Lymphedema Pumps

Policy # 00081
Original Effective Date: 04/13/1994
Current Effective Date: 09/01/2024
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Returned to Active Status: 09/01/2024

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Ultraviolet Light Therapy Delivery Devices for Home Use is addressed separately in medical policy 00131.

Note: Bioimpedance Devices for Detection and Management of Lymphedema is addressed separately in medical policy 00780.

Note: Noncontact Ultrasound Treatment for Wounds is addressed separately in medical policy 00808.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of lymphedema pumps to treat the trunk or chest in patients with lymphedema with or without involvement of the upper and/or lower limbs to be **investigational.***

Based on review of available data, the Company considers the use of lymphedema pumps applied to the head and neck to treat lymphedema to be **investigational.***

Based on review of available data, the Company considers the use of pneumatic compression pumps to treat venous ulcers to be **investigational.***

Note: Limb lymphedema pumps for treatment of lymphedema in extremities are not subject to this medical policy review.

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Background/Overview

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 are also proposed to supplement standard care for patients with 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.

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. 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 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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Several pneumatic compression pumps, indicated for the primary or adjunctive treatment of primary or secondary (eg, 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 the 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).

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

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Description
Pneumatic compression pumps are proposed as a treatment for patients with lymphedema who have failed conservative measures. They are also proposed to supplement standard care for patients with venous ulcers. A variety of pumps are available; they can be single chamber (nonsegmented) or multichamber (segmented) and have varying designs and complexity.

Summary of Evidence
For individuals who have lymphedema who failed to respond to conservative therapy who receive pneumatic compression pumps applied to the 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 (eg, amount of fluid removed) rather than health outcomes (eg, 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 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 1 RCT comparing treatment with a pneumatic compression pump along with lymphedema self-management compared to self-management alone. Relevant outcomes are symptoms, change in disease status, functional outcomes, and quality of life. 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 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 venous ulcers who receive pneumatic compression pumps, the evidence includes RCTs and two systematic reviews 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. Another meta-analysis of 6 trials compared pneumatic compression pumps to care with bandage pressure therapy and found no differences between groups for the rate of wound healing, area of wound healed, or the rate of adverse events between groups. Moreover, the 2 trials comparing lymphedema pumps with continuous compression did not find significant between-group differences in healing rates. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Venous Forum et al

In 2022, the American Venous Forum, American Vein and Lymphatic Society, and the Society for Vascular Medicine published an expert opinion consensus statement on lymphedema diagnosis and treatment. The following statements were issued regarding use of pneumatic compression:

- "Sequential pneumatic compression should be recommended for lymphedema patients." (92% panel agreement; 32% strongly agree)
- "Sequential pneumatic compression should be used for treatment of early stages of lymphedema." (62% panel agreement - consensus not reached; 38% panel disagreement; 2% strongly disagreed)

International Union of Phlebology
A 2013 consensus statement from the International Union of Phlebology indicated that primary lymphedema could be managed effectively by a sequenced and targeted management program based on a combination of decongestive lymphatic therapy and compression therapy. Treatment should include compression garments, self-massage, skin care, exercises, and, if desired, pneumatic compression therapy applied in the home.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
A 2002 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."

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT04797390[a]	A Randomized Trial of an Advanced Pneumatic Compression Device vs. Usual Care for Head and Neck Lymphedema	250	Dec 2023

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

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08/16/2001	Medical Policy Committee review
08/20/2001	Managed Care Advisory Council approval
06/24/2002	Format revised. No substance change to policy.
07/15/2003	Medical Policy Committee review. Format revised. No substance change to policy.
08/25/2003	Managed Care Advisory Council approval
12/07/2004	Medical Director review
12/14/2004	Medical Policy Committee review. Format revision. No substance change to policy.
01/31/2005	Managed Care Advisory Council approval
01/04/2006	Medical Director review
01/17/2006	Medical Policy Committee review. Format revision.
02/23/2006	Quality Care Advisory Council approval
07/07/2006	Format revision; including, addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
01/10/2007	Medical Director review
01/17/2007	Medical Policy Committee approval. Coverage eligibility unchanged.
01/09/2008	Medical Director review
01/23/2008	Medical Policy Committee approval. No change to coverage eligibility. Archived 01/16/2008.
06/06/2024	Medical Policy Committee review
06/12/2024	Medical Policy Implementation Committee approval. Policy reactivated from retirement. This policy has investigational statements for treatment of the trunk or chest and the head and neck and for the use of pneumatic compression pumps to treat venous ulcers.
09/18/2024	Coding update.

Next Scheduled Review Date: 06/2025

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Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2023 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	No Codes
HCPCS	E0650, E0651, E0652, E0655, E0656, E0657, E0660, E0665, E0666, E0667, E0668, E0669, E0670, E0671, E0672, E0673, E0675, E0676 Add code effective 10/01/2024: E0683
ICD-10 Diagnosis	C76.0, C77.0, I83.001-I83.009, I83.011-I83.019, I83.021-I83.029, I83.201-I83.209, I83.211-I83.219, I83.221-I83.229, I87.011-I87.019, I87.031-I87.039, I87.311-I87.319, I87.331-I87.339

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

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NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.