LOUISIANA BLUE

Compression Devices and Garments for Treatment of Lymphedema, Venous Ulcers, and Arterial Insufficiency

Policy # 00081
Original Effective Date: 04/13/1994
Current Effective Date: 12/01/2025
Archived Date: 01/23/2008
Retired Date: 10/17/2018
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.***

Based on review of available data, the Company considers the use of pneumatic compression pumps to treat peripheral artery disease (e.g., intermittent claudication, ischemia, arterial insufficiency) 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

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.

Arterial Insufficiency
A variety of factors can limit the successful performance of recommended exercise therapy regimens in patients with peripheral artery disease (PAD). For patients with claudication, cilostazol has evidence of benefit for improving symptoms. Statin therapy for PAD is associated with reduction in limb events (e.g., claudication, lower extremity revascularization, critical limb ischemia), but evidence for the use of statins to improve PAD symptoms is not definitive.

Preferred treatment for patients with chronic limb-threatening ischemia manifesting as rest pain, ischemic ulceration, or gangrene, is revascularization (percutaneous or surgical). Many patients are poor candidates for revascularization due to medical comorbidities.

Some therapies have been investigated and include spinal cord stimulation, transcutaneous nerve stimulation, heat therapy, pneumatic compression therapy, and extracorporeal shockwave therapy. The quality of evidence for these therapies is overall low.

Pneumatic Compression Pumps
Pneumatic compression pumps (PCPs) may be used in lymphedema or wound care clinics, purchased, or rented for home use; home use is addressed herein. PCPs consist of pneumatic cuffs connected to a pump. These pumps use compressed air to apply pressure to the affected limb. The intention is to force excess lymph fluid out of the limb and into central body compartments in which lymphatic drainage should be preserved. Many PCPs are available, with varying materials, designs, degrees of pressure, and complexity. There are 3 primary types of pumps. Single chamber nonprogrammable pumps are the simplest pumps, consisting of a single chamber that is inflated at 1 time to apply uniform pressure. Multichamber nonprogrammable pumps have multiple chambers ranging from 2 to 12 or more. The chambers are inflated sequentially and have a fixed pressure in each compartment. They can either have the same pressure in each compartment or a pressure gradient, but they do not include the ability to adjust the pressure manually in individual compartments. Single- or multi-chamber programmable pumps are similar to the pumps described above except that it is possible to adjust the pressure manually in the individual compartments and/or the length and frequency of the inflation cycles. In some situations, including patients with scarring, contractures, or highly sensitive skin, programmable pumps are generally considered the preferred option. PCPs are also proposed to supplement standard care for patients with venous ulcers.

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

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Powerpress Unit (listed above) as well as NanoTherm™‡ (ThermoTek), CTU676 devices (Compression Technologies), and Recovery+™‡ (Pulsar Scientific).

Several pneumatic compression devices have been cleared by the FDA also for peripheral artery disease or to aid in the treatment and healing of arterial leg ulcers. Examples include PlasmaFlow (ManaMed), ARTAIRA Arterial Compression Device (AIROS Medical), ALP®‡ 501 RB Pneumatic Compression System (Currie Medical Specialties).

FDA product code: JOW.

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 regulations, other plan medical policies, and accredited national guidelines.

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 and peripheral artery disease. 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 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 (eg, amount of fluid removed) rather than health outcomes (eg, 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 venous ulcers who receive 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. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have peripheral artery disease who receive pneumatic compression pumps, the evidence includes systematic reviews, RCTs and case series. 2018 systematic review and meta-analysis of RCTs evaluated the efficacy of high-pressure intermittent limb compression as an alternative modality for disabling intermittent claudication. Limitations included small sample size, low-quality studies with risk of bias, significant heterogeneity and limited generalizability. The authors concluded that intermittent limb compression could be beneficial in improving absolute claudication distance along with supervised exercise and surgery, also noting that there are few studies comparing limb compression with other commonly used therapies and that further studies are needed to better guide the use in the treatment of claudication. Medical societies recommend considering pumps in patients with intractable severe PAD (grade 2B recommendation, weak recommendation, effectiveness is uncertain or not well established). Well-designed large scale RCTs

with long-term follow-up are necessary to determine optimal treatment protocols and clinical utility. The evidence is insufficient to determine the effects of the technology on health outcomes.

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 Academy of Family Physicians

In 2019, the American Academy of Family Physicians published recommendations for diagnosis and treatment of venous ulcers. The following statements were issued regarding use of intermittent pneumatic compression.

- "Intermittent pneumatic compression may be considered when there is generalized, refractory edema from venous insufficiency; lymphatic obstruction; and significant ulceration of the lower extremity. Although intermittent pneumatic compression is more effective than no compression, its effectiveness compared with other forms of compression is unclear. Intermittent pneumatic compression may improve ulcer healing when added to layered compression."

American College of Cardiology/American Heart Association

The 2024 ACC/AHA/AACVPR/APMA/ABC/SCAI/SVM/SVN/SVS/SIR/VESS guideline for the management of lower extremity peripheral artery disease: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines noted that in patients with chronic limb-threatening ischemia (CLTI) for whom revascularization is not an option, arterial intermittent pneumatic compression devices may be considered to augment wound healing or ameliorate ischemic rest pain (weak recommendation 2b, usefulness is less well established based on moderate-quality evidence from nonrandomized or observational studies), adding that intermittent pneumatic compression does not appear to reduce rate of major amputation and further research is warranted.

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.

Society for Vascular Surgery and American Venous Forum
The 2014 joint guidelines from the Society for Vascular Surgery and the American Venous Forum on the management of venous ulcers included the following statement on pneumatic compression:

> "We suggest use of intermittent pneumatic compression when other compression options are not available, cannot be used, or have failed to aid in venous leg ulcer healing after prolonged compression therapy. [GRADE - 2; LEVEL OF EVIDENCE - C]"

Wound Healing Society
A 2015 guideline from the Wound Healing Society states that for patients with venous ulcers, intermittent pneumatic pressure can be used with or without compression dressings and can provide another option in patients who cannot or will not use an adequate compression dressing system.

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."

B. "Chronic Venous Insufficiency With Venous Stasis Ulcers
Chronic venous insufficiency (CVI) of the lower extremities is a condition caused by abnormalities of the venous wall and valves, leading to obstruction or reflux of blood flow in the veins. Signs of CVI include hyperpigmentation, stasis dermatitis, chronic edema, and venous ulcers."

"Pneumatic compression devices are covered in the home setting for the treatment of CVI of the lower extremities only if the patient has one or more venous stasis ulcer(s) which have failed to heal after a 6 month trial of conservative therapy directed by the treating physician. The trial of conservative therapy must include a compression bandage system or compression garment, appropriate dressings for the wound, exercise, and elevation of the limb."

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 2.

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT06418282[a]	An Open-label, Multi-center, Prospective VA Study to Evaluate the Effectiveness and Health Economics of a Novel Portable Non-Pneumatic Active Compression Device (NPCD) for Lymphedema/ Phlebolymphedema	50	Jan 2025
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)	136	Sep 2024

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

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Policy History

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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

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	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.
06/05/2025	Medical Policy Committee review
06/11/2025	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/04/2025	Medical Policy Committee review
09/10/2025	Medical Policy Implementation Committee approval. Title changed from "Lymphedema Pumps" to "Compression Devices and Garments for Treatment of Lymphedema, Venous Ulcers, and Arterial Insufficiency". Added an investigational statement for the use of pneumatic compression pumps to treat peripheral artery disease (e.g., intermittent claudication, ischemia, arterial insufficiency).
10/01/2025	Coding Update

Next Scheduled Review Date: 09/2026

Coding

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2024 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.

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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, E0683 Add codes effective 10/01/2025: E0658, E0659 Add code effective 12/01/2025: E0677
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, I89.0, L04.0, R22.0, R22.1

*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.

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.