Policy Number	MED202.060
Policy Effective Date	01/01/2026

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
Single-compartment or multi-chamber *nonprogrammable* pneumatic compression pumps applied to the limbs **may be considered medically necessary** for the treatment of lymphedema that has failed to respond to conservative measures, such as elevation of the limb and use of compression garments.

Single-compartment or multi-chamber *programmable* pneumatic compression pumps applied to the limbs **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 (e.g., significant scarring, recent surgery) that prevent satisfactory compression with single-compartment or multi-chamber nonprogrammable compression pumps; or
3. The individual has had an inadequate response to an initial course of treatment with a nonprogrammable pneumatic compression pump applied to the limbs. (See Policy Guidelines)

Single-compartment or multi-chamber *nonprogrammable* pneumatic compression pumps applied to the chest or trunk in addition to the limbs **may be considered medically necessary** for the treatment of lymphedema that has failed to adequately respond to both conservative measures and nonprogrammable pneumatic compression to the limbs only.

Single-compartment or multi-chamber *programmable* pneumatic compression pumps applied to the chest or trunk in addition to the limbs **may be considered medically necessary** for the treatment of lymphedema when:
1. The individual is otherwise eligible for *nonprogrammable* pneumatic pumps applied to the chest or trunk in addition to the limbs; and
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 multi-chamber *nonprogrammable* compression pumps; or
3. The individual has had an inadequate response to an initial course of treatment with a *nonprogrammable* pneumatic compression pump applied to the chest or trunk in addition to the limbs. (see Policy Guidelines)

Single-compartment or multi-chamber compression pumps **are considered experimental, investigational and/or unproven** in all situations other than those specified above, including when applied to the head or neck.

Programmable, wearable non-pneumatic compression pumps (e.g., Koya Dayspring) applied to the limbs **may be considered medically necessary** for the treatment of lymphedema when:
1. The individual is otherwise eligible for a *programmable* pneumatic compression pump; and
2. 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.

Programmable, wearable non-pneumatic compression pumps **are considered experimental, investigational and/or unproven** in all other situations not specified above.

Chronic Limb-Threatening Ischemia (CLTI)
For individuals with chronic limb-threatening ischemia (CLTI) for whom revascularization is not an option, the use of an intermittent pneumatic compression device **may be considered medically necessary** to augment wound healing or ameliorate ischemic rest pain.

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)

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 graduated compression.

Policy Guidelines

Medically necessary positions for treatment of lymphedema at body sites other than the limbs are based on clinical input. 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. Clinical input was mixed on the use of compression pumps for the treatment of head and neck lymphedema. Ongoing evidence generation in head and neck cancer populations is expected to elucidate clinical benefit.

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 multi-chamber (segmented) and have varying designs and complexity. Non-pneumatic, programmable, wearable devices are also available.

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 magnetic resonance imaging (MRI), computed tomography (CT), 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 I-lll).
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 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.

Chronic Limb-Threatening Ischemia (CLTI)

Chronic limb-threatening ischemia is a condition characterized by chronic (>2 wk) ischemic rest pain, nonhealing wounds and ulcers, or gangrene attributable to objectively proven arterial occlusive disease. Current nomenclature has evolved from the previous commonly used term of chronic limb ischemia (CLI) to reflect the chronic nature of this condition and its potentially limb-threatening nature with associated risk for amputation and to distinguish it from acute limb ischemia (ALI). Acute (≤2 wk) hypoperfusion of the limb that may be characterized by pain, pallor, pulselessness, poikilothermia (inability to maintain core temperature), paresthesias, and/or paralysis.

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. Multi-chamber 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.

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 have been 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 Unit (listed above);
5. NanoTherm™ (ThermoTek);
6. CTU676 devices (Compression Technologies); and
7. 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.

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

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.

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 (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 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. (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 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 trunk and/or chest 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 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 (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. (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 (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 was 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 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 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 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.

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 2 and 3. 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 2. Summary of Key RCT Characteristics

Study	Countries	Sites	Dates	Participants	Interventions[a]	
					Active	**Comparator**
Ridner et al. (2021) (13)	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 3. 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) (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 4 and 5 display notable limitations identified in the study.

Table 4. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-up[e]
Ridner et al. (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. 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 5. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Ridner et al. (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 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 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 (e.g., 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 (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.

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 policy.

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 (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. (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 (e.g., not blinded, unclear allocation or concealment). There was a high degree of heterogeneity among trials, and findings from other RCTs were not pooled. Neither of the 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

A 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.

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

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 the3 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 sufficient to determine that the technology results in an improvement in the net health outcome.

Clinical 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.

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.

Practice Guidelines and Position Statements

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)

American College of Cardiology, American Heart Association, et al.

The 2024 Guideline for the Management of Lower Extremity Peripheral Artery Disease: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines includes the following recommendation on pneumatic compression for chronic limb-threatening ischemia (CLTI): “In patients with CLTI for whom revascularization is not an option, arterial intermittent pneumatic compression devices may be considered to augment wound healing or ameliorate ischemic rest pain.” (Strength of Recommendation: 2B [weak, benefit ≥ risk]; Level of Evidence B-NR [Nonrandomized: Moderate-quality evidence from 1 or more well-designed, well-executed nonrandomized studies, observational studies, or registry studies. Meta-analyses of such studies.]) (26)

Medicare National Coverage

A 2002 national coverage determination for pneumatic compression devices by the Centers for Medicare & Medicaid Services has stated the following (27):

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 6.

Table 6. Summary of Key Trials

NCT Number	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.

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, E0658, E0659, E0660, E0665, E0666, E0667, E0668, E0669, E0670, E0671, E0672, E0673, E0675, E0676, E0677, E0678, E0679, E0680, E0681, E0682, E0683 [Deleted 1/2024: K1024, K1025, K1031, K1032, K1033]

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

References

1. DiSipio T, Rye S, Newman B, et al. Incidence of unilateral arm lymphoedema after breast cancer: a systematic review and meta-analysis. Lancet Oncol. May 2013; 14(6):500-515. PMID 23540561
2. International Society of Lymphology Executive Committee. The Diagnosis and Treatment of Peripheral Lymphedema: 2023 Consensus Document of the International Society of Lymphology. 2023; Available at: <https://www.journals.edu> (accessed November 25, 2024).
3. Oremus M, Walker K, Dayes I, et al. Technology Assessment: Diagnosis and Treatment of Secondary Lymphedema (Project ID: LYMT0908). Rockville, MD: Agency for Healthcare Research and Quality; 2010.
4. Oremus M, Dayes I, Walker K, et al. Systematic review: conservative treatments for secondary lymphedema. BMC Cancer. Jan 4 2012; 12:6. PMID 22216837
5. Shao Y, Qi K, Zhou QH, et al. Intermittent pneumatic compression pump for breast cancer-related lymphedema: a systematic review and meta-analysis of randomized controlled trials. Oncol Res Treat. Apr 2014; 37(4):170-174. PMID 24732640
6. Hou S, Li Y, Lu W, et al. Efficacy of intermittent pneumatic compression on breast cancer-related upper limb lymphedema: a systematic review and meta-analysis in clinical studies. Gland Surg. Aug 31 2024; 13(8):1358-1369. PMID 39282029
7. Yao M, Peng P, Ding X, et al. Comparison of Intermittent Pneumatic Compression Pump as Adjunct to Decongestive Lymphatic Therapy against Decongestive Therapy Alone for Upper Limb Lymphedema after Breast Cancer Surgery: A Systematic Review and Meta-Analysis. Breast Care (Basel). Jun 2024; 19(3):155-164. PMID 38894955
8. Fife CE, Davey S, Maus EA, et al. A randomized controlled trial comparing two types of pneumatic compression for breast cancer-related lymphedema treatment in the home. Support Care Cancer. May 2 2012; 20(12):3279-3286. PMID 22549506
9. Ridner SH, Murphy B, Deng J, et al. A randomized clinical trial comparing advanced pneumatic truncal, chest, and arm treatment to arm treatment only in self-care of arm lymphedema. Breast Cancer Res Treat. Jan 2012; 131(1):147-158. PMID 21960113

10. Cheng JT, Leite VF, Tennison JM, et al. Rehabilitation Interventions for Head and Neck Cancer-Associated Lymphedema: A Systematic Review. JAMA Otolaryngol Head Neck Surg. Aug 01 2023; 149(8):743-753. PMID 37382963
11. Shires CB, Harris P, Dewan K. Feasibility of machine-delivered sequential massage for the management of lymphedema in the head and neck cancer survivor. Laryngoscope Investig Otolaryngol. Jun 2022; 7(3):774-778. PMID 35734055
12. Gutierrez C, Mayrovitz HN, Naqvi SHS, et al. Longitudinal effects of a novel advanced pneumatic compression device on patient-reported outcomes in the management of cancer-related head and neck lymphedema: A preliminary report. Head Neck. Aug 2020; 42(8):1791-1799. PMID 32187788
13. Ridner SH, Dietrich MS, Deng J, et al. Advanced pneumatic compression for treatment of lymphedema of the head and neck: a randomized wait-list controlled trial. Support Care Cancer. Feb 2021; 29(2):795-803. PMID 32488435
14. Rockson SG, Whitworth PW, Cooper A, et al. Safety and effectiveness of a novel nonpneumatic active compression device for treating breast cancer-related lymphedema: A multicenter randomized, crossover trial (NILE). J Vasc Surg Venous Lymphat Disord. Nov 2022; 10(6):1359-1366. PMID 35952956
15. Barfield M, Winokur R, Berland T, et al. Results from a comparative study to evaluate the treatment effectiveness of a nonpneumatic compression device vs an advanced pneumatic compression device for lower extremity lymphedema swelling (TEAYS study). J Vasc Surg Venous Lymphat Disord. Jan 2025; 13(1):101965. PMID 39222789
16. Nelson EA, Hillman A, Thomas K. Intermittent pneumatic compression for treating venous leg ulcers. Cochrane Database Syst Rev. May 12 2014; 5(5):CD001899. PMID 24820100
17. Dolibog P, Franek A, Taradaj J, et al. A comparative clinical study on five types of compression therapy in patients with venous leg ulcers. Int J Med Sci. Jan 2014; 11(1):34-43. PMID 24396284
18. Dolibog P, Franek A, Taradaj J, et al. A randomized, controlled clinical pilot study comparing three types of compression therapy to treat venous leg ulcers in patients with superficial and/or segmental deep venous reflux. Ostomy Wound Manage. Aug 2013; 59(8):22-30. PMID 23934375
19. Alvarez OM, Markowitz L, Parker R, et al. Faster healing and a lower rate of recurrence of venous ulcers treated with intermittent pneumatic compression: results of a randomized controlled trial. Eplasty. Jun 5 2020; 20:e6. PMID 32636985
20. Bonkemeyer Millan S, Gan R, Townsend PE. Venous Ulcers: Diagnosis and Treatment. Am Fam Physician. Sep 01 2019; 100(5):298-305. PMID 31478635
21. Lurie F, Malgor RD, Carman T, et al. The American Venous Forum, American Vein and Lymphatic Society and the Society for Vascular Medicine expert opinion consensus on lymphedema diagnosis and treatment. Phlebology. May 2022; 37(4):252-266. PMID 35258350
22. Lee BB, Andrade M, Antignani PL, et al. Diagnosis and treatment of primary lymphedema. Consensus document of the International Union of Phlebology (IUP)-2013. Int Angiol. Dec 2013; 32(6):541-574. PMID 24212289

23. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines). Survivorship. Version 2.2025. May 23, 2025. Available at: <https://www.nccn.org> (accessed June 16, 2025).
24. O'Donnell TF, Jr., Passman MA, Marston WA, et al. Management of venous leg ulcers: clinical practice guidelines of the Society for Vascular Surgery® and the American Venous Forum. J Vasc Surg. Aug 2014; 60(2 Suppl):3s-59s. PMID 24974070
25. Marston W, Tang J, Kirsner RS, et al. Wound Healing Society 2015 update on guidelines for venous ulcers. Wound Repair Regen. 2016; 24(1):136-144. PMID 26663616
26. Gornik HL, Aronow HD, Goodney PP, et al. 2024 ACC/AHA/AACVPR/APMA/ABC/SCAI/ SVM/SVN/SVS/SIR/VESS guideline for the management of lower extremity peripheral artery disease: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Circulation. 2024; 149:e1313–e1410. PMID 38743805
27. Centers for Medicare and Medicaid Services. National Coverage Determination (NCD) for Pneumatic Compression Devices (280.6) (2002). Available at <https://www.cms.gov> (accessed September 1, 2025).

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 <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
01/01/2026	Document updated. The following changes were made to Coverage: Added: 1)“single-compartment or multi-chamber pneumatic” compression pumps to coverage statements for lymphedema; 2) coverage for single-compartment or multi-chamber nonprogrammable and programmable pneumatic compression pumps applied to the chest or trunk for treatment of lymphedema when criteria are met; 3) coverage for programmable, wearable non-pneumatic compression devices (e.g., Koya Dayspring) for the treatment of lymphedema when criteria are met; 4) coverage criteria for the use of an intermittent pneumatic compression device for individuals with chronic limb-threatening ischemia. 5) Programmable, wearable non-pneumatic compression pumps are considered experimental, investigational

	and/or unproven in all other situations not specified above. Added references 1, 2, 6, 7, 10, 15, 20, 23, 26; others updated; some removed.
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