

MEDICAL POLICY

POLICY TITLE	COMPRESSION DEVICES FOR TREATMENT OF LYMPHEDEMA AND PERIPHERAL VASCULAR DISEASE (FORMERLY PNEUMATIC COMPRESSION DEVICES FOR TREATMENT OF LYMPHEDEMA AND CHRONIC VENOUS INSUFFICIENCY)
POLICY NUMBER	MP 6.013

Effective Date:	1/1/2024
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I. POLICY

Compression Pumps for Treatment of Lymphedema:

Single Compartment or Multichamber Nonprogrammable pumps

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

Single Compartment or Multichamber Programmable pumps

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

- The individual is otherwise eligible for nonprogrammable pumps; and
- There is documentation of EITHER of the following:
 - the individual has unique characteristics that prevent satisfactory pneumatic compression with single-compartment or multichamber nonprogrammable lymphedema pumps (e.g., significant scarring or contractures); OR
 - the individual did not achieve adequate symptom relief with a non-programmable single compartment or multichamber pump

Single compartment or multichamber *programmable* lymphedema pumps applied to the chest* or trunk may be considered **medically necessary** for the treatment of lymphedema when:

- The individual has lymphedema of an extremity; and
- The individual is otherwise eligible for nonprogrammable pumps; and
- The individual has lymphedema extending onto the chest and/or trunk that extends past the limitations of a standard compression sleeve used with pneumatic compression therapy device, single compartment or multichamber nonprogrammable lymphedema pumps.

*Note: Compression head/neck garments for the treatment of head and neck cancer may come with an attached chest garment. In this case, if an individual meets criteria for the head/neck lymphedema pump, then the chest garment would also be medically necessary.

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Single compartment or multichamber *programmable* lymphedema pumps applied to the head and neck may be considered **medically necessary** for the treatment of lymphedema when the individual meets all of the following:

- Has completed cancer treatment for histologically proven head and neck cancer (HNC); and
- Has recovered from acute treatment effects; and
- Has no evidence of active disease; and
- Has documentation of severe lymphedema of the head and/or neck; and
- Has failed to respond to conservative treatments measures such as the use of compression garments, simple lymphatic drainage, and manual lymphatic drainage.

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

Single compartment or multichamber lymphedema pumps applied to the limb for the treatment of lymphedema are considered **investigational** in all other situations. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

The use of lymphedema pumps to treat the trunk or chest in patients with lymphedema limited to the upper and/or lower limbs is considered **investigational** as there is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure

Compression Pumps for Treatment of Chronic Venous Insufficiency (CVI) with Venous Stasis Ulcers:

Single Compartment or Multichamber Nonprogrammable Compression Devices

Single compartment or multichamber *nonprogrammable* pneumatic compression devices may be considered **medically necessary** in the home setting for the treatment of CVI with venous stasis ulcers when ALL of the following conditions are met:

- The patient has had a six (6) month trial of conservative therapy directed by a physician; and
- The conservative therapy included all of the following:
 - Compression bandage system or compression garment
 - Appropriate wound dressings
 - Exercise
 - Elevation of the limb

Single Compartment or Multichamber Programmable Compression Devices

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Single compartment or multichamber *programmable* pneumatic compression devices may be considered **medically necessary** for the treatment of CVI in patients when ALL of the following conditions are met:

- Extremity ulcer(s) or wound(s); and
- Continued symptoms with use of a non-programmable pump; and
- Current participation in an active wound care management program, including debridement, etc., in either an outpatient facility or office setting.

Compression devices for the treatment of CVI with venous stasis ulcers are considered **investigational** in all situations not specified above as there is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Compression Pumps for Treatment of Other Indications:

Compression pumps for treatment of indications other than those listed above* including, but not limited to, peripheral arterial occlusive disease/arterial insufficiency are considered **not medically necessary** as there is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

*For VTE prophylaxis see MP 6.053

Note: Compression appliances/garments are only medically necessary when criteria are met for the compression pump.

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)

II. PRODUCT VARIATIONS

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

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>

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III. DESCRIPTION/BACKGROUND

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Pneumatic compression pumps are proposed as a treatment option for patients with lymphedema who have failed conservative measures e.g., compression garments, manual massage. They are also proposed to supplement standard care for patients with venous ulcers. A variety of pumps are available; they can be single chamber (non-segmented) or multi-chamber (segmented) and have varying design and complexity.

Lymphedema and Venous Ulcers

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. Simple lymphatic drainage is an easier version of manual lymphatic drainage that the patient learns and can perform at home. 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 are proposed as a treatment for venous ulcers, especially for patients who do not respond to these standard therapies. 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.

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 that are 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, design, degree of pressure, and complexity. There are 3 primary types of pumps:

- Single-chamber nonprogrammable pumps: These are the simplest pumps, consisting of a single chamber that is inflated at one time to apply uniform pressure.

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- Multichamber nonprogrammable pumps: They 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 manually adjust the pressure in individual compartments.
- Single- or multichamber programmable pumps: They 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

While pneumatic compression devices require the patient to remain immobile, non-pneumatic compression devices allow patients to remain active and mobile during compression treatment. One device currently available is the Dayspring® active wearable compression system. This system is a calibrated non-pneumatic (airless) compression system that consists of a Controller and a segmented Garment with programmable compression segments. This system creates a calibrated pressure gradient that compresses sequentially in distal to proximal directions to help the patient move and drain excess lymph fluid. The Dayspring® system uses patented technology where the spring-like segments use shape-memory alloy that contracts and relaxes when connected to the controller.

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™ system (Tactile Medical, formerly Tactile Systems Technology); and the Powerpress Unit Sequential Circulator (Neomedic).

Several pneumatic compression devices have been cleared by FDA 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).

One non-pneumatic compression device has been cleared by the FDA through the 510(k) process. Dayspring® (Koya Medical, Inc) is a prescription-only wearable compression system that is intended to increase lymphatic flow in the treatment of many conditions including lymphedema, chronic edema, venous insufficiency, and the reduction of wound healing time.

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FDA product code: JOW.

IV. RATIONALE

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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 of RCTs. Relevant outcomes are symptoms, change in disease status, functional outcomes, and quality of life. Most of the RCTs were rated as moderate-to-high quality by an Agency for Healthcare Research and Quality review, and about half reported significant improvement 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 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 a 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. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have limb lymphedema which has spread to the chest and/or trunk, guidance from the National Lymphedema Network has been considered. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have venous ulcers who receive pneumatic compression pumps, the evidence includes several RCTs and a systematic review of RCTs. 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. Moreover, the 2 trials comparing lymphedema pumps with continuous compression did not find significant between-group differences in healing rates.

For individuals who have chronic venous insufficiency with extremity ulcers, guidance from The American Venous Forum, American Vein and Lymphatic Society and The Society for Vascular

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Medicine has been considered. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have peripheral arterial occlusive disease/arterial insufficiency, the evidence includes small pilot studies with short-term follow up. Well-designed large scale randomized control trials with long-term follow up are necessary to determine optimal treatment protocols for the use of pneumatic compression therapy devices for individuals with this condition. The evidence is insufficient to determine the effects of the technology on health outcomes.

V. DEFINITIONS

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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 vessels can cause PVD and may affect any blood vessel outside of the heart including the arteries, veins, or lymphatic vessels.

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

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Capital Blue Cross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any

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medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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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.

Not medically necessary; therefore, not covered:

Procedure Codes								
E0675*								

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

Covered when Medically Necessary:

Procedure Codes								
E0650	E0651	E0652	E0655	E0656	E0657	E0660	E0665	E0666
E0667	E0668	E0669	E0670	E0671	E0672	E0673	E0676	E0677
E0678	E0679	E0680	E0681	E0682	E1399*			

*Used to bill for Head and Neck garment

ICD-10-CM Diagnosis Code	Description
I87.2	Venous insufficiency (chronic) (peripheral)
I89.0	Lymphedema, not elsewhere classified
I97.2	Postmastectomy lymphedema syndrome
Q82.0	Hereditary lymphedema

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MP 6.013	CAC 12/02/03
	CAC 9/28/04
	CAC 9/27/05 Retire/Use DME Criteria
	CAC 1/30/07 Reinstate policy – Milliman Criteria

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	CAC 5/27/08
	CAC 3/31/09
	CAC 3/30/10 Consensus review.
	CAC 7/26/11 Adopted BCBSA medically necessary criteria for treatment of lymphedema. Remains medically necessary after failure of conservative treatment. BCBSA medically necessary criteria for programmable lymphedema pumps also added. Added investigational statement for two-phase multichamber lymphedema pumps.
	CAC 10/30/12 Consensus review. References updated. Added statement to provide clarity that single compartment or multichamber lymphedema pumps are considered investigational in all situations other than those specified above in the first two policy statements. FEP variation revised to refer to the FEP manual. Codes reviewed 10/18/12
	12/20/12 Administrative update. 2013 Codes added
	CAC 3/26/13 Minor revision. Statement on two-phase pumps deleted. Statement added that use of lymphedema pumps to treat the trunk or chest in patients with lymphedema limited to the upper and/or lower limbs is considered investigational.
	05/13/2013 Administrative update. Code review completed.
	CAC 1/28/14 Consensus review. “Applied to the limb” added to the first three policy statements to provide clarity. References updated.
	CAC 1/27/15 Consensus review. No change to policy statements. Rationale added. References updated. Codes Reviewed.
	12/1/15 Medicare update. Changed LCD number from L11503 to L33829 due to NHIC update to ICD 10.
	CAC 1/26/16 Consensus review. No change to policy statements. References and rationale updated. Coding reviewed and HCPCS E0675 removed as it was not applicable to policy.
	7/15/2016 Administrative update. Change NHIC to Noridian in references. LCD number remain the same.
	1/1/17 Administrative update. Variation reformatting.
	CAC 3/28/17 Consensus review. No change to policy statements. References and updated. Coding reviewed. Added E0675 to not medically necessary
	1/1/18 Administrative update. Medicare variations removed from Commercial Policies
	1/18/18 Consensus review. No change to policy statements. References and rationale updated.
	2/20/19 Consensus review. No change to policy statements. References and rationale updated.

MEDICAL POLICY

POLICY TITLE	COMPRESSION DEVICES FOR TREATMENT OF LYMPHEDEMA AND PERIPHERAL VASCULAR DISEASE (FORMERLY PNEUMATIC COMPRESSION DEVICES FOR TREATMENT OF LYMPHEDEMA AND CHRONIC VENOUS INSUFFICIENCY)
POLICY NUMBER	MP 6.013

	8/13/19 Minor review. End Diastolic Pneumatic Compression Boot as a Treatment of Peripheral Vascular Disease and Lymphedema is being added to the policy statement. Coding section updated. References updated. Effective 2/1/2020.
	6/17/20 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 <i>programmable</i> lymphedema pumps criteria. References reviewed and updated. Coding reviewed.
	6/3/21 Consensus review. No change to policy statement or coding. References updated.
	4/19/2022 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.
	6/23/2023 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.

TOP

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