Medical Policy

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***Current Policy Effective Date: 11/1/24**
(See policy history boxes for previous effective dates)

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

Description/Background

Lymphedema is an abnormal accumulation of lymph fluid in subcutaneous tissues or body cavities resulting from obstruction of lymphatic flow. Lymphedema can be subdivided into primary and secondary categories. Primary lymphedema has no recognizable etiology, while secondary lymphedema is related to a variety of causes including surgical removal of lymph nodes, post-radiation fibrosis, scarring of lymphatic channels, or congenital anomalies. Conservative therapy is the initial treatment for lymphedema and includes general measures such as limb elevation and exercise as well as the use of compression garments and compression bandaging. Another conservative treatment is manual lymphatic drainage, a massage-like technique used to move edema fluid from distal to proximal areas. Manual lymphatic drainage is performed by physical therapists with special training. Complete decongestive therapy is a comprehensive program that includes manual lymphatic drainage in conjunction with a range of other conservative treatments. Rarely, surgery is used as a treatment option. Pneumatic compression pumps are proposed as a treatment for patients with lymphedema who have failed conservative measures.

Pneumatic compression pumps may be used in lymphedema or wound care clinics, purchased, or rented for home use; home use is addressed herein. Pneumatic compression pumps consist of pneumatic cuffs connected to a pump. These pumps use compressed air to apply pressure to the affected limb. The intention is to force excess lymph fluid out of the limb and into central body compartments in which lymphatic drainage should be preserved. Many pneumatic compression pumps are available, with varying materials, designs, degrees of pressure, and complexity. There are 3 primary types of pumps. Single chamber nonprogrammable pumps are the simplest pumps, consisting of a single chamber that is inflated at 1 time to apply uniform pressure. 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.

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.

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.

Medical Policy Statement

Pneumatic compression pumps and appliances for upper and lower extremities are established for the treatment of lymphedema in individuals who have failed conservative therapies.

Pneumatic compression pumps and appliances for the trunk/chest are established. It may be considered a useful therapeutic option when indicated.

Pneumatic compression pumps and appliances for the head/neck are experimental/investigational. This service has not been scientifically demonstrated to improve patient clinical outcomes.

Inclusionary and Exclusionary Guidelines

Inclusions:
Single-compartment or multichamber *nonprogrammable (without calibrated gradient pressure)* lymphedema pumps applied to the limb is 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:

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

*__Conservative measures__: 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

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

1. Lymphedema beyond the upper and lower extremities; and
2. Have failed conservative therapy**; and
3. 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.
- Non-pneumatic Compression Devices are **experimental/investigational**. This service has not been scientifically demonstrated to improve patient clinical outcomes.
- 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.

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

Multichamber Appliances (used in conjunction with E0651)

E0656	Segmental pneumatic appliance for use with pneumatic compressor, trunk
E0657	Segmental pneumatic appliance for use with pneumatic compressor, 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.

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

Code	Nomenclature
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
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
E0660	E0665	E0666	E0667	E0668	E0669
E0671	E0672	E0673	E0677		

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

E0676	E0678	E0679	E0680	E0681	E0682
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.

Rationale

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

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

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

LYMPHEDEMA—Pneumatic Compression Pumps Applied to the Limb Only

Clinical Context and 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.

The following **PICOs** was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with lymphedema who have failed to respond to conservative therapy. Individuals with lymphedema are actively managed by lymphedema therapists and physiatrists.

Interventions

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

Comparators
The following practices are currently being used to treat lymphedema; physiotherapy and, manual lymphatic drainage. Lymphedema therapists and physiatrists provide care.

Outcomes
The general outcomes of interest are symptoms, change in disease status, functional outcomes and QOL.

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

Review of Evidence

Systematic Reviews
In 2010, the Agency for Healthcare Research and Quality published a technology assessment on the diagnosis and treatment of secondary lymphedema that included discussion of intermittent pneumatic compression (IPC) pumps.[2] 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.[3] 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.[4] 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).

Randomized Controlled Trials

A 2015 RCT from Japan included 31 women with unilateral upper-extremity lymphedema after mastectomy.[5] To be eligible; patients had to have experienced at least a 10% increased volume in the affected limb or more than 2 cm difference in circumference between limbs. Patients were randomized to decongestive physical therapy alone (n=15) or decongestive physical therapy plus IPC (n=16). Pneumatic compression was delivered using a pump marketed in Japan (Mark II Plus) and was applied for 45 minutes after manual lymphatic drainage. Both groups underwent 5 weekly sessions for 3 weeks (a total of 15 sessions). At the immediate post-treatment and 1-month follow-up points, there were no statistically significant differences in groups for any outcomes, including arm circumference and dermal thickness of the arm and forearm.

Tastaban et al (2020) conducted an RCT in 76 patients with unilateral arm lymphedema related to breast cancer.[6] Patients received complex decongestive treatment alone (n=38) or complex decongestive treatment plus intermittent pneumatic compression (n=38). Intermittent pneumatic compression was delivered for 30 minutes. All patients received complex decongestive treatment, which consisted of skin care, manual lymphatic drainage, compression bandaging, and exercise. Patients received 20 sessions of therapy over the course of 4 weeks. Both groups saw decreases in excess volume after 4 weeks, but between-group differences were not significant (percent reduction in excess volume, 54.6% with intermittent pneumatic compression vs. 49.6% without; p=0.140). Symptoms of heaviness and tightness were significantly lower among patients who received intermittent pneumatic compression, as assessed by visual analog scale scores (heaviness, 2.0 vs. 3.0; p=0.024; tightness, 2.0 vs. 2.5; p=0.048).

Section Summary: Lymphedema--Pneumatic Compression Pumps Applied to the Limb Only

A number of RCTs have been published. Most published RCTs were rated as moderate-to-high quality by an Agency for Healthcare Research and Quality review, and about half reported significant improvements with pumps compared with conservative care.

Lymphedema--Pneumatic Compression Pumps Applied to the Trunk and/or Chest as Well as Limb

Clinical Context and Therapy Purpose

The purpose of pneumatic compression pumps in individuals who have lymphedema is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following **PICOs** was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with lymphedema. Lymphedema and its treatment are described in the first indication.

Interventions
The treatment being considered is the use of pneumatic lymphatic pumps on the trunk and/or chest, as well as the limb. Pneumatic compression pumps are described in the first indication.

Comparators
The following practices are currently being used to treat lymphedema; physiotherapy and manual lymphatic drainage. Lymphedema therapists and physiatrists provide care.

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

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 principles described in the first indication.

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.[7] 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 two of these outcomes (edema volume reported as a percent, $p=0.047$; 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.[8] 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 was 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=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. This trial was limited by small sample size, failure to adjust statistically for multiple primary outcomes, and use of intermediate outcomes (e.g., amount of fluid removed) rather than health outcomes (e.g., functional status, quality of life). The other RCT did not find statistically significant differences between groups for any of the efficacy outcomes. The available evidence does not demonstrate that pumps treating the trunk or chest provide incremental improvement beyond that provided by pumps treating the affected limb only.

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 individuals who have lymphedema who failed to respond to conservative therapy is to provide a treatment option that is an alternative to or an improvement on existing therapies.

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

Populations

The relevant population of interest is individuals 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.

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

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 on use of the Flexitouch system and were instructed on time of use, which varied based upon size of garment and ranged from 23 to 45 minutes. Patients who were initially randomized to lymphedema self-management only could opt to continue on after the initial 8-week period to receive the Flexitouch system for a subsequent 8-week treatment period. A summary of the design and key results are included in Tables 1 and 2. Adherence to the device was low; at week 8, only 4 of the 19 patients still enrolled in the intervention group used the Flexitouch system as prescribed for at least 5 days (only 1 patient used it twice a day, every day).

Table 1. Summary of Key RCT Characteristics

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

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

Table 2. Summary of Key RCT Results

Study	LSIDS-HN, change from baseline (median [IQR])				Swelling, median change from baseline in percentage grids with observable swelling			Adverse events
Ridner (2021)	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.

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.	1. Unclear what therapies were included as part of the self-care kit		1. Longer-term outcomes not evaluated

		Low rates of adherence			

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 4. Study Design and Conduct Limitations

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

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

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

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

Non-Pneumatic Compression Devices

Clinical Context and Therapy Purpose

The purpose of non-pneumatic compression devices in individuals who have lymphedema is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following **PICOs** was used to select literature to inform this review.

Populations
The relevant population of interest is individuals with lymphedema. Lymphedema and its treatment are described in the first indication.

Interventions
The treatment being considered is the use of non-pneumatic lymphatic devices on the extremities.

Comparators
The following practices are currently being used to treat lymphedema; physiotherapy and manual lymphatic drainage. Lymphedema therapists and physiatrists provide care.

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

Study Selection Criteria
Methodologically credible studies were selected using the principles described in the first indication.

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.[11] 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 study is limited by the small number of patients, lack of randomization and control group, and short follow-up.

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).[12] 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. Limitations of the study include the small sample size, lack of randomization and control group, and short duration of follow-up.

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.[13] 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% ± 7% in the intervention group versus 49.8% ± 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. The study is limited by the small sample size, short follow-up time period, and potential risk of carryover effects.

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 of RCTs. Relevant outcomes are symptoms, change in disease status, functional outcomes, and quality of life. Most RCTs were rated as moderate-to-high quality by an Agency for Healthcare Research and Quality review, and about half reported significant improvements with pumps compared with conservative care. The evidence is sufficient to determine that the technology results in a meaningful 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 trunk and/or chest as well as a limb, the evidence includes 2 RCTs comparing treatment with and without truncal involvement. Relevant outcomes are symptoms, change in disease status, functional outcomes, and quality of life. In 1 RCT, 2 of 4 key outcomes were significantly better with truncal involvement than without. This trial was limited by small sample size, failure to adjust statistically for multiple primary outcomes, and use of intermediate outcomes (e.g., amount of fluid removed) rather than health outcomes (e.g., functional status, quality of life). The evidence is sufficient to determine the effects of the technology on health outcomes.

For individuals who have lymphedema who failed to respond to conservative therapy who receive pneumatic compression pumps applied to the head/neck area, the evidence includes one functional usability study. This functional usability study assessed ease of use, fit, comfort, and potential clinical benefits of advanced pneumatic compression treatment of cancer-related head and neck lymphedema. The available evidence does not demonstrate that pumps treating the head or neck provide incremental improvement beyond that provided by pumps treating the affected limb only. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have lymphedema who failed to respond to conservative therapy who received non-pneumatic compression devices applied to the extremities, the evidence includes one clinical evaluation of the device, one non-randomized, open label study of the safety and effectiveness of this device, and a subanlysis of a randomized crossover trial. The available evidence does not demonstrate that non-pneumatic compression devices provide improvement beyond that provided by pneumatic compression pumps in treating affected limbs. The evidence is insufficient to determine the effects of this technology on health outcomes.

SUPPLEMENTAL INFORMATION

PRACTICE GUIDELINES AND POSITION STATEMENTS

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

National Lymphedema Network[19]

In their 2023 National Lymphedma 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
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)	160	Sep 2024

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

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.

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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References

1. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Special Report: Comparative Efficacy of Different Types of Pneumatic Compression Pumps for the Treatment of Lymphedema. *TEC Assessments* 1998;Volume 13:Tab 2.
2. 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.
3. Oremus M, Dayes I, Walker K, et al. Systematic review: conservative treatments for secondary lymphedema. *BMC Cancer.* Jan 4 2012;12:6. PMID 22216837
4. 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
5. Uzkeser H, Karatay S, Erdemci B, et al. Efficacy of manual lymphatic drainage and intermittent pneumatic compression pump use in the treatment of lymphedema after mastectomy: a randomized controlled trial. *Breast Cancer.* May 2015;22(3):300-307. PMID 23925581

6. Tastaban E, Soyder A, Aydin E, et al. Role of intermittent pneumatic compression in the treatment of breast cancer-related lymphoedema: a randomized controlled trial. Clin Rehabil. Feb 2020; 34(2): 220-228. PMID 31795748
7. 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
8. 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
9. 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
10. 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
11. Rockson SG, Karaca-Mandic P, Skoracki R, Hock K, Nguyen M, Shadduck K, Gingerich P, Campione E, Leifer A, Armer J. Clinical Evaluation of a Novel Wearable Compression Technology in the Treatment of Lymphedema, an Open-Label Controlled Study. Lymphat Res Biol. 2022a Apr;20(2):125-132.
12. Rockson SG, Skoracki R. Effectiveness of a Nonpneumatic Active Compression Device in Older Adults with Breast Cancer-Related Lymphedema: A Subanalysis of a Randomized Crossover Trial. Lymphat Res Biol. 2023 Dec;21(6):581-584.
13. Rockson SG, Whitworth PW, Cooper A, Kania S, Karnofel H, Nguyen M, Shadduck K, Gingerich P, Armer J. 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. 2022c Nov;10(6):1359-1366.e1.
14. 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
15. 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
16. O'Donnell TF, Jr., Passman MA, Marston WA, et al. Management of venous leg ulcers: clinical practice guidelines of the Society for Vascular Surgery (R) and the American Venous Forum. J Vasc Surg. Aug 2014;60(2 Suppl):3s-59s. PMID 24974070
17. 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
18. Centers for Medicare and Medicaid Services. National Coverage Determination (NCD) for Pneumatic Compression Devices (280.6). 2002; http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=225&ncdver=1&NCAId=50&NcaName=Lymphedema+Pumps&CoverageSelection=National&KeyWord=lymphedema+pumps&KeyWordLookUp=Title&KeyWordSearchType=And&clickon=search&bc=gAAAABAAEAAA&. Accessed July 2024.
19. National Lymphedema Network. 2023 National Lymphedema Network Conference. Lymphedema Therapy. https://lymphnet.org. Accessed July 2024.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through July 2024, 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)

Next Review Date: 3rd Qtr. 2025

Pre-Consolidation Medical Policy History

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

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: PNEUMATIC COMPRESSION PUMPS AND APPLIANCES (E.G., FLEXITOUCH™ 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.*