
Medical Policy



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***Current Policy Effective Date: 11/1/26**
(See policy history boxes for previous effective dates)

Title: Compression Pumps and Appliances (e.g., Flexitouch™ System, Koya Dayspring® System) for Lymphedema

Description

Compression pumps and appliances are proposed as a treatment for individuals with lymphedema who have failed conservative measures. A variety of pumps are available; they can be pneumatic or non-pneumatic, single chamber (nonsegmental) or multichambered (segmented) and have varying designs and complexity.

Medical Policy Statement

Pneumatic compression pumps and appliances for upper and lower extremities are established when criteria are met.

Pneumatic compression pumps and appliances for the trunk/chest are established when criteria are met.

Pneumatic compression pumps and appliances for the head/neck are experimental/investigational. There is insufficient evidence to determine that the technology results in an improvement in net health outcomes.

Non-pneumatic compression appliances for upper and lower extremities are established when criteria are met.

Inclusionary and Exclusionary Guidelines

Inclusions:

Single-compartment or multichamber *nonprogrammable (without calibrated gradient pressure)* lymphedema pumps applied to the limb are established for the treatment of lymphedema that has failed to respond to conservative measures.*

Single-compartment or multichamber *programmable (with calibrated gradient pressure)* lymphedema pumps applied to the limb are established for the treatment of lymphedema when:

- The individual is otherwise eligible for nonprogrammable pumps; and
- There is documentation that the individual has unique characteristics that prevent satisfactory pneumatic compression with single-compartment or multichamber nonprogrammable lymphedema pumps (e.g., significant scarring, recent surgery).

The individual has had an inadequate response to an initial course of treatment with a nonprogrammable pneumatic compression pump.

Programmable, wearable non-pneumatic compression pumps (e.g., Koya Dayspring) applied to the limbs are established for the treatment of lymphedema when:

- The individual is otherwise eligible for a programmable pneumatic compression pump;
AND
- 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.

A non-pneumatic compression device applied to the limb is established for the treatment of lymphedema that has failed to respond to conservative measures.*

***Conservative measures:** a four-week trial of conservative therapy demonstrating failed responses to treatment is required. The four-week trial of conservative therapy must include all of the following:

- Regular and compliant use of an appropriate compression bandage system or compression garment to provide adequate graduated compression
 - Adequate compression is defined as (1) sufficient pressure at the lowest pressure point to cause fluid movement, and (2) sufficient pressure across the gradient (from highest to lowest pressure point) to move fluid from distal to proximal. The compression used must not create a tourniquet effect at any point.
 - The garment may be prefabricated or custom-fabricated but must provide adequate graduated compression starting with a minimum of 30 mmHg distally.
- Regular exercise
- Elevation of the limb

The use of lymphedema pumps and appliances to treat the trunk or chest is limited to individuals with:

- Lymphedema beyond the upper and lower extremities; and
- Have failed conservative therapy**;

- Have failed therapy with lymphedema pumps and appliances to the upper and lower extremities only.

****Conservative measures:** a four-week trial of conservative therapy must include all of the following:

- At least four weeks of regular, daily, multiple-hour home usage of the E0650 or E0651 after careful, in-person fitting, training and supervision by a technician who is skilled in and who regularly and successfully uses the appliance provided
- Compliant use of an appropriate compression bandage system or compression garment to provide adequate graduated compression
 - Adequate compression is defined as (1) sufficient pressure at the lowest pressure point to cause fluid movement and (2) sufficient pressure across the gradient (from highest to lowest pressure point) to move fluid from distal to proximal. The compression used must not create a tourniquet effect at any point.
 - The garment may be prefabricated or custom-fabricated but must provide adequate graduated compression starting with a minimum of 30 mmHg distally.
- Regular exercise
- Elevation where appropriate
- Manual lymphatic drainage (where available) and self-manual lymphatic drainage (MLD) for at least 30 minutes per day
- Evaluation of diet and implementation of any necessary change
- Medications as appropriate (e.g., diuretics and/or other treatment of congestive failure, etc.)
- Correction (where possible) of anemia and/or hypoproteinemia

Exclusions:

- Single-compartment or multichamber lymphedema pumps applied to the limb are considered **experimental/investigational** in all situations not mentioned above.
- The use of lymphedema pumps to treat head/neck lymphedema in patients is considered **experimental/investigational**.

Coding:

Single-Compartment Pumps

E0650	Pneumatic compressor, nonsegmental home model.
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Single-Compartment Appliances (used in conjunction with E0650)

E0655	Nonsegmental pneumatic appliance for use with pneumatic compressor, half arm
E0660	Nonsegmental pneumatic appliance for use with pneumatic compressor, full leg
E0665	Nonsegmental pneumatic appliance for use with pneumatic compressor, full arm
E0666	Nonsegmental pneumatic appliance for use with pneumatic compressor, half leg

Multichamber Pumps

E0651	Pneumatic compressor, segmental home model without calibrated gradient pressure
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Multichamber Appliances (used in conjunction with E0651)

E0656	Segmental pneumatic appliance for use with pneumatic compressor, trunk
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E0657	Segmental pneumatic appliance for use with pneumatic compressor, chest
E0658	Segmental pneumatic appliance for use with pneumatic compressor, integrated, 2 full arms and chest
E0659	E0659Segmental pneumatic appliance for use with pneumatic compressor, integrated, head, neck and chest
E0667	Segmental pneumatic appliance for use with pneumatic compressor, full leg
E0668	Segmental pneumatic appliance for use with pneumatic compressor, full arm
E0669	Segmental pneumatic appliance for use with pneumatic compressor, half leg

Multichamber Programmable Pumps

E0652	Pneumatic compressor, segmental home model with calibrated gradient pressure.
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Multichamber Appliances (used in conjunction with E0652)

E0671	Segmental gradient pressure pneumatic appliance, full leg
E0672	Segmental gradient pressure pneumatic appliance, full arm
E0673	Segmental gradient pressure pneumatic appliance, half leg

Non-pneumatic Appliance

E0678	Non-pneumatic sequential compression garment, full leg
E0679	Non-pneumatic sequential compression garment, half leg
E0680	Non-pneumatic compression controller with sequential calibrated gradient pressure
E0681	Non-pneumatic compression controller without calibrated gradient pressure
E0682	Non-pneumatic compression controller without calibrated gradient pressure, full arm
E1399	Durable medical equipment, miscellaneous

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

E0650	E0651	E0652	E0655	E0656	E0657
E0658	E0660	E0665	E0666	E0667	E0668
E0669	E0671	E0672	E0673	E0677	E0678
E0679	E0680	E0681	E0682		

Other codes (investigational, not medically necessary, etc.):

E0676 E0659
E1399

Note: Code(s) may not be covered by all contracts or certificates. Please consult customer or provider inquiry resources at BCBSM or BCN to verify coverage.

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.

Pneumatic 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.

Non-pneumatic Compression Devices

A non-pneumatic Compression System or Garment (e.g., Koya Dayspring System) is a wearable compression device that uses sequential gradient compression for the treatment and management of patients with lymphedema and provides patients with mobility during treatment.

The Koya Dayspring® consists of a programmable, segmental controller with a sleeve garment that can be sized to fit the individual. The garment contains a shape memory alloy made with nickel/titanium (Ni-Ti) that is programmed by a rechargeable controller to shrink in a cyclic manner, applying active gradient pressure from the distal to proximal end of the limb. This mechanistic action is similar to the motion of advanced pneumatic compression devices and is purported to provide comparable compression to existing pneumatic pumps via segments that contract and relax flexible frames in a segmental appliance without the use of air. Up to 14 independently controlled segments can be programmed to deliver 0–100 mmHg of compression pressure, with typical initial settings in a range of 30–40 mmHg. A mobile phone application can be used to program and individualize pressures; to start, stop, and pause

therapy; and to track device usage. The function of the device allows for mobility and range of motion during treatment. According to the manufacturer, the device is built on Flexframe2 technology, a patented mobile platform that provides calibrated sequential gradient.

SUMMARY OF EVIDENCE

For individuals who have lymphedema who failed to respond to conservative therapy who receive pneumatic compression pumps applied to limb only, the evidence includes RCTs and systematic reviews 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 RCTs were rated as moderate-to-high quality by an Agency for Healthcare Research and Quality review, and about half reported significant improvements with pumps compared with conservative care. 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. There is sufficient evidence to determine that the technology results in an improvement in net health outcomes.

For individuals who have lymphedema who failed to respond to conservative therapy who receive pneumatic compression pumps applied to trunk and/or chest as well as a limb, the evidence includes 2 RCTs comparing treatment with and without truncal involvement. Relevant outcomes are symptoms, change in disease status, functional outcomes, and quality of life. In 1 RCT, 2 of 4 key outcomes were significantly better with truncal involvement than without. This trial was limited by small sample size, failure to adjust statistically for multiple primary outcomes, and use of intermediate outcomes (e.g., amount of fluid removed) rather than health outcomes (e.g., functional status, quality of life). 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. There is sufficient evidence to determine that the technology results in an improvement in net health outcomes.

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 two RCTs 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 second RCT compared daily use of an APCD versus usual therapist-guided treatment and showed similar improvements in patient-reported symptoms in both groups, with modest additional reductions in external swelling and fewer

access barriers in the APCD group despite short-term follow-up. 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. There is insufficient evidence to determine that the technology results in an improvement in net health outcomes.

For individuals who have lymphedema who failed to respond to conservative therapy who received non-pneumatic compression devices applied to extremities, the evidence includes one clinical evaluation of the device, one non-randomized, open label study of the safety and effectiveness of this device, a randomized crossover trial and a comparative study. The studies show non-pneumatic compression devices can be an effective treatment for decreasing limb volume in patients with lower extremity lymphedema while improving quality of life, adherence, mobility and patient satisfaction. There is sufficient evidence to determine that the technology results in an improvement in net health outcomes.

Rationale

Evidence reviews assess 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 individuals 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. The following is a summary of the key literature to date.

LYMPHEDEMA—Pneumatic Compression Pumps Applied to the Limb Only

Clinical Context and Purpose

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

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 discussion of intermittent pneumatic compression (IPC) pumps.³ Reviewers (Oremus et al) identified 12 studies focusing on treatment of lymphedema with IPC pumps. Seven studies were moderate-to-high-quality RCTs, three were low-quality RCTs, and two were observational studies. There

was a high degree of heterogeneity between studies regarding types of lymphedema pumps used, comparison interventions (e.g., compression bandages, laser, massage), and intervention protocols. Statistically, IPC 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 They identified 36 English-language studies on a variety of treatments, 30 of which were RCTs and 6 were observational studies. Six RCTs evaluated IPC. Study findings were not pooled. According to reviewers, 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 treatment of breast cancer-related lymphedema.⁵ They 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 Trunk and/or Chest as Well as Limb

Review of Evidence

Randomized Controlled Trials

Due to U.S. Food and Drug Administration approval of lymphedema pumps that treat the truncal area as well as the affected limb, researchers have assessed truncal clearance as part of lymphedema treatment. This literature review focuses on RCTs comparing pneumatic compression for patients who had lymphedema with and without treatment of the trunk or chest. Two RCTs were identified; both were industry-sponsored, published in 2012, and included women with breast cancer who had documented postsurgical upper-extremity lymphedema.

Fife et al (2012) compared treatment using the Flexitouch system with treatment using the Bio Compression Systems Sequential Circulator.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 4 key outcomes at 12 weeks. There was statistically significant week by group interactions in two of these outcomes (edema volume reported as a percentage, $p=0.047$; tissue water, $p=0.049$), both favoring treatment with the Flexitouch system. Groups did not differ significantly on the other 2 outcomes (affected arm volume at 12 weeks, $p=0.141$; edema volume reported in milliliters, $p=0.050$). Moreover, had there been statistical adjustments for multiple comparisons (i.e., if $p<0.0125$ had been used instead of $p<0.05$ to adjust for the 4 comparisons), none of the differences would have been statistically significant. The trial was limited by its small sample size, missing data on the local tissue water outcome, and unclear blinding of outcome assessment. Also, the volume of tissue reported (a primary outcome) is of less clinical significance than outcomes such as symptoms or functional status.

Ridner et al (2012) compared treatment using the Flexitouch system for an arm only vs arm, chest, and trunk therapy in women with breast cancer who had arm lymphedema.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, the change in the volume of the affected arm was -2.66 mL in the experimental group and -0.38 mL in the control group ($p=0.609$). In addition, the mean number of symptoms reported at 30 days was 10.0 in the experimental group and 6.0 in the control group ($p=0.145$).

Section Summary: Lymphedema--Pneumatic Compression Pumps Applied to the Trunk and/or Chest

Two published RCTs have compared pneumatic compression treatment with and without truncal involvement. In one RCT, 2 of 4 key outcomes were significantly better with truncal involvement than without. In this trial a statistically significant reduction in bioelectrical impedance and arm circumference within both groups was achieved.

Pneumatic Compression Pumps Applied to the Head and Neck

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.¹¹ 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.¹⁰ 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.¹² 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.¹³ 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) evaluated the Flexitouch system for head and neck lymphedema in an open-label, randomized, wait-list controlled study.¹⁰ 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 in the 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).

Murphy et al (2026) conducted a multi-site, open-label, RCT comparing an APCD device (Flexitouch Plus) with usual care for treatment-naïve head and neck cancer-related lymphedema.¹⁴ Patients (N=236) were randomized 1:1 to usual care (therapist-guided lymphedema therapy and self-management) or daily APCD use (32-minute sessions) for 2 months, with outcomes assessed using patient-reported symptom scales, clinician-reported measures, and imaging. At 2 months, lymphedema symptom burden (Vanderbilt Head and Neck Symptom Survey plus General Symptom Survey [VHNSS] and Lymphedema Symptom Intensity and Distress Survey-Head and Neck [LSIDS] scores) improved significantly in both groups with no between-group differences. However, APCD demonstrated greater improvement in external lymphedema on clinician-reported measures, including statistically significant reductions in swelling (digital photography and Head and Neck Cancer Related Lymphedema and Fibrosis Grading [HN-LEFG] scores), whereas improvements in usual care were smaller or not statistically significant. Six-month data (currently published in abstract form) also shows that APCD and usual care produced similar improvements in lymphedema symptom severity, with no clinically meaningful differences between groups.¹⁵ APCD showed modest advantages in reducing internal swelling at select sites (e.g., base of tongue) and a general, though mostly non-significant, trend toward improvement across most anatomical regions.

Table 1. Summary of Key RCT Characteristics

Study	Countries	Sites	Dates	Participants	Interventions ^a	
					Active	Comparator
Ridner (2021)	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 (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)

Murphy (2026)	US	10	NR	N=236 pathologically confirmed cancer of the head and neck, who completed curative intent therapy, no evidence of cancer at the time of study and who were diagnosed with either internal or external head and neck cancer-associated lymphedema and had at least one core lymphedema-associated symptom with a severity of ≥ 4 out of 10	Flexitouch Plus system as a 32-min treatment to be utilized daily (n=119)	Therapist-guided lymphedema treatment n=117)
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NR: not reported; RCT: randomized controlled trial.

^aAll 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)	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	
	LSIDS, change from baseline (95% CI; p value)				VHNSS, change from baseline (95% CI; p value)			
Murphy (2026)	Soft tissue	Neurological		Pain	Solid swallowing	Liquid swallowing	Mucosal sensitivity	
Flexitouch Plus system	-0.36 (-0.63 to -0.10; p=.008)	-0.17 (-0.46 to 0.13; p=.275)		-0.38 (-0.76 to 0.00; p=.050)	-0.27 (-0.63 to 0.08; p=.136)	-0.20 (-0.53 to 0.12; p=.233)	-0.33 (-0.63 to -0.3; p=.032)	3 adverse events reported
Usual care (TGLT)	-0.38 (-0.67 to -0.11; p=.008)	-0.16 (-0.44 to 0.12; p=.250)		-0.27 (-0.64 to 0.09; p=.136)	-0.45 (-0.79 to -0.11; p=.011)	-0.18 (-0.49 to 0.12; p=.244)	-0.37 (-0.63 to -0.11; p=0.005)	

	p =.007)							
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IQR: interquartile range; LSIDS-HN: Lymphedema Symptom Intensity and Distress Survey-Head and Neck; RCT: randomized controlled trial. TGLT, therapist-guided lymphedema treatment; VHNSS, Vanderbilt Head and Neck Symptom Survey plus General Symptom Survey.

Table 3. Study Relevance Limitations

Study	Population ^a	Intervention ^b	Comparator ^c	Outcomes ^d	Duration of Follow-up ^e
Ridner (2021)		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
Murphy (2026)			1. Unclear what therapies were included as part of usual care		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.

^aPopulation key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.

^bIntervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.

^cComparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.

^dOutcomes 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.

^eFollow-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)		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
Murphy (2026)		1. Blinding not feasible; most measures were patient-reported				2. Missing outcome data was not imputed

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

^aAllocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.

^bBlinding 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

Two RCTs and a systematic review have assessed the use of pneumatic compression treatment for head and neck lymphedema. One 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. Another RCT comparing daily use of an APCD versus usual therapist-guided treatment showed similar improvements in patient-reported symptoms in both groups, with modest additional reductions in external swelling and fewer access barriers in the APCD group despite short-term follow-up. 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.

Non-Pneumatic Compression Devices

Review of Evidence

Rockson et al. (2022) conducted a nonrandomized open-label pilot study in 40 subjects to evaluate the quality of life (QoL) and limb volume maintenance efficacy of a novel wearable compression system (Dayspring) in the treatment of unilateral upper extremity breast cancer-related lymphedema.¹⁶ Subjects were instructed to use the Dayspring device on one arm at least once a day, and could continue any other prescribed self-care procedures, including the use of compression garments. The contralateral (unaffected) limb was used as a control. After 28 days of use, subjects had a statistically significant 18% ($p < 0.001$) improvement in overall QoL as measured by the Lymphedema Quality-of-Life Questionnaire compared with baseline. Individual QoL domains also improved. Limb volume was reduced by an average of 2% ($p = 0.042$). Adherence was 98% over the course of the study; the average daily use was 43.9 minutes. The low-profile device is easy to use and allows for mobility during treatment, addressing a potential barrier to adherence with pneumatic compression devices.

Rockson et al. (2022) completed a nonrandomized, open-label, 12-week pilot study to evaluate the safety and effectiveness of the Dayspring compression device in the treatment of lower extremity lymphedema (LEL).¹⁷ Subjects were directed to wear the device for up to one hour per day, and could continue ongoing maintenance care (bandaging, compression garments, massage). Outcome measures included quality of life (QOL) using the Lymphedema Quality of Life Questionnaire (LYMQOL) and change in lower limb volume. The contralateral (unaffected) limb was used for comparison. Twenty-four subjects were enrolled; 18 completed the study.

Overall QOL scores improved by 8% to 16% (mean 12%; $p=0.02$). The mean change in edema was -427.1 cm^3 ($p<0.001$, 95% confidence interval [CI] = $-677, -178$), for an average reduction of 39.4%. Treatment adherence data was not collected. The NPCD produced statistically significant improvements in QOL, functioning, and edema volume of patients with LEL.

Rockson et al. (2022) conducted a randomized crossover noninferiority trial ($n=52$) to evaluate the efficacy of the Dayspring compression device versus an advanced pneumatic compression device (Flexitouch Plus) in treating breast cancer-related lymphedema.¹⁸ Subjects in the intervention and control groups were instructed to use the assigned device once a day for at least one hour, for 28 days. Then all subjects had a four week “washout” period, without any use of an active compression device. Subjects then crossed over to the alternate compression device for the following 28 days. Subjects could also continue the use of compression sleeves and/or manual lymph drainage procedures. Outcome measures included reduction in limb volume (treatment response was defined as a $>2\%$ reduction in edema volume); quality of life (QOL) using the Lymphedema Quality of Life Questionnaire (LYMQOL); adherence; and adverse or safety events. Two patients were lost to follow up. The intervention group had a mean reduction in edema of 64.6% (95% confidence interval [CI], 31.71-97.58), versus 27.7% (95% CI, 4.80-60.14) in the control group ($p<0.05$), for an overall response rate of 88% versus 42% ($p<0.05$), respectively. Adherence was $95.6\% \pm 7\%$ in the intervention group versus $49.8\% \pm 26\%$ in the control group ($p<0.01$). Overall QOL scores were significantly improved in the intervention group (2.44 points; $p<0.05$), while no significant change was seen in the control group.

Barfield et al. (2024) reported on results from a comparative study evaluating the effectiveness of a nonpneumatic compression device (NPCD) in comparison to an advanced pneumatic compression device (APCD) for lower extremity lymphedema swelling (TEAYS study).²⁰ A randomized, crossover head-to-head study was performed at nine sites in 2023. Patients were randomized to either the NPCD or a commercially available APCD. Patients used the randomly assigned initial device for 90 days with a 4-week washout period before a comparable 90-day use of the second device. A total of 71 patients (108 affected limbs) with lower extremity lymphedema were analyzed. Compared with the APCD, the NPCD was associated with a greater mean decrease in limb edema volume (a mean limb volume decreases of $369.9 \pm 68.19 \text{ mL}$ [$P < .05$] vs $83.1 \pm 67.99 \text{ mL}$ [$P < .05$]). Significant improvement in Quality of Life was achieved for NPCD and not for APCD treatment (score improvement of 1.01 ± 0.23 [$P < .05$] for NPCD vs 0.17 ± 0.18 [$P > .05$] for APCD). Patients reported greater adherence (81% vs 56%; $P < .001$) and satisfaction with the NPCD (78% vs 22%) compared with APCD. No device-related adverse events were reported. The novel NPCD is an effective treatment for decreasing limb volume in patients with lower extremity lymphedema. The NPCD was more effective than an APCD and resulted in superior limb volume decrease, greater improved quality of life, adherence, mobility, and patient satisfaction.

SUPPLEMENTAL INFORMATION

CLINICAL INPUT FROM PHYSICIAN SPECIALTY SOCIETIES, ACADEMIC MEDICAL CENTERS AND EXTERNAL STAKEHOLDERS (PRACTICING CLINICIANS AND RESEARCH BASED EXPERTS IN THE FIELD)

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 body sites other than the limbs provides a clinically meaningful improvement in net health outcome and represents generally accepted medical practice. In addition, respondents endorsed the use of non-pneumatic compression devices, noting that such devices permit maintaining mobility and compliance with treatment. 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 are 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.

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.²³ Treatment should include compression garments, self-massage, skin care, exercises, and, if desired, pneumatic compression therapy applied in the home.

National Lymphedema Network²⁴

In their 2023 National Lymphedema Network Conference, they state “Intermittent Pneumatic Compression Therapy (IPC) is a supportive intervention for some individuals going through CDT treatment. IPC involves a pneumatic sleeve being applied to the limb which inflates and deflates sequentially applying pressure to encourage fluid absorption and decongestion in the limb. IPC can be used in both treatment and self-care phases. Various types of pneumatic pumps exist to treat lymphedema. Selection and use of IPC should be done in consultation with a trained therapist or fitter.”

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			
NCT07217288	Complete Decongestive Therapy Versus Non-pneumatic Compression Therapy in Post Mastectomy Lymphedema (CDT)	52	Apr 2027
NCT06418282	Clinical Study to Evaluate the Effectiveness and Health Economics of a Novel Portable Non-Pneumatic Active Compression Device (NPCD) for Lymphedema/Phlebolymphedema (GRANDE)	100	Dec 2027
Unpublished			

NCT05659394 ^a	Intermittent Pneumatic Compression of the Thigh for the Treatment of Lower Limb Wounds: a Randomised Control Trial (IPCOTT)	160	Sep 2024
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NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

Regulatory Status

Several pneumatic compression pumps, indicated for the primary or adjunctive treatment of primary or secondary (e.g., postmastectomy) lymphedema, have been cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process. Examples of devices with these indications intended for home or clinic/hospital use include the Compression Pump, Model GS-128 (MedMark Technologies); the Sequential Circulator® (Bio Compression Systems); the Lympha-Press® and Lympha-Press Optimal (Mego Afek); the Flexitouch™ system (Tactile Medical, formerly Tactile Systems Technology); and the Powerpress Unit Sequential Circulator (Neomedic).

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

Food and Drug Administration product code: JOW.

In September 2021, the Dayspring Lite device obtained U.S. Food and Drug Administration (FDA) approval via the 510(k)-approval process as a compressible limb sleeve (K212287). Dayspring Lite is a prescription only wearable compression system, intended for use in a clinic or home setting by medical professionals and patients who are under medical supervision. FDA indications include the following conditions: Chronic edema, lymphedema, venous insufficiency, and wound healing.

Government Regulations

National:

NCD: Pneumatic Compression Devices (280.6), effective 01/14/2002.¹⁸

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

- A. "Lymphedema ...Pneumatic compression devices are covered in the home setting for the treatment of lymphedema if the patient has undergone a four-week trial of conservative therapy and the treating physician determines that there has been no significant improvement or if significant symptoms remain after the trial. The trial of conservative therapy must include use of an appropriate compression bandage system or compression garment, exercise, and elevation of the limb. The garment may be prefabricated or custom-fabricated but must provide adequate graduated compression."

Local:

LCD: L33829, Pneumatic Compression Devices, effective on or after 10/22/2023. Retired 11/14/24.

I - LYMPHEDEMA

A PCD coded as E0650 or E0651 is covered for both primary and secondary lymphedema in beneficiaries with chronic and severe lymphedema when all of the following three requirements are met:

1. The beneficiary has a diagnosis of lymphedema as defined above, and
2. The beneficiary has persistence of chronic and severe lymphedema as identified by the documented presence of at least one of the following clinical findings:
 - Marked hyperkeratosis with hyperplasia and hyperpigmentation,
 - Papillomatosis cutis lymphostatica,
 - Deformity of elephantiasis,
 - Skin breakdown with persisting lymphorrhea,
 - Detailed measurements over time confirming the persistence of the lymphedema with a history evidencing a likely etiology, and
3. In addition to this documented persistence, the lymphedema is then documented to be unresponsive to other clinical treatment over the course of a required four-week trial. (See below for trial guidelines.)

A PCD coded as E0650 or E0651 used to treat lymphedema that does not meet all of the requirements above is not eligible for reimbursement. Claims will be denied as not reasonable and necessary.

A PCD coded as E0650 or E0651 used to treat edema from causes other than lymphedema is not eligible for reimbursement. Claims will be denied as not reasonable and necessary.

A PCD coded as E0652 is not covered for the treatment of lymphedema of the extremities alone even if the criteria in this section are met. Claims will be denied as not reasonable and necessary. Refer below to the sections III - LYMPHEDEMA EXTENDING ONTO THE CHEST, TRUNK AND/OR ABDOMEN and PCD Code Selection for additional information about the limited coverage for PCD coded as E0652.

Four-Week Trial for Lymphedema

A four-week trial of conservative therapy demonstrating failed response to treatment is required. The four-week trial of conservative therapy must include all of the following:

- Regular and compliant use of an appropriate compression bandage system or compression garment to provide adequate graduated compression
 - Adequate compression is defined as (1) sufficient pressure at the lowest pressure point to cause fluid movement, and (2) sufficient pressure across the gradient (from highest to lowest pressure point) to move fluid from distal to proximal. The compression used must not create a tourniquet effect at any point.
 - The garment may be prefabricated or custom-fabricated but must provide adequate graduated compression starting with a minimum of 30 mmHg distally.
- Regular exercise
- Elevation of the limb

When available, manual lymphatic drainage is a key component of conservative treatment as is appropriate medication treatment when there is concurrent congestive failure.

III - LYMPHEDEMA EXTENDING ONTO THE CHEST, TRUNK AND/OR ABDOMEN

A segmented, calibrated gradient pneumatic compression device (HCPCS code E0652) is only covered when the individual has unique characteristics which prevent them from receiving adequate satisfactory pneumatic compression treatment using a nonsegmented device along with a segmented appliance or compression device without manual control of the pressure in each chamber.

A PCD coded as E0652, is covered for the treatment of lymphedema extending onto the chest, trunk and/or abdomen when all of the following are met:

- The beneficiary has lymphedema of an extremity as defined above
- The coverage criteria for an E0650 or E0651 are met
- The beneficiary has lymphedema extending onto the chest, trunk and/or abdomen that extends past the limits of a standard compression sleeve, and the chest, trunk and/or abdominal lymphedema has failed to improve with a four-week trial.

A PCD coded as E0652 used to treat lymphedema extending onto the chest, trunk and/or abdomen that does not meet all of the requirements above is not eligible for reimbursement. Claims will be denied as not reasonable and necessary.

A PCD coded as E0652 used to treat lymphedema not extending onto the chest, trunk and/or abdomen or CVI is not eligible for reimbursement. Claims will be denied as not reasonable and necessary.

Four-Week Trial for Lymphedema Extending onto the Chest, Trunk and/or Abdomen

A four-week trial of conservative therapy demonstrating failed response to treatment with and E0650 or E0651 is required. The four-week trial of conservative therapy must include all of the following:

- At least four weeks of regular, daily, multiple-hour home usage of the E0650 or E0651 after careful, in-person fitting, training and supervision by a technician who is skilled in and who regularly and successfully uses the appliance provided
- Compliant use of an appropriate compression bandage system or compression garment to provide adequate graduated compression
 - Adequate compression is defined as (1) sufficient pressure at the lowest pressure point to cause fluid movement and (2) sufficient pressure across the gradient (from highest to lowest pressure point) to move fluid from distal to proximal. The compression used must not create a tourniquet effect at any point.
 - The garment may be prefabricated or custom-fabricated but must provide adequate graduated compression starting with a minimum of 30 mmHg distally.
- Regular exercise
- Elevation where appropriate
- Manual lymphatic drainage (where available) and self-manual lymphatic drainage (MLD) for at least 30 minutes per day
- Evaluation of diet and implementation of any necessary change
- Medications as appropriate (e.g., diuretics and/or other treatment of congestive failure, etc.)

- Correction (where possible) of anemia and/or hypoproteinemia

At the end of the four-week trial, if there has been improvement of the lymphedema extending onto the chest, trunk and/or abdomen, then reimbursement is not justified. Where improvement has occurred, the trial of conservative therapy must be continued with subsequent reassessment at intervals at least a week apart. When and only when no significant improvement has occurred in the most recent four weeks and the coverage criteria above are still met, codes for pneumatic compression devices are eligible for reimbursement.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Pneumatic Compression Pumps for Venous Ulcers
 - Lymphedema—Surgical Treatments
 - Bioimpedance Devices for Cancer Related Extremity Lymphedema
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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through June 2026, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
11/1/18	8/21/18	8/21/18	Joint policy established
11/1/19	8/20/19		- Added “and appliances” to title and MPS - Coverage now established for trunk/chest pumps/appliances when failed conservative therapy and pneumatic compression therapy to extremities only - Clarification added for programmable and nonprogrammable pumps and appliances - Updated government section.
11/1/20	8/18/20		Routine policy maintenance, no change in policy status.
11/1/21	8/17/21		Updated rationale, added reference #6, no change in policy status.
11/1/22	8/16/22		Added codes K1024, K1025, K1031, and K1032 as E/I. Updated rationale, added reference# 10. No change in policy status.
11/1/23	8/15/23		Added code E0677 as established. Routine policy maintenance, no change in policy status. Vendor managed: Northwood. (ds)
11/1/24	8/20/24		Add to background non-pneumatic compression devices, added references 11-13 to rationale supporting non-coverage. Added to inclusion section. Deleted K1024, K1025, K1031, K1032. Added codes E0678-E0682 as E/I EFD 1/1/24. Vendor managed: Northwood (ds)
11/1/25	8/19/25		Updated rationale, references added. Title changed to Compression Pumps & Appliances (e.g., Flexitouch™ System, Koya Dayspring® System) for Lymphedema. Codes E0678, E0679, E0680, E0681 & E0682 now

			established. Policy formatting changes made. Vendor managed: Northwood (ds)
11/1/26	8/18/26		Added bullet to the inclusion section "The individual has had an inadequate response to an initial course of treatment with a nonprogrammable pneumatic compression pump". Added section in the inclusions to address the Koya Dayspring. Added code E0658 as established and code E0659 as E/I. Rationale updated, 2 references added. Vendor managed: Northwood (ds, no)

Next Review Date: 3rd Qtr. 2027

Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN:	Revised:
BCBSM:	Revised:

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY COMPRESSION PUMPS AND APPLIANCES (E.G., FLEXITOUCH™ SYSTEM, KOYA
DAYSPRING® SYSTEM) FOR LYMPHEDEMA

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered per policy
BCNA (Medicare Advantage)	See government section
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.
- *Duplicate (back-up) equipment is not a covered benefit.*