MEDICAL POLICY

POLICY TITLE	COMPRESSION DEVICES FOR TREATMENT OF LYMPHEDEMA AND PERIPHERAL VASCULAR DISEASE
POLICY NUMBER	MP 6.013

CLINICAL BENEFIT	☐ MINIMIZE SAFETY RISK OR CONCERN. ☐ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☒ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	**2/1/2026**

POLICY

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

Single-compartment or multichamber *programmable* pneumatic compression pumps applied to the limbs may be considered **medically necessary** for the treatment of lymphedema when:

1. The individual is otherwise eligible for nonprogrammable pumps; and
2. There is documentation that the individual has unique characteristics (e.g., significant scarring) that prevent satisfactory pneumatic compression with single-compartment or multichamber nonprogrammable compression pumps; or
3. The individual has had an inadequate response to an initial course of treatment with a nonprogrammable pneumatic compression pump applied to the limbs (see Policy Guidelines).

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

Single-compartment or multichamber *programmable* pneumatic compression pumps applied to the chest or trunk in addition to the limbs may be considered **medically necessary** for the treatment of lymphedema when:

1. The individual is otherwise eligible for nonprogrammable pneumatic pumps applied to the chest or trunk in addition to the limbs; and
2. There is documentation that the individual has unique characteristics (eq, significant scarring, recent surgery) that prevent satisfactory pneumatic compression with single-compartment or multichamber nonprogrammable compression pumps; or
3. The individual has had an inadequate response to an initial course of treatment with nonprogrammable pneumatic compression pump applied to the chest or trunk in addition to the limbs (see Policy Guidelines).

Single-compartment or multichamber compression pumps are considered **investigational** in all other situations other than those specified above, including when applied to the head or neck.

MEDICAL POLICY

POLICY TITLE	COMPRESSION DEVICES FOR TREATMENT OF LYMPHEDEMA AND PERIPHERAL VASCULAR DISEASE
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Programmable, wearable non-pneumatic compression pumps (e.g., Koya Dayspring) applied to the limbs may be considered **medically necessary** for the treatment of lymphedema when:

1. The individual is otherwise eligible for a programmable pneumatic compression pump; and
2. There is documentation that the individual has lifestyle considerations or mobility requirements where treatment compliance with a traditional programmable, pneumatic compression system is expected to be insufficient.

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

The use of pneumatic or non-pneumatic compression pumps to treat venous ulcers or peripheral arterial occlusive disease/arterial insufficiency are considered **investigational**. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Note: Lymphedema pumps for use following a mastectomy is a mandated benefit according to Pennsylvania Act 51 of 1997.

Policy Guidelines

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

Cross-References:

MP 2.190 Bioimpedance Devices for Detection and Management of Lymphedema
MP 6.053 Postsurgical Home Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis
MP 8.001 Physical Medicine and Specialized Physical Medicine Treatments (Outpatient)

PRODUCT VARIATIONS

This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations. Please see additional information below.

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FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies

DESCRIPTION/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. 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.

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-lll).
Stage I (mild)	Early accumulation of fluid relatively high in protein content (e.g., in comparison with "venous" edema) which subsides with limb elevation. Pitting may occur. An increase in various types of proliferating cells may also be seen.

Stage II (moderate)	Involves the permanent accumulation of pathologic solids such as fat and proteins and limb elevation alone rarely reduces tissue swelling, and pitting is manifest. Later in this stage, the limb may not pit as excess subcutaneous fat and fibrosis develop.
Stage III (severe)	Encompasses lymphostatic elephantiasis where pitting can be absent and trophic skin changes such as acanthosis, alterations in skin character and thickness, further deposition of fat and fibrosis, and warty overgrowths have developed. It should be noted that a limb may exhibit more than one stage, which may reflect alterations in different lymphatic territories.

Management and Treatment

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

Venous Ulcers

Venous ulcers, which occur most commonly on the medial distal leg, can develop in patients with chronic venous insufficiency when leg veins become blocked. Standard treatment for venous ulcers includes compression bandages or hosiery supplemented by conservative measures such as leg elevation.

Compression Pumps

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

single chamber that is inflated at 1 time to apply uniform pressure. Multichamber nonprogrammable pumps have multiple chambers ranging from 2 to 12 or more. The chambers are inflated sequentially and have a fixed pressure in each compartment. They can either have the same pressure in each compartment or a pressure gradient, but they do not include the ability to adjust the pressure manually in individual compartments. Single- or multi-chamber programmable pumps are similar to the pumps described above except that it is possible to adjust the pressure manually in the individual compartments and/or the length and frequency of the inflation cycles. In some situations, including patients with scarring, contractures, or highly sensitive skin, programmable pumps are generally considered the preferred option. PCPs are also proposed to supplement standard care for patients with venous ulcers. Recently, non-pneumatic, wearable compression pumps have become available. These garments can be programmed to provide graduated sequential compression therapy while providing patients with a functional range of motion and mobility.

Regulatory Status

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

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

In 2024, the FDA cleared the Dayspring (Koya Medical, Inc.) non-pneumatic, wearable limb compression system. The device is intended for use in a clinic or home setting by medical professionals and patients who are under medical supervision to increase lymphatic flow in the treatment of various conditions, including lymphedema and venous insufficiency.

FDA product code: JOW.

RATIONALE

Summary of Evidence

For individuals who have lymphedema who failed to respond to conservative therapy who receive pneumatic compression pumps applied to limb only, the evidence includes randomized controlled trials (RCTs) and systematic reviews primarily focusing on upper-limb lymphedema secondary to breast cancer. Relevant outcomes are symptoms, change in disease status, functional outcomes, and quality of life. Most of these RCTs were deemed moderate-to-high quality by the Agency for Healthcare Research and Quality, and about half reported significant

improvements with the use of pumps compared to conservative care. Recent meta-analyses indicate that incorporating intermittent pneumatic compression (IPC) with complete decongestive therapy can further enhance lymphedema management within four weeks post-treatment. Similar findings are observed when IPC is combined with decongestive lymphatic therapy compared to decongestive lymphatic therapy alone in managing upper limb lymphedema after breast cancer surgery, with the former combined regimen showing improved external rotation joint mobility. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have lymphedema who failed to respond to conservative therapy who receive pneumatic compression pumps applied to limb and chest and/or trunk, the evidence includes two RCTs of the Flexitouch system (Tactile Medical), published in 2012, comparing treatment with and without truncal involvement. Relevant outcomes are symptoms, change in disease status, functional outcomes, and quality of life. In one RCT, two (of 4) key outcomes were significantly better with truncal involvement than without. This trial was limited by small sample size, failure to adjust statistically for multiple primary outcomes, and use of intermediate outcomes (e.g., amount of fluid removed) rather than health outcomes (e.g., functional status, quality of life). The second RCT did not find statistically significant differences between groups for any of the efficacy outcomes. The available evidence does not demonstrate that pumps treating the trunk or chest provide incremental improvement beyond that provided by pumps treating the affected limb only. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have lymphedema who failed to respond to conservative therapy who receive pneumatic compression pumps applied to the head and neck, the evidence includes one RCT and a systematic review to assess the use of pneumatic compression treatment for head and neck lymphedema. Relevant outcomes are symptoms, change in disease status, functional outcomes, and quality of life. The RCT, comparing treatment with a pneumatic compression pump along with lymphedema self-management compared to self-management alone, examined the feasibility, adherence, and safety of the Flexitouch advanced pneumatic compression device (APCD) by Tactile Medical. The findings showed some improvements in patient-reported outcomes and swelling, although adherence was low, with only one patient using the device twice daily as prescribed. The systematic review also suggested benefits from using the APCD, and it was considered safe and feasible according to the observational studies that reported adverse events. Most studies included participants who had completed or were concurrently undergoing complete decongestive therapy. Out of the 5 observational studies included in the systematic review, four (80%) had potential conflicts of interest related to the funding source. The only study not sponsored by the industry highlighted difficulties in obtaining the APCD, with fewer than half of the patients receiving the device as prescribed. Further research with larger sample sizes and comparisons against the criterion standard of complete decongestive therapy is necessary to establish the efficacy of this treatment approach. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have lymphedema who failed to respond to conservative therapy who receive non-pneumatic compression pumps applied to limb only, the evidence includes randomized crossover trials. Relevant outcomes are symptoms, change in disease status, functional outcomes, and quality of life. Randomized crossover trials have compared use of non-pneumatic, wearable, compression devices to traditional, pneumatic compression devices in both upper and lower extremity lymphedema. These studies have consistently supported noninferior reductions in limb edema volume, higher rates of patient compliance, and improvements on quality of life assessments with use in the short-term (28 to 90 days). Additionally, clinical input supports the use of non-pneumatic, wearable compression devices on the basis of this research and clinical experience. These devices may be particularly suitable for individuals who have an active lifestyle or mobility requirements where traditional pneumatic compression devices are expected to impede sufficient compliance with treatment. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

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

Additional Information

2025 Input

Clinical input was sought to help determine whether the use of pneumatic compression pumps for individuals with lymphedema would provide a clinically meaningful improvement in net health outcome and represents generally accepted medical practice in selected patients. In response to requests, clinical input was received from 3 respondents identified by the National Commission on Lymphatic Diseases (NCLD) or an academic medical center. In addition to this request, a plastic surgeon specializing in lymphedema research and reconstruction at a major academic medical center was interviewed.

For individuals with lymphedema who failed to respond to conservative therapy, clinical input supports that use of pneumatic compression pumps applied to the chest and/or trunk in addition to the limbs is consistent with generally accepted medical practice and its use is expected to provide a clinically meaningful improvement in the net health outcome in individuals who do not respond to limb compression alone. For individuals with lymphedema who failed to respond to conservative therapy, use of pneumatic compression pumps applied to the head or neck was mixed, with respondents citing limited direct experience. Ongoing evidence generation in

patients treated for head and neck cancers is expected to elucidate clinical benefit. Respondents also supported the use of novel non-pneumatic compression pumps, noting that the evidence supports their noninferiority compared to traditional, pneumatic devices - and helps to support patient compliance with treatment.

DEFINITIONS

LYMPHEDEMA refers to the abnormal accumulation of lymph fluid in subcutaneous tissues or body cavities as a result of obstruction of lymphatic flow causing swelling of the extremities. Lymphedema may be subdivided into two types:

- Primary lymphedema, which has no recognizable etiology; and
- Secondary lymphedema, which has a variety of causes including surgical removal of lymph nodes, post-radiation fibrosis, scarring of lymphatic channels, or congenital anomalies.

Treatment of lymphedema may include the use of pharmaceuticals, mechanical appliances, such as compression garments, bandaging, manual massage, lymphedema pumps, or in rare incidences, surgery.

PERIPHERAL VASCULAR DISEASE (PVD) refers to a slow and progressive circulation disorder. Narrowing, blockage, or spasms in a blood vessel can cause PVD and may affect any blood vessel outside of the heart including the arteries, veins, or lymphatic vessels.

DISCLAIMER

Capital Blue Cross' medical policies are used to determine coverage for specific medical technologies, procedures, equipment, and services. These medical policies do not constitute medical advice and are subject to change as required by law or applicable clinical evidence from independent treatment guidelines. Treating providers are solely responsible for medical advice and treatment of members. These polices are not a guarantee of coverage or payment. Payment of claims is subject to a determination regarding the member's benefit program and eligibility on the date of service, and a determination that the services are medically necessary and appropriate. Final processing of a claim is based upon the terms of contract that applies to the members' benefit program, including benefit limitations and exclusions. If a provider or a member has a question concerning this medical policy, please contact Capital Blue Cross' Provider Services or Member Services.

CODING INFORMATION

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined

by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational; therefore, not covered:

Procedure Codes								
E0659	E0675*	E0683	E1399**					

***This code can be used for the Syncardon Device, the Circulator Boot, and other devices used to treat arterial insufficiency

** This code can be used to bill for a head and neck lymphedema garment

Covered when Medically Necessary:

Procedure Codes								
E0650	E0651	E0652	E0655	E0656	E0657	E0658	E0660	E0665
E0666	E0667	E0668	E0669	E0670	E0671	E0672	E0673	E0676
E0677	E0678	E0679	E0680	E0681	E0682			

ICD-10-CM Diagnosis Code	Description
I89.0	Lymphedema, not elsewhere classified
I97.2	Postmastectomy lymphedema syndrome
Q82.0	Hereditary lymphedema

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POLICY HISTORY

MP 6.013	**06/17/2020 Minor Review**. Revised the following criterion under programmable devices for CVI from, “continued moderate to severe pain with the use of a non-programmable pump despite trials of oral prescription pain medication” to “continued symptoms with the use of a non-programmable pump”. Added “the individual did not achieve adequate symptom relief with a non-programmable single compartment or multichamber pump” to single compartment or multichamber *programmable* lymphedema pumps criteria. References reviewed and updated. Coding reviewed.
	06/03/2021 Consensus Review. No change to policy statement or coding. References updated.
	04/19/2022 Major Review. Added examples of conservative therapy and unique characteristics. Added MN criteria for chest/trunk and head/neck. Updated FEP, background, rationale, coding, and references.

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	06/23/2023 Minor Review. Expanded scope of policy to include non-pneumatic devices. Title change. Syncardon therapy and End Diastolic Compression Boot statements combined into one general NMN statement that "compression pumps for treatment of indications other than those listed above, including, but not limited to, peripheral arterial occlusive disease/arterial insufficiency are considered NMN". Updated background, rationale, definitions, and references. From coding table deleted codes 93799 and 99199; added E0677, K1024-25, and K1031-33 for non-pneumatic compression devices.
	10/18/2023 Administrative Update. Addition of Note to bottom of policy statement for clarity. Note: Compression appliances/garments are only medically necessary when criteria are met for the compression pump.
	12/12/2023 Administrative Update. Deleted K1024-K1033 and added E0678-E0682.
	09/18/2024 Administrative Update. New code E0683 added effective 10/01/2024.
	01/03/2025 Minor Review. Updated criteria for pneumatic pumps (CVI for venous stasis ulcers and chest/trunk/head/neck are now INV); nonpneumatic devices are also INV. E0656, E0657, E0670, E0677-83, and E1399 moved to INV coding table. Updated background, rationale, and references.
	06/16/2025 Administrative Update. Removed Benefit Variations Section and updated Disclaimer.
	09/11/2025 Minor Review. A third allowance has been given for Single-compartment or multichamber *programmable* pneumatic pumps. Pneumatic compression pumps are now MN with criteria for the chest/trunk. Non-pneumatic compression pumps are now MN with criteria for lymphedema. Policy guidelines added. Updated background, rationale, and references. Coding table updated to align with updated statements.