancer-related lymphedema.[5,] 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).

Hou et al (2024) conducted a systematic review and meta-analysis of 12 studies (identified through March 2024) comparing the efficacy of IPC as an addition to complete decongestive therapy (CDT) for treatment of breast cancer-related upper limb lymphedema.[6,] Results showed that additional application of IPC to CDT could further improve lymphedema within 4 weeks after the treatment period (standardized mean difference (SMD), -0.2 mL; 95% CI, -0.33 to -0.07 mL). However, this additional benefit was weakened within about 9.4±2.6 weeks' follow-up duration after ceasing physical therapy (SMD, -0.15 mL; 95% CI, -0.33 to 0.04 mL). To sustain the synergistic benefits of CDT and IPC in fostering lymphatic drainage and alleviating lymphedema, the authors recommend periodic, continuous treatment. The duration of treatment examined in the studies spanned from 4 to 12 weeks, which may introduce potential bias.

Yao et al (2024) conducted a systematic review and meta-analysis of 9 RCTs to compare the efficacy of decongestive lymphatic therapy (DLT) with IPC versus DLT alone in the management of upper limb lymphedema following breast cancer surgery.[7,] The pooled SMD for percentage volume reduction was 0.63 (95% CI, -0.24 to 1.50; I^2 = 91%), showing no significant difference between the DLT alone and DLT combined with IPC (p=.15). Pain and heaviness scores were also comparable between the groups. There was a significant difference in external rotation joint mobility (SMD = 0.62; 95% CI, 0.08 to 1.16; I^2 = 23.8%), favoring DLT with IPC. Overall, the study indicates that DLT with IPC is as effective as DLT alone in managing upper limb lymphedema following breast cancer surgery. DLT with IPC has a more pronounced effect on enhancing external rotation joint mobility.

Section Summary: Lymphedema–Pneumatic Compression Pumps Applied to the Limb Only
Multiple RCTs and systematic reviews have been conducted primarily focusing on upper-limb lymphedema secondary to breast cancer. Most of these RCTs were deemed moderate-to-high quality by the Agency for Healthcare Research and Quality, and about half reported significant improvements with the use of pumps compared to conservative care. Recent meta-analyses indicate that incorporating intermittent pneumatic compression (IPC) with complete decongestive therapy can further enhance lymphedema management within four weeks post-treatment. Similar findings are observed when IPC is combined with decongestive lymphatic therapy compared to decongestive lymphatic therapy alone in managing upper limb lymphedema after breast cancer surgery, with the former combined regimen showing improved external rotation joint mobility.

Lymphedema–Pneumatic Compression Pumps Applied to the Limb and Chest and/or Trunk

Clinical Context and Therapy Purpose

The purpose of pneumatic compression pumps applied to the limb and chest and/or trunk 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 limb and chest and/or trunk.

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 (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.[8,] 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.
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.[9,] 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 Limb and Chest and/or Trunk

Two industry-sponsored RCTs of the Flexitouch system (Tactile Medical), published in 2012, have compared treatment with and without truncal involvement. In one RCT, two (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 (eg, functional status, quality of life). The second 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.

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
Systematic Reviews
Cheng et al. (2023) performed a systematic review and meta-analysis of 23 studies published through January 2023 (N=2147 participants) to evaluate rehabilitation interventions for lymphedema of the head and neck.[10,]. The studies were categorized by type of intervention, encompassing standard lymphedema therapy (standard or modified CDT, early manual lymphatic drainage, focused exercise) and adjunct therapies (advanced pneumatic compression devices (APCDs), kinesio taping, photobiomodulation, acupuncture/moxibustion, sodium selenite supplement use). Six studies (n=399 participants), including one RCT and five observational studies, assessed the Flexitouch APCD (Tactile Medical). The RCT by Ridner et al. (2021) detailed below (n=49) revealed that most participants, who had either finished CDT or lacked access to it, used the device for a single 32-minute session per day during the 8-week industry-sponsored trial, as opposed to the recommended two sessions per day. In the observational studies, the majority of participants also adhered to one 32-minute session daily. The duration of the intervention in these studies varied from a single session to six months. Most studies featured participants who had completed CDT or were concurrently undergoing CDT, while one study specifically noted that none of its participants used CDT. Four studies (80%) were funded by or had authors affiliated with Flexitouch. The single non-industry-sponsored study reported difficulties in obtaining the APCD, with only 35 (of 84) participants (42%) receiving the device as prescribed.[11,] Although the included studies showed benefits of using APCD, they had a high risk of bias and were therefore considered low-quality evidence. The Ridner RCT involved a 2-month intervention compared to a waitlist control group. This trial showed improvements in clinician-rated external lymphedema and subjective swallowing in the APCD group, although no improvement was found in endoscopic assessments of internal lymphedema. The largest observational study, conducted by Gutierrez et al (2020) with 205 participants who had used the APCD for over 5 years following a diagnosis of head and neck cancer-associated lymphedema, reported subjective improvements in symptoms and function after APCD use.[12,] Overall, the current evidence does not provide sufficient information to determine the optimal timing, duration, and intensity of APCD use in the management of lymphedema associated with head and neck.

Randomized Controlled Trial

Ridner et al (2021) (included in the above systematic review) evaluated the Flexitouch system for head and neck lymphedema in an open-label, randomized, wait-list controlled study.[13,] 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)[13,]	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, and had either already received lymphedema therapy or were unable to access therapy due to barriers (eg, 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.
[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)[13,]	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)[13,]		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. 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)[13],		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 and a systematic review have assessed the use of pneumatic compression treatment for head and neck lymphedema. The RCT, comparing treatment with a pneumatic compression pump along with lymphedema self-management compared to self-management alone, examined the feasibility, adherence, and safety of the Flexitouch advanced pneumatic compression device (APCD) by Tactile Medical. The findings showed some improvements in patient-reported outcomes and swelling, although adherence was low, with only one patient using the device twice daily as prescribed. The systematic review also suggested benefits from using the APCD, and it was considered safe and feasible according to the observational studies that reported adverse events. Most studies included participants who had completed or were concurrently undergoing CDT. Out of the 5 observational studies included in the systematic review, four (80%) were funded by or had authors affiliated with Flexitouch. The only study not sponsored by the industry highlighted difficulties in obtaining the APCD, with fewer than half of the patients receiving the device as prescribed. Further research with larger sample sizes and comparisons against the gold standard of CDT is necessary to establish the efficacy of this treatment approach.

Lymphedema–Non-Pneumatic Compression Pumps Applied to the Limb Only

Clinical Context and Therapy Purpose

The purpose of non-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 non-pneumatic compression pumps applied to limb only, such as the Koya Dayspring system, which is available in full leg, lower leg, or arm models.

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 pumps applied to the limb.

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

Randomized Clinical Trials

Rockson et al (2022) reported on findings from the multicenter, randomized, crossover trial (NILE) of advanced pneumatic compression devices (APCD) compared to non-pneumatic compression devices (NPCD) among 50 adult women with unilateral, upper extremity, breast cancer-related lymphedema.[14,] Patients were randomly assigned to either NPCD (Koya Dayspring) or a commercially available APCD for an initial 28 day treatment phase, before undergoing a 4-week washout period prior to crossover to the alternate device. The mean time interval since surgery or radiation treatment was 59 ± 59.6 months and the mean elapsed time interval since lymphedema diagnosis was 54 ± 48.5 months. Static compression garments were in use by all patients at enrollment. The primary, noninferiority endpoint was change in limb edema volume, with treatment response defined as a >2% reduction in edema volume. Secondary outcome measures included quality of life assessed via the Lymphedema Quality of Life Questionnaire (LYMQOL) and treatment adherence. The trial found superior edema volume reduction with NPCD (64.6%, 95% CI, 31.71-97.58) compared to APCD (27.7%; 95% CI, 4.80-60.14; p <.05), resulting in an overall response rate of 88% vs. 42% (p <.05),

respectively. These results were coupled with a statistically significant 2.44 point improvement in LYMQOL during NPCD treatment compared to no significant change with APCD. Adherence to treatment with the NPCD was 95.6% compared to 49.8% for APCD ($p < 0.01$). The crossover washout period duration was considered sufficient as baseline edema volume measurements were comparable on day 0 within each treatment group.

Barfield et al (2024) conducted a multicenter, randomized, crossover trial (TEAYS) of APCD compared to NPCD among 71 patients (108 affected limbs) with primary or secondary unilateral or bilateral lower extremity lymphedema or phlebolymphedema.[15,] Patients were randomly assigned to either the NPCD (Koya Dayspring) or a commercially available APCD for an initial 90 day treatment phase, before undergoing a 30-day washout period prior to crossover to the alternate device. At enrollment, all patients were receiving conservative therapy and 56% had prior experience using a pneumatic compression device. The primary, endpoint was change in limb edema volume. Additional efficacy outcome measures included quality of life assessed via the Lymphedema Quality of Life Questionnaire (LYMQOL) and treatment adherence. The trial found statistically significant edema volume reduction with NPCD (369.9 ± 68.2 mL) compared to APCD (83.1 ± 67.99 mL, $p <.005$). These results were coupled with a statistically significant 1.01 point improvement in LYMQOL during NPCD treatment compared to no significant change with APCD. Adherence to treatment with the NPCD was 81% compared to 56% for APCD ($p < 0.05$). An additional analysis indicated no impact on order of device randomization on treatment response or adherence. It is unclear whether previous patient experience with APCDs prior to enrollment impacted compliance. However, in the subset of APCD treatment naive participants (n=31), similar improvements in limb edema reduction and treatment adherence were seen as in the broader study population.

Section Summary: Lymphedema–Non-Pneumatic Compression Pumps Applied to the Limb Only
Randomized crossover trials have compared use of NPCDs to APCDs in both upper and lower extremity lymphedema. These studies have consistently supported noninferior reductions in limb edema volume, higher rates of patient compliance, and improvements on quality of life assessments with use in short-term observation (28 to 90 days). Additionally, clinical input supports the use of non-pneumatic, wearable compression devices on the basis of this research and clinical experience. These devices may be particularly suitable for individuals who have an active lifestyle or mobility requirements where traditional pneumatic compression devices are expected to impede sufficient compliance with treatment.

Pneumatic and Non-Pneumatic Compression Pumps Applied to Venous Ulcers

Clinical Context and Therapy Purpose

The purpose of pneumatic and non-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 or non-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.[16,] 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-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.[17,] 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.[18,]

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).[19,] 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

RCTs and a systematic review have assessed the use of pneumatic compression treatment for venous ulcers. A meta-analysis of 3 trials found significantly higher healing rates with lymphedema pumps plus continuous compression than with continuous compression alone; however, 2 of the 3 trials were judged to be at high risk of bias. A more recent small RCT comparing lymphedema pumps with continuous compression did not find significant between-group differences in healing rates. Prospective, comparative studies addressing the use of non-pneumatic compression devices for the treatment of venous ulcers were not identified.

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.

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise stated.

2025 Input

In response to requests, clinical input was received from 3 respondents identified by the National Commission on Lymphatic Diseases (NCLD) or an academic medical center. Respondents affirmed that the use of pneumatic compression pumps in individuals with lymphedema to the chest or trunk in addition to the limbs provides a clinically meaningful improvement in net health outcome and represents generally accepted medical practice in patients that do not respond to limb compression alone. In addition, respondents endorsed the use of non-pneumatic compression devices, noting that such devices permit maintaining mobility and compliance with treatment. For individuals with lymphedema who failed to respond to conservative therapy, use of pneumatic compression pumps applied to the head or neck was mixed, with respondents citing limited direct experience. Ongoing evidence generation in patients treated for head and neck cancers is expected to elucidate clinical benefit. Additional details are available in the Appendix. In addition to this request, a plastic surgeon specializing in lymphedema research and reconstruction at a major academic medical center was interviewed.

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.

American Academy of Family Physicians

In 2019, the American Academy of Family Physicians published recommendations for diagnosis and treatment of venous ulcers.[20,] The following statements were issued regarding use of intermittent pneumatic compression.

- "Intermittent pneumatic compression may be considered when there is generalized, refractory edema from venous insufficiency; lymphatic obstruction; and significant ulceration of the lower extremity. Although intermittent pneumatic compression is more effective than no compression, its effectiveness compared with other forms of compression is unclear. Intermittent pneumatic compression may improve ulcer healing when added to layered compression."

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.[21,] 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.[22,] Treatment should include compression garments, self-massage, skin care, exercises, and, if desired, pneumatic compression therapy applied in the home.

National Comprehensive Cancer Network

The National Comprehensive Cancer Network (NCCN) guidelines on survivorship (v.2.2025) recommend that survivors at risk for lymphedema be referred to a certified lymphedema specialist for consideration of the following compression treatments: "fit for compression garments, review use of garments, pneumatic compression for ongoing home management, and review use of multilayered bandage wrapping."[23,]

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[24,]: "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.[25,]

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

A 2002 national coverage determination for pneumatic compression devices by the Centers for Medicare & Medicaid Services has stated the following[26,]:

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 unpublished trials that might influence this review are listed in Table 5.

Table 5. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT06418282[a]	An Open-label, Multi-center, Prospective VA Study to Evaluate the Effectiveness and Health Economics of a Novel Portable Non-Pneumatic Active Compression Device (NPCD) for Lymphedema/ Phlebolymphedema	50	Jan 2025
Unpublished			
NCT04797390[a]	A Randomized Trial of an Advanced Pneumatic Compression Device vs. Usual Care for Head and Neck Lymphedema	250	Jan 2025
NCT05659394[a]	Intermittent Pneumatic Compression of the Thigh for the Treatment of Lower Limb Wounds: a Randomised Control Trial (IPCOTT)	136	Mar 2024

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

Appendix 1

2025 Clinical Input

Objective

Clinical input was sought to help determine whether the use of pneumatic compression pumps in individuals with lymphedema to body sites other than the limbs provides a clinically meaningful improvement in net health outcome and represents generally accepted medical practice in selected patients. In response to requests, clinical input was received from 3 respondents identified by the National Commission on Lymphatic Diseases (NCLD) or an academic medical center.

Respondents

Clinical input was provided by the following specialty societies and physician members identified by a specialty society or clinical health system:

- Stanley G. Rockson, MD, identified by the National Commission on Lymphatic Diseases (NCLD)
- Babak Mehrara, MD, identified by the NCLD
- David W. Chang, MD, University of Chicago Medicine

Ratings

Clinical Indication	Respondent	Identified by	Confidence Level That Clinical Use is Expected to Provide a Clinically Meaningful Improvement in Net Health Outcome (Low – Intermediate – High)						Confidence Level That Clinical Use Is Consistent with Generally Accepted Medical Practice (Low – Intermediate – High)					
			Yes or No	1	2	3	4	5	Yes or No	1	2	3	4	5
Use of pneumatic compression pumps applied to chest and/or trunk in addition to limb in individuals with lymphedema who failed to respond to conservative therapy	Dr. Rockson*	NCLD	Yes				■		Yes					■
	Dr. Mehrara*		Yes				■		Yes				■	
	Dr. Chang*	University of Chicago	Yes			■			Yes			■		
Use of pneumatic compression pumps applied to head and/or neck in individuals with lymphedema who failed to respond to conservative therapy	Dr. Rockson*	NCLD	Yes				■		Yes				■	
	Dr. Mehrara*		NR						NR					
	Dr. Chang*	University of Chicago	Yes		■				Yes		■			

NCLD: National Commission on Lymphatic Diseases; NR: no response.
* Indicates that conflicts of interest related to the topic where clinical input is being sought were identified by this respondent (see Appendix).

Respondent Profile

#	Respondent	Clinical Specialty	Board Certification
1	Stanley G. Rockson, MD, Stanford University	Cardiovascular Medicine	Diplomate, Internal Medicine; Cardiovascular Medicine
2	Babak Mehrara, MD, Memorial Sloan Kettering Cancer Center	Plastic Surgery	Plastic Surgery; Microsurgery
3	David W. Chang, MD, University of Chicago Medicine	Plastic & Reconstructive Surgery	Plastic & Reconstructive Surgery; Microsurgery; Hand Surgery

Respondent Conflict of Interest Disclosure

#	1) Research support related to the topic where clinical input is being sought		2) Positions, paid or unpaid, related to the topic where clinical input is being sought		3) Reportable, more than $1,000, health care–related assets or sources of income for myself, my spouse, or my dependent children related to the topic where clinical input is being sought		4) Reportable, more than $350, gifts or travel reimbursements for myself, my spouse, or my dependent children related to the topic where clinical input is being sought	
	YES/NO	Explanation	YES/NO	Explanation	YES/NO	Explanation	YES/NO	Explanation
1	Yes	Clinical trials sponsored by Stanford University and Celltaxis LLC	Yes	I am have an endowed chair and serve as the Allan and Tina Neill Professor of Lymphatic Research and Medicine at Stanford; this is a salaried position.	Yes	I serve as a consultant for Koya, Inc.	No	
2	Yes	I have grant funding from the NIH.	No		No		No	

#	1) Research support related to the topic where clinical input is being sought		2) Positions, paid or unpaid, related to the topic where clinical input is being sought	3) Reportable, more than $1,000, health care–related assets or sources of income for myself, my spouse, or my dependent children related to the topic where clinical input is being sought	4) Reportable, more than $350, gifts or travel reimbursements for myself, my spouse, or my dependent children related to the topic where clinical input is being sought
3	Yes	I have an ongoing prospective randomized trial regarding the use of biobridge nanofibrils with vascularized lymph-node transplants; was an NCI and now industry(Firbrolign) sponsored	No	No	No

Specialty Society respondents provided aggregate information that may be relevant to the group of clinicians who provided input to the Society-level response.

Clinical Input Responses

Question 1: We are seeking your rationale on whether using pneumatic compression pumps applied to chest and/or trunk in addition to limb in individuals with lymphedema who failed to respond to conservative therapy provides a clinically meaningful improvement in net health outcome.

#	Rationale
1	The use of trunk compression provides a hypothetical scenario in which the pneumatic compression can optimally help to decompress the affected limbs by facilitating the enhanced capacity of the central lymphatic circulation to accommodate increased flow rates This application is hypothetical and is not directly supported by comparative studies. Contraindications would either anatomy that prohibits this approach because of pain, or individuals in whom the compliance of the R heart renders this approach hemodynamically dangerous.
2	These devices may be helpful in patients with limb swelling that does not respond to traditional compression garments. Often patients have swelling of the axilla or trunk in addition to limb swelling. Conservative treatment of lymphedema with compression and decongestive therapy relies on rerouting lymphatic drainage to functional central lymphatic pathways. Thus, the use of chest or trunk compression may be beneficial in this process. Outcomes could include reductions in limb volume, BIS, improvement in skin changes, decreased incidence of infections. Patient reported outcomes may also be useful. Inclusion criteria: stage II-III lymphedema with truncal involvement; failure of conservative therapy. Exclusion: active infections, cardiopulmonary disease (eg. COPD), other contraindications (eg. rib fractures), recurrent disease in the axilla or limb.
3	In my experience, some patients do feel there's benefit to compression pumps while some do not. I think for some patients the compression pumps can be useful for chest/trunk/limbs.

Question 2: We are seeking your rationale on whether using pneumatic compression pumps applied to head and/or neck in individuals with lymphedema who failed to respond to conservative therapy provides a clinically meaningful improvement in net health outcome.

#	Rationale
1	Similar considerations apply here, but the use of this technology is hypothetical in this context and is not supported by outcomes studies
2	We do not have experience with this application

#	Rationale
3	I know some have used it for head and neck but don't have enough experience to comment on its effectiveness.

Question 3: Please describe clinical situations where use of programmable pneumatic compression pumps for lymphedema is clinically indicated and preferred versus nonprogrammable pneumatic compression.

#	Rationale
1	Similar considerations apply here, but the use of this technology is hypothetical in this context and is not supported by outcomes studies
2	Clinical Scenarios: limb and trunk lymphedema particularly in patients with advanced stage disease; genital or trunk lymphedema; failure of traditional CDT or surgery.
3	I usually leave this decision to the patient and lymphedema specialist who the patient is working with as the experience can vary.

Question 4: Is there evidence to support use of non-pneumatic, continuous, static compression pumps in individuals with lymphedema (e.g., Koya Dayspring)?

#	Rationale
1	Yes, there are published studies that indicate that the Koya Dayspring outperforms existing pneumatic technology, assessed in non-inferiority comparative crossover design
2	NA
3	I think for some patients this can be helpful.

References

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Documentation for Clinical Review

Please provide the following documentation:

- History and physical and/or consultation notes including:
  - Reason pneumatic compression pump required
  - Office and progress notes for the past three months
  - Documentation of prior conservative treatment including type, duration and effectiveness
  - Documentation of individual's characteristics preventing use of nonprogrammable pump or non-pneumatic pump, as applicable
- Treatment plan including estimated length of time device is needed (number of months)
- Prescription for pump and/or appliance

Post Service (in addition to the above, please include the following):

- Provider progress notes documenting response to initial treatment with the pump including:
  - Documentation of patient's compliance and tolerance to treatment plan
  - Documentation of decreased edema with pre- and post-treatment measurements and/or documented improvement in functional capacity
- Prescription and/or recommended treatment plan including estimated length of time (in months) device is further required

Coding

The list of codes in this Medical Policy is intended as a general reference and may not cover all codes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy.

Type	Code	Description
CPT®	None	
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

Type	Code	Description
	E0670	Segmental pneumatic appliance for use with pneumatic compressor, integrated, two 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
	E0675	Pneumatic compression device, high pressure, rapid inflation/deflation cycle, for arterial insufficiency (unilateral or bilateral system)
	E0676	Intermittent limb compression device (includes all accessories), not otherwise specified
	E0678	Nonpneumatic sequential compression garment, full leg
	E0679	Nonpneumatic sequential compression garment, half leg
	E0680	Nonpneumatic compression controller with sequential calibrated gradient pressure
	E0681	Nonpneumatic compression controller without calibrated gradient pressure
	E0682	Nonpneumatic sequential compression garment, full arm
	E0683	Nonpneumatic, nonsequential, peristaltic wave compression pump

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
10/15/2007	BCBSA Medical Policy adoption
12/18/2009	Policy revision without position change
07/22/2011	Administrative Review
03/29/2013	Policy revision with position change
06/28/2013	Policy Guideline clarification
01/30/2015	Policy title change from Compression Therapy for Lymphedema and Venous Stasis Ulcers Policy revision with position change effective 3/30/2015
03/30/2015	Policy revision with position change
12/30/2016	Policy revision without position change
05/01/2017	Policy revision without position change
05/01/2018	Policy revision without position change
05/01/2019	Policy revision without position change
05/01/2020	Annual review. No change to policy statement. Literature review updated.
11/01/2020	Administrative update. Policy guidelines updates
05/01/2021	Annual review. No change to policy statement. Literature review updated.
10/01/2021	Policy statement and literature updated.
11/01/2021	Code update.
05/01/2022	Annual review. No change to policy statement. Literature review updated.
05/01/2023	Annual review. Policy statement, guidelines and literature updated.
03/01/2024	Code update.
05/01/2024	Annual review. No change to policy statement. Policy guidelines and literature review updated.
03/01/2025	Annual review. No change to policy statement. Literature review updated.
09/01/2025	Annual review. Policy statement, guidelines, and literature review updated. Policy title changed from "Pneumatic Compression Pumps for Treatment of Lymphedema and Venous Ulcers" to current one. Coding update.

Definitions of Decision Determinations

Healthcare Services: For the purpose of this Medical Policy, Healthcare Services means procedures, treatments, supplies, devices, and equipment.

Medically Necessary: Healthcare Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield of California, are: (a) consistent with Blue Shield of California medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the member; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the member's illness, injury, or disease.

Investigational or Experimental: Healthcare Services which do not meet ALL of the following five (5) elements are considered investigational or experimental:

A. The technology must have final approval from the appropriate government regulatory bodies.
   - This criterion applies to drugs, biological products, devices and any other product or procedure that must have final approval to market from the U.S. Food and Drug Administration ("FDA") or any other federal governmental body with authority to regulate the use of the technology.
   - Any approval that is granted as an interim step in the FDA's or any other federal governmental body's regulatory process is not sufficient.
   - The indications for which the technology is approved need not be the same as those which Blue Shield of California is evaluating.

B. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.
   - The evidence should consist of well-designed and well-conducted investigations published in peer-reviewed journals. The quality of the body of studies and the consistency of the results are considered in evaluating the evidence.
   - The evidence should demonstrate that the technology can measure or alter the physiological changes related to a disease, injury, illness, or condition. In addition, there should be evidence, or a convincing argument based on established medical facts that such measurement or alteration affects health outcomes.

C. The technology must improve the net health outcome.
   - The technology's beneficial effects on health outcomes should outweigh any harmful effects on health outcomes.

D. The technology must be as beneficial as any established alternatives.
   - The technology should improve the net health outcome as much as, or more than, established alternatives.

E. The improvement must be attainable outside the investigational setting.
   - When used under the usual conditions of medical practice, the technology should be reasonably expected to satisfy Criteria C and D.

Feedback

Blue Shield of California is interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into

consideration. Our medical policies are available to view or download at www.blueshieldca.com/provider.

For medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as member health services contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member health services contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT	
BEFORE Red font: Verbiage removed	**AFTER** Blue font: Verbiage Changes/Additions
Pneumatic Compression Pumps for Treatment of Lymphedema and Venous Ulcers 1.01.18 **Policy Statement:** I. Single-compartment or multichamber *nonprogrammable* lymphedema pumps applied to the limb may be considered **medically necessary** when **either** of the following criteria is met: A. Treatment of lymphedema post mastectomy (in accordance with the "Women's Health and Cancer Rights Act of 1998") B. The treatment of lymphedema that has failed to respond to conservative measures, including, but not limited to, elevation of the limb and use of compression garments, or manual lymph drainage II. Single-compartment or multichamber *programmable* lymphedema pumps applied to the limb may be considered **medically necessary** when **either** of the following criteria is met: A. Treatment of lymphedema post mastectomy (in accordance with the "Women's Health and Cancer Rights Act of 1998") B. The treatment of lymphedema when **both** of the following criteria are met: 1. The individual is otherwise eligible for nonprogrammable pumps 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., contractures, dermatitis, highly sensitive skin, significant scarring, ulcerations)	**Compression Pumps for Treatment of Lymphedema and Venous Ulcers 1.01.18** **Policy Statement:** I. Single-compartment or multichamber *nonprogrammable* pneumatic compression pumps applied to the affected body sites (e.g., limb, trunk, chest, head, neck) may be considered **medically necessary** when **either** of the following criteria is met: A. Treatment of lymphedema post mastectomy (in accordance with the "Women's Health and Cancer Rights Act of 1998") B. Treatment of lymphedema that has failed to respond to conservative measures, including, but not limited to, elevation of the limb and use of compression garments, or manual lymph drainage II. Single-compartment or multichamber *programmable* pneumatic compression pumps applied to the affected body sites (e.g., limb, trunk, chest, head, neck) may be considered **medically necessary** when **either** of the following criteria is met: A. Treatment of lymphedema post mastectomy (in accordance with the "Women's Health and Cancer Rights Act of 1998") B. Treatment of lymphedema when the following criteria are met: 1. The individual is otherwise eligible for nonprogrammable pneumatic pumps 2. There is documentation that the individual has unique characteristics (e.g., significant scarring, recent surgery) that prevent satisfactory pneumatic compression with single-compartment or multichamber nonprogrammable compression pumps 3. The individual has had an adequate response to an initial course of treatment with a nonprogrammable pneumatic compression pump (see Policy Guidelines)

POLICY STATEMENT	
BEFORE Red font: Verbiage removed	AFTER Blue font: Verbiage Changes/Additions
III. Single-compartment or multichamber lymphedema pumps applied to the limb are considered **investigational** in all situations not specified above in the first 2 policy statements.	III. Single-compartment or multichamber lymphedema pumps are considered **investigational** in all situations not specified above in the first 2 policy statements.
IV. 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 **investigational**.	IV. Programmable, wearable non-pneumatic compression pumps (e.g., Koya Dayspring) applied to the limbs may be considered **medically necessary** for the treatment of lymphedema: A. The individual is otherwise eligible for a programmable pneumatic compression pump B. There is documentation that the individual has lifestyle considerations or mobility requirements where treatment compliance with a traditional programmable, pneumatic compression system is expected to be insufficient
V. The use of lymphedema pumps applied to the head and neck to treat lymphedema is considered **investigational**.	V. Programmable, wearable non-pneumatic compression pumps are considered **investigational** in all other situations not specified above.
VI. The use of pneumatic compression pumps to treat venous ulcers is considered **investigational**.	VI. The use of pneumatic or non-pneumatic compression pumps to treat venous ulcers is considered **investigational**.
VII. Continued use of a pneumatic compression pump may be considered **medically necessary** when documentation supports **both** of the following: A. Individual tolerance and compliance to the prescribed treatment plan B. Effectiveness of the pump as evidenced by decreased edema with pre- and post-treatment measurements and/or documented improvement in functional capacity	VII. Continued use of a pneumatic and non-pneumatic compression pump may be considered **medically necessary** when documentation supports **both** of the following: A. Individual tolerance and compliance to the prescribed treatment plan B. Effectiveness of the pump as evidenced by decreased edema with pre- and post-treatment measurements and/or documented improvement in functional capacity