Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

Nonprofit corporations and independent licensees of the Blue Cross and Blue Shield Association

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

Title: PNEUMATIC COMPRESSION PUMPS AND APPLIANCES FOR VENOUS ULCERS

Description/Background

Venous Ulcers

Venous ulcers (also known as stasis ulcers) can occur when the venous return from the legs is impaired, leading to high pressure in the veins of the leg. Lower extremity veins have one-way valves that keep blood flowing toward your heart. When these valves fail or the veins become scarred and blocked, venous stasis results, with blood pooling in the legs. This is called venous insufficiency. Elevated venous pressure in the leg veins leads to a build-up of fluid (edema), which prevents nutrients and oxygen from getting to tissues which may lead to ulceration of the overlying skin. Most venous ulcers occur on the leg, above the ankle. Venous ulcers will not generally heal unless the venous pressure and edema are relieved.

Diagnosis

The diagnosis of venous ulcers is generally clinical; however, tests such as ankle-brachial index, color duplex ultrasonography, plethysmography and venography may be helpful if the diagnosis is unclear.[1]

Treatment

Standard treatment for venous ulcers includes compression bandages or hosiery supplemented by leg elevation. Pneumatic compression pumps and appliances may also be beneficial, in particular when venous insufficiency is accompanied by edema

Arterial Ulcers

Arterial insufficiency (ischemic) ulcers typically occur distally on the toes or on pressure areas, such as the heel, malleoli, and shin. Ulcers have well-demarcated edges, giving them a “punched-out” appearance, often with an overlying necrotic eschar. Unlike venous ulcers, arterial ulcers typically are very painful.

Diagnosis
For many patients, a history of risk factors or symptoms of peripheral artery disease (PAD), in combination with physical examination findings, is sufficient to establish a diagnosis of PAD. For patients with atypical symptoms, or a pulse examination that is equivocal, the ankle-brachial index (ABI) testing is diagnostic.

Treatment
The management of arterial ulcers begins with a comprehensive medical history. The primary goal of treatment is to increase circulation to the area, either medically or surgically. For non-surgical measures, modifying contributing factors can slow or stop the progression of local ischemia. Surgical options range from revascularization in order to restore normal blood flow to amputation and rehabilitation in extreme cases.

Neuropathic Ulcers
Diabetic neuropathy is responsible for the vast majority of neuropathic ulcers. Diabetic patients may have up to a 25% lifetime risk of developing a foot ulcer. Other causes of peripheral neuropathy (e.g., spinal cord disorders, tabes dorsalis, alcohol abuse, nutritional deficiencies, and autoimmune diseases) may result in similar ulcerations.

Diagnosis
Sensory examination confirms decreased sensation in the involved areas. Ulcers can become deep, and underlying osteomyelitis should be considered when ulcers do not heal with off-loading therapies.

Treatment
The management of venous ulcers begins with a comprehensive assessment of the ulcer and the patient's overall medical condition. Treatment options include conservative management, mechanical treatment, medications and surgical options.

Many pneumatic compression pumps are available. There are three primary types of pumps as follows:

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

Non-pneumatic Compression Devices
A non-pneumatic Compression System or Garment (e.g., Koya Dayspring System) is a wearable compression device that uses sequential gradient compression for the treatment and management of patients with lymphedema and provides patients with mobility during treatment.

The Koya Dayspring® consists of a programmable, segmental controller with a sleeve garment that can be sized to fit the individual. The garment contains a shape memory alloy made with

nickel/titanium (Ni-Ti) that is programmed by a rechargeable controller to shrink in a cyclic manner, applying active gradient pressure from the distal to proximal end of the limb. This mechanistic action is similar to the motion of advanced pneumatic compression devices and is purported to provide comparable compression to existing pneumatic pumps via segments that contract and relax flexible frames in a segmental appliance without the use of air. Up to 14 independently controlled segments can be programmed to deliver 0–100 mmHg of compression pressure, with typical initial settings in a range of 30–40 mmHg. A mobile phone application can be used to program and individualize pressures; to start, stop, and pause therapy; and to track device usage. The function of the device allows for mobility and range of motion during treatment. According to the manufacturer, the device is built on Flexframe2 technology, a patented mobile platform that provides calibrated sequential gradient.

This policy addresses coverage of pneumatic compression pumps and appliances for venous ulcers.

Regulatory Status

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

Food and Drug Administration product code: JOW.

Medical Policy Statement

Pneumatic compression pumps and appliances [nonprogrammable] for venous ulcers of the lower extremities are established. It may be considered a useful therapeutic option when indicated.

Inclusionary and Exclusionary Guidelines

Inclusions:
Pneumatic compression devices is established for the treatment of chronic venous insufficiency (CVI) of the lower extremities only if all of the following is present:

- Edema in the affected lower extremity
- One or more venous stasis ulcer(s)
- The ulcer(s) have failed to heal after a six-month trial of conservative therapy directed by the treating physician.

Six-Month Trial for CVI
A six-month trial of conservative therapy demonstrating failed response to treatment is required. The six-month trial of conservative therapy must include all of the following:

- Compliant use of an appropriate compression bandage system or compression garment to provide adequate graduated compression
    - Adequate compression is defined as (1) sufficient pressure at the lowest pressure point to cause fluid movement and (2) sufficient pressure across the gradient (from highest to lowest pressure point) to move fluid from distal to proximal. The compression used must not create a tourniquet effect at any point.
    - The garment may be prefabricated or custom-fabricated but must provide adequate graduated compression starting with a minimum of 30 mmHg distally.
- Medications as appropriate (e.g., diuretics and/or other treatment of congestive failure, etc.)
- Regular exercise
- Elevation of the limb
- Appropriate wound care for the ulcer (including sharp debridement where appropriate)

Exclusions:

- Pneumatic compression devices used to treat ulcers in locations other than the lower extremity or ulcers and wounds from other causes.
- At the end of the six-month trial, if there has been improvement, then a pneumatic compression device is no longer considered reasonable and necessary.
- Pneumatic compression devices and appliances, segmental home model with calibrated gradient pressure, are experimental/investigational for CVI.
- Non-pneumatic compression devices.

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

E0650	E0651	E0660	E0666	E0667	E0669

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

E0652	E0671	E0672	E0673	E0676	E0678
E0679	E0680	E0681	E0682	E1399	

Note: Individual policy criteria determine the coverage status of the CPT/HCPCS code(s) on this policy. Codes listed in this policy may have different coverage positions (such as established or experimental/investigational) in other medical policies.

Rationale

Venous Ulcers

Clinical Context and Purpose

The purpose of pneumatic compression pumps in individuals who have venous ulcers is to provide a treatment option that is an alternative to or an adjunct to existing therapies.

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

Populations
The relevant population(s) of interest are individuals 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.

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

Comparators
The following practices are currently being used to treat venous ulcers; local wound care and compression bandages or hosiery supplemented by conservative measures such as leg elevation. Medications and surgical options are also available.

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

Venous ulcers are a chronic condition and follow-up of at least six weeks to six months would be desirable to assess outcomes.

Randomized Controlled Trials
The analysis of venous ulcers focused on RCTs evaluating preferred outcomes for wound healing. Complete healing is generally considered the most clinically relevant outcome; a 50% reduction in wound area over time and time to heal are also considered acceptable outcomes.

A Cochrane review updated by Nelson et al (2014), addressed intermittent pneumatic compression (IPC) pumps for treating venous leg ulcers.[2] Reviewers identified nine RCTs. Five trials compared pneumatic compression pumps plus continuous compression with continuous compression alone, two trials compared compression pumps with continuous compression (stockings or bandages), one trial compared compression pumps with wound dressings only, and one trial compared two IPC regimens. In a meta-analysis, 3 of the 5 trials evaluating the incremental benefit of pneumatic compression pumps over continuous compression alone, there was a significantly higher rate of healing with combined treatment (relative risk, 1.31; 95% confidence interval, 1.06 to 1.63). The authors concluded that IPC may increase healing compared with no compression. It is unclear whether it can be used instead of compression bandages. There was evidence that IPC may improve healing when added to compression bandages.

An RCT by Dolibog et al (2014) was published after the Cochrane review literature search.[3] The trial included 147 patients with venous ulcers. It compared 5 types of compression therapy: IPC using a 12-chamber Flowtron device, stockings, multilayer bandages, 2-layer bandages, and Unna boots. All patients received standard drug therapy; the compression interventions lasted two months. Rates of complete healing at the end of treatment were similar in 3 of the treatment groups: 16 (57%) of 28 patients in the pneumatic compression group, 17 (57%) of 30 in the stockings group, and 17 (59%) of 29 in the multilayer bandage group. On the other hand, rates of healing were much lower in the other 2 groups: 5 (17%) of 30 in the 2-layer bandage group and 6 (20%) of 30 in the Unna boot group. A pilot

study by Dolibog et al (2013), included in the Cochrane review, had similar findings.[4] The authors concluded that the most effective therapeutic procedure for the treatment of venous leg ulcers was the use of intermittent pneumatic compression, stockings and multi-layer compression bandaging.

In a prospective observational study, Naik et al (2019), studied IPC devices applied in the thigh region of the affected limb in patients with lower limb ulcerations of both venous and mixed aetiologies.[5] The compression system consists of a circumferential three-chamber thigh garment and an electronic pneumatic compression pump operating over a repeated 4-minute cycle. Patients were recruited from outpatient wound clinics. Those recruited were treated with standard therapy in addition to IPC, which was applied for 2 hours per day, and followed up for a total of 8 weeks. The primary objective of the study was to examine the effects of IPC on wound healing over an 8-week period. The other objectives were to assess patients' experiences of pain and the acceptability of IPC device. Twenty-one patients were recruited, and wounds progressed towards healing in 95.24% (20/21) of the patients. Pain scores decreased in 83.33% (15/18) of the patients. Most patients felt that the thigh-applied IPC device was comfortable and easy to apply and remove. The authors concluded that the thigh administered IPC device can be recommended for use in routine clinical practice, especially when other treatment options are limited.

Alvarez et al (2020) conducted an RCT in 52 patients with large (>20 cm^2) chronic venous leg ulcers that compared intermittent pneumatic compression plus standard compression therapy (n=27) to standard compression therapy alone (n=25).[6] Compression therapy consisted of a nonadherent primary wound dressing plus a 4-layer compression bandage (n = 25). The mean age and size of the ulcers were 1.4 years and 31 cm^2, respectively, and did not differ significantly between groups. Intermittent pneumatic compression was performed using a 4-chamber pneumatic leg sleeve and gradient, sequential pump. All pumps were calibrated to a pressure setting of 50 mm Hg on each subject, and treatments were for 1 hour twice daily. Evaluations were performed weekly to measure edema, local pain, granulation, and wound healing. The median time to wound closure by 9 months was 141 days for the intermittent pneumatic compression-treated group and 211 days for the control group (P = .031). The rate of healing was 0.8 ± 0.4 mm/d for the control group and 2.1 ± 0.8 mm/d for the group treated with intermittent pneumatic compression (P < .05). When compared with subjects treated with standard care, the group treated with intermittent pneumatic compression reported less pain at each evaluation point for the first 6 weeks of the trial. At weeks 1, 2, and 3, the visual analog pain scores were significantly lower for the intermittent pneumatic compression-treated group (P < .05). The authors concluded that intermittent pneumatic compression is a valuable adjunct to compression therapy in the management of large or painful venous ulcers.

Non-Pneumatic Compression Devices

Clinical Context and Therapy Purpose
The purpose of non-pneumatic compression devices in individuals who venous ulcers is to provide a treatment option that is an alternative to or an improvement on existing therapies.

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

Populations

The relevant population of interest is individuals with venous ulcers or chronic venous insufficiency (CVI).

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

Comparators
The following practices are currently being used to treat venous ulcers; conservative management, mechanical treatment, medications and surgical options.

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

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

Review of Evidence
There are no clinical studies identified addressing non-pneumatic compression device use for venous ulcers. Well-designed clinical studies are needed to determine the effectiveness of this device for this clinical indication.

Summary of Evidence
For individuals using a pneumatic compression pumps for venous ulceration, the evidence includes a Cochrane review of RCTs on pneumatic compression pumps for treating venous leg ulcers conducted a meta-analysis of three trials. This analysis found significantly higher healing rates with lymphedema pumps plus continuous compression than with continuous compression alone. A more recent observational study also found that IPC devices assisted in wound healing. The evidence is sufficient to determine the effects of this technology on health outcomes.

For individuals using a non-pneumatic compression device for venous ulceration, there are no clinical studies identified addressing non-pneumatic compression device use for venous ulcers. Well-designed clinical studies are needed to determine the effectiveness of this device for this clinical indication. The evidence is insufficient to determine the effects of this technology on health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines And Position Statements

Society for Vascular Surgery and American Venous Forum

The joint guidelines from the Society for Vascular Surgery and the American Venous Forum (2014) on the management of venous ulcers included the following statement on pneumatic compression:[7]

"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.[8]

Ongoing and Unpublished Clinical Trials
No clinical trials were found on ClinicalTrials.gov for pneumatic compression devices and venous ulcers.

Government Regulations

National:

No NCD available.

Local:

Pneumatic Compression Devices, L33829, effective on or after 10/22/2023.[8]

II - CHRONIC VENOUS INSUFFICIENCY WITH VENOUS STASIS ULCERS (CVI)
A PCD coded as E0650 or E0651 is covered for the treatment of CVI of the lower extremities only if the patient has all of the following:

- Edema in the affected lower extremity
- One or more venous stasis ulcer(s)
- The ulcer(s) have failed to heal after a six-month trial of conservative therapy directed by the treating physician.

A PCD coded as E0650 or E0651 used to treat CVI that does not meet all of the requirements above is not eligible for reimbursement. Claims will be denied as not reasonable and necessary.

A PCD coded as E0650 or E0651 used to treat ulcers in locations other than the lower extremity or ulcers and wounds from other causes is not eligible for reimbursement. Claims will be denied as not reasonable and necessary.

A PCD coded as E0652 is not covered for the treatment of CVI even if the criteria in this section are met. Claims will be denied as not reasonable and necessary. Refer below to the sections.

Six-Month Trial for CVI

A six-month trial of conservative therapy demonstrating failed response to treatment is required. The six-month trial of conservative therapy must include all of the following:

- Compliant use of an appropriate compression bandage system or compression garment to provide adequate graduated compression
    - Adequate compression is defined as (1) sufficient pressure at the lowest pressure point to cause fluid movement and (2) sufficient pressure across the gradient (from highest to lowest pressure point) to move fluid from distal to proximal. The compression used must not create a tourniquet effect at any point.
    - The garment may be prefabricated or custom-fabricated but must provide adequate graduated compression starting with a minimum of 30 mmHg distally.
- Medications as appropriate (e.g., diuretics and/or other treatment of congestive failure, etc.)
- Regular exercise
- Elevation of the limb
- Appropriate wound care for the ulcer (including sharp debridement where appropriate)

At the end of the six-month trial, if there has been improvement, then reimbursement for a PCD is not reasonable and necessary. Where improvement has occurred, the trial of conservative therapy must be continued with subsequent reassessments. When no significant improvement has occurred for a continuous period of six months and the coverage criteria above are still met, then the use of a PCD to treat CVI is eligible for reimbursement.

The trial of conservative therapy must be documented in the beneficiary's medical record before prescribing any type of pneumatic compression device. This assessment may be performed by the prescribing physician or any other licensed/certified medical professional (LCMP) directly involved in the beneficiary's CVI treatment.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Pneumatic Compression Pumps for Lymphedema
- Lymphedema—Surgical Treatments

References

1. Collins L, Seraj S. Diagnosis and treatment of venous ulcers. American Family Physician. April 2010;81(8):989-996.
2. Nelson EA, Hillman A, Thomas K. Intermittent pneumatic compression for treating venous leg ulcers. Cochrane Database Syst Rev. May 2014;5:CD001899.
3. Dolibog P, Franek A, Taradaj J, et al. A comparative clinical study on five types of compression therapy in patients with venous leg ulcers. Int J Med Sci. Dec 2013;11(1):34-43.

4. Dolibog P, Franek A, Taradaj J, et al. A randomized controlled clinical pilot study comparing three types of compression therapy to treat venous leg ulcers in patients with superficial and/or segmental deep venous reflux. Ostomy Wound Manage. Aug 2013;59(8):22-30
5. Naik G, Ivins NM, Harding KG. A prospective pilot study of thigh-administered intermittent pneumatic compression in the management of hard-to-heal lower limb venous and mixed aetiology ulcers. Int Wound J. Apr 2019. [Epub ahead of print].
6. Alvarez OM, Markowitz L, Parker R, Wendelken ME. Faster healing and a lower rate of recurrence of venous ulcers treated with intermittent pneumatic compression: results of a randomized controlled trial. Eplasty. June 2020: 20: e6. PMID 32636985
7. O'Donnell TF, Jr., Passman MA, Marston WA, et al. Management of venous leg ulcers: clinical practice guidelines of the Society for Vascular Surgery (R) and the American Venous Forum. J Vasc Surg. Aug 2014;60(2 Suppl):3s-59s. PMID 24974070
8. Marston W, Tang J, Kirsner RS, et al. Wound Healing Society 2015 update on guidelines for venous ulcers. Wound Repair Regen. Jan-Feb 2016; 24(1): 136-44. PMID 26663616
9. Centers for Medicare and Medicaid Services. Local Coverage Determination (LCD) for Pneumatic Compression Devices (L33829). Available at www.cms.gov/medicare-coverage-database/. Accessed July 2024.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through July 2024, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
11/1/19	9/5/19		Joint policy established
11/1/20	8/18/20		Routine policy maintenance, no changes in policy status.
11/1/21	8/17/21		Added reference #7, routine maintenance, no change in policy status.
11/1/22	8/16/22		Added codes K1024, K1025, K1031 and K1032 as E/I. Routine policy maintenance, no change in policy status.
11/1/23	8/15/23		Routine policy maintenance, no change in policy status. Vendor managed: Northwood. (ds)
11/1/24	8/20/24		Updated rationale section added reference 6. Delete K1024, K1025, K1031, K1032, 12/31/23; new codes E0678-E0682 added as E/I. Vendor managed: Northwood (ds)

Next Review Date: 3rd Qtr. 2025

Pre-Consolidation Medical Policy History

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

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: PNEUMATIC COMPRESSION PUMPS AND APPLIANCES FOR VENOUS ULCERS

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Coverage per policy
BCNA (Medicare Advantage)	See government section
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.
- Duplicate (back-up) equipment is not a covered benefit.