

Corporate Medical Policy

Pneumatic Compression Pumps for Treatment of Lymphedema and Venous Ulcers

File Name: pneumatic_compression_pumps_for_lymphedema_and_venous_ulcers
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Last CAP Review: 6/2019
Next CAP Review: 5/2020
Last Review: 6/2019

Description of Procedure or Service

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 design and complexity.

Background

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, postradiation 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 use of compression garments and compression bandaging. Another conservative treatment is manual lymphatic drainage (MLD), a massage-like technique used to move edema fluid from distal to proximal areas. MLD is performed by physical therapists with special training. Complete decongestive therapy is a comprehensive program that includes MLD in conjunction with a range of other conservative treatments. Rarely, surgery is used as a treatment option.

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 are proposed as a treatment for venous ulcers, especially for patients who do not respond to these standard therapies.

Pneumatic compression pumps consist of pneumatic cuffs connected to a pump. They 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 for treating lymphedema are available, with varying materials, designs, degrees of pressure, and complexity. There are three primary types of pumps as follows:

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

Multichamber nonprogrammable pumps: 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: These are similar to the pumps described above except that it is possible to make manual adjustments in the pressure in the individual compartments and/or the length and frequency of the inflation cycles. In some situations, including in patients with

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scarring, contractures, or highly sensitive skin, programmable pumps are generally considered the preferred option.

Pneumatic compression pumps may be used in lymphedema clinics or purchased or rented for home use. This policy addresses the home use of these pumps.

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 that are intended for home or clinic/hospital use include the Compression pump, Model GS-128 (Medmark Technologies, LLC, Perkasi, PA); the Sequential Circulator® (Bio Compression Systems, Inc., Moonachie, NJ); the Lympha-Press® and Lympha-Press Optimal (Mego Afek, Israel); the Flexitouch™ (Tactile Medical, formerly Tactile Systems Technology, Inc.); and the PowerPress Unit Sequential Circulator (Neomedic, Chatsworth, CA).

Several pneumatic compression devices are cleared by the 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, Inc.), CTU676® (Compression Technologies), and Recovery+™ (Pulsar Scientific).

Related Policies

Bioimpedance Devices for Detection of Lymphedema

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

BCBSNC will provide coverage for Pneumatic Compression Pumps when they are determined to be medically necessary because the medical criteria and guidelines shown below are met.

Benefits Application

Please refer to certificate for availability of benefit. See Covered Services section for Durable Medical Equipment.

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

Lymphedema pumps/sequential pneumatic compression devices require a physician prescription to rent or purchase to be eligible for coverage.

The individual certificate should be reviewed to verify eligibility requirements and any prior approval or preauthorization necessary for the rental/purchase of equipment.

Equipment should be rented for the first two months to establish effectiveness and patient compliance.

The DME supplier must meet eligibility and/or credentialing requirements as defined by the Plan to be eligible for reimbursement.

When Pneumatic Compression Pumps are covered

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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 and use of compression garments.

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

- 1) The individual is otherwise eligible for nonprogrammable pumps; and
- 2) There is documentation that the individual has unique characteristics that prevent satisfactory pneumatic compression with single-compartment or multichamber nonprogrammable lymphedema pumps (e.g., significant scarring).

When Pneumatic Compression Pumps are not covered

Single compartment or multichamber lymphedema pumps applied to the limb are considered **investigational** in all situations other than those specified above and as specified in Policy Guidelines (see below).

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**.

The use of pneumatic compression pumps to treat venous ulcers is considered **investigational**.

The use of active cooling devices with sequential or intermittent pneumatic compression is considered **not medically necessary** for all indications, including, but not limited to post operative care.

Policy Guidelines

Lymphedema pumps/sequential pneumatic compression devices are eligible for **initial coverage** when **ALL** of the following criteria are met:

1. Confirmed diagnosis of primary or secondary lymphedema; **and**
2. Lymphedema is associated with functional impairment e.g., impairment of activities of daily living; **and**
3. When there is failure of a four-week trial of conservative medical therapies, (examples include elevation of the affected limb, exercise, massage, use of an appropriate compression bandage system or compression garment); **and**
4. The patient has demonstrated compliance with past recommended medical treatment(s).

Continued use of lymphedema pumps/sequential pneumatic compression devices are considered eligible for coverage **when there is documented effectiveness of the pump**, with a decrease in edema as documented by pre- and post-treatment measurements and/or documented improvement in functional capacity.

Pneumatic compression devices **are covered as a treatment of last resort**; for example, other more conservative treatments must have been tried first and found to be inadequate. Such treatments would include leg or arm elevation and custom fabricated gradient pressure stockings or sleeves.

A segmented pneumatic compression device with manual control of the pressure in each chamber (HCPCS code E0652) is considered medically necessary only when the patient has unique characteristics that prevent them from receiving satisfactory pneumatic compression treatment using a nonsegmented device with a segmented appliance/sleeve or a segmented compression device without manual control of pressure in each chamber. Such conditions include significant scarring, sensitive skin or the presence of contracture with documentation of the need for a specified pressure to a localized area. In addition, the criteria above must be met.

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For individuals who have lymphedema who failed to respond to conservative therapy who receive pneumatic compression pumps applied to the 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. The majority of these 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 two RCTs comparing treatment with and without truncal involvement. Relevant outcomes are symptoms, change in disease status, functional outcomes, and quality of life. In one 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 such as functional status or 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 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 three trials found significantly higher healing rate 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 two trials comparing lymphedema pumps with continuous compression did not find significant between-group differences in healing rates. The evidence is insufficient to determine the effects of the technology on health outcomes.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: A6545, E0650, E0651, E0652, E0655, E0656, E0657, E0660, E0665, E0666, E0667, E0668, E0669, E0670, E0671, E0672, E0673, E0675, E0676

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

Senior Director of Health Affairs

BCBSNC Matrix Program - Certificate Language

Marcks P. Lymphedema. Pathogenesis, prevention, and treatment. *Cancer Pract.* 1997;5(1):32-8.

Boris M, Weindorf S. The risk of genital edema after external pump compression for lower limb lymphedema. *Lymphology.* 1998;31(1):15-20

BCBSA Medical Policy Reference Manual - 7/10/98

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Region C SMEPOS Supplies Manual (Autumn 1998)

Cassley-Smith, JR, Casley-Smith. JR. Other treatments for lymphoedema.
http://www.lymphedema.org.au/tret_oth.htm. 3/3/99.

Medical Policy Advisory Group 12/2/1999

Specialty Matched Consultant Advisory Panel - 10/2000

Medical Policy Advisory Group - 10/2000

BCBSA Medical Policy Reference Manual - Policy 1.01.18 - 7/12/02

Region C DMERC Carrier Policy 40.0302; Effective Date: January 14, 2002

Specialty Matched Consultant Advisory Panel - 8/2002

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.18, 4/29/03.

Specialty Matched Consultant Advisory Panel - 8/2004

Blue Cross and Blue Shield Association Technology Assessment Program (TEC). Special report: comparative efficacy of different types of pneumatic compression pumps for the treatment of lymphedema. 1998 Apr;13 (2)

Centers for Medicare and Medicaid Services (CMS). National Coverage Determination for Pneumatic Compression Devices, Publication number 100-3, Manual section number 280.6. Retrieved June 18, 2007 from http://www.cms.hhs.gov/mcd/viewncd.asp?ncd_id=280.6&ncd_version=1&basket=ncd%3A280%2E6%3A1%3APneumatic+Compression+Devices.

Palmetto GBA-Statistical Analysis Durable Medical Equipment Carrier (SADMERC). Durable Medical Equipment Coding System (DMECS) Product Search for HCPCS codes E0650, E0651, E0652. Retrieved August 13, 2007 from <http://www3.palmettogba.com/dmecs/do/productsearch>.

Rockson, SG, Miller LT, Senie R, et al. American Cancer Society Lymphedema Workshop. Workgroup III: Diagnosis and management of lymphedema. Cancer. 1998;83(12 Suppl American):2882-2885. Retrieved September 12, 2007 from <http://www3.interscience.wiley.com/cgi-bin/fulltext/75501219/PDFSTART>.

Wilburn O, Wilburn P, Rockson SG. A Pilot, Prospective Evaluation of a Novel Alternative For Maintenance Therapy of Breast Cancer-Associated Lymphedema. BMC Cancer. 2006 Mar 29;6(1):84. Retrieved July 7, 2007 from <http://www.pubmedcentral.nih.gov/articlerender.fcgi?tool=pubmed&pubmedid=16571129>.

National Lymphedema Network (NLN) [website]. Position statement of the national lymphedema network. Treatment. August 10, 2006. Retrieved June 18, 2007 from <http://www.lymphnet.org/pdfDocs/nlntreatment.pdf>

BCBSNC Internal Medical Directors' review 8/27/07

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.18, 8/12/10

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.18, 10/14/11

Specialty Matched Consultant Advisory Panel 5/16/12

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.18, 10/11/12

Specialty Matched Consultant Advisory Panel 5/15/13

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.18, 10/10/13

Specialty Matched Consultant Advisory Panel 5/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.18, 9/11/14

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Specialty Matched Consultant Advisory Panel 5/2015

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.18, 9/10/15

Specialty Matched Consultant Advisory Panel 5/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.18, 3/9/17

Specialty Matched Consultant Advisory Panel 5/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.18, 3/8/2018

Specialty Matched Consultant Advisory Panel 5/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.18, 3/14/2019

Specialty Matched Consultant Advisory Panel 6/2019

Policy Implementation/Update Information

6/94	Original policy issued.
8/96	Reaffirmed
5/97	Revised. Added DME Supplier information and Source as contract language.
5/99	Revised. Expanded definition section of the policy for clarification in understanding. Added HCFA guidelines from 1998. Referenced articles indicating the dangers and potential complications of lymphedema pumps. Review of 1998 BCBSA policy.
9/99	Reformatted, Medical Term Definitions Added
12/99	Reaffirmed. Medical Policy Advisory Group
4/00	Revised. Added statement to the Benefits Application section which states the equipment should be rented for two months.
10/00	Specialty Matched Consultant Advisory Panel review. No change recommended in criteria. System coding changes. Medical Policy Advisory Group review. No change in criteria. Approve.
4/02	Format changes.
10/02	Specialty Matched Consultant Advisory Panel review 8/15/02. Under when covered section, number 3 - added "...exercise, massage, use of an appropriate compression bandage system....". For continued use - added "as documented by pre- and post-treatment measurements" to "with a decrease in edema...".
1/03	Disclaimer added.
4/04	Benefits Application and Billing/Coding sections updated for consistency.
9/23/04	Specialty Matched Consultant Advisory Panel review 8/27/04. No changes recommended to criteria.
11/27/06	Under When Covered section, #3-A four week trial of conservative medical therapies will be required. Under When Not Covered section-added "Two-phase lymph preparation and drainage therapy devices (e.g., Flexitouch® Lymphedema System) are not covered. The devices are considered investigational and BCBSNC does not cover investigational services." Policy guidelines added. Policy status changed to "Active policy, no longer scheduled for routine literature review." Notification given 11/27/06. Effective date 1/29/07. (pmo)

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- 10/8/07 Additional information re: types of pneumatic compression devices added to "**Description**" section. Under "**When Covered**" section-added medical necessity criteria for segmented pneumatic compression devices with manual control in each chamber- "A segmented pneumatic compression device with manual control of the pressure in each chamber (HCPCS code E0652) is considered medically necessary only when the patient has unique characteristics that prevent them from receiving satisfactory pneumatic compression treatment using a nonsegmented device with a segmented appliance/sleeve or a segmented compression device without manual control of pressure in each chamber. Such conditions include significant scarring, sensitive skin or the presence of contracture with documentation of the need for a specified pressure to a localized area." The other criteria in the current policy must be met also. Under "**When not Covered**" section, deleted statement re: two phase lymph preparation and drainage therapy devices (e.g., Flexitouch® Lymphedema System) being not covered/investigational. Under "**Policy Guidelines**", deleted the paragraph currently in the policy and added information re: the various types of lymphedema pumps and examples of each; also added the following "Lymphedema systems, such as the Flexitouch® Lymphedema System, are comparable to Type III pneumatic compression devices. There are no published peer reviewed controlled clinical trials that demonstrate the superiority of the Flexitouch® Lymphedema System over other comparable units (e.g., those listed under Type III above [HCPCS code E0652]). For medically necessary services, the Plan may compare the cost-effectiveness of alternative services or supplies when determining which of the services or supplies will be covered; therefore this device will not be covered. (Refer to policy number ADM9066 Medical Necessity.) Added Key Words, Medical Term Definitions and Reference Sources. Notification given 10/8/07. Effective date 12/17/07. (pmo)
- 01/05/09 HCPCS codes A6545, E0656 and E0657 effective January 1, 2009 added to Billing/Coding section. (pmo)
- 2/2/09 Under Benefits Application, clarified that a physician prescription is required: "Lymphedema pumps/sequential compression devices require a *physician* prescription to rent or purchase to be eligible for coverage." Under Policy Guidelines, removed the last paragraph re: Flexitouch® Lymphedema System. Added Flexitouch® 2-Phase Lymph Preparation and Drainage System™ (Model PD32-120) as a Type III device. Key words added. (pmo)
- 6/22/10 Policy Number(s) removed (amw)
- 2/15/11 Description section extensively revised. Criteria in the **When Covered** section changed to read: "Single compartment or multichamber nonprogrammable lymphedema pumps may be considered **medically necessary** for the treatment of lymphedema that has failed to respond to conservative measures, such as elevation of the limb and use of compression garments. Single compartment or multichamber programmable lymphedema pumps are considered **medically necessary** for the treatment of lymphedema when: 1) The individual is otherwise eligible for nonprogrammable pumps; and 2) There is documentation that the individual has unique characteristics that prevent satisfactory pneumatic compression with single-compartment or multichamber nonprogrammable lymphedema pumps (e.g., significant scarring)." Information previously in the When Covered section was moved to the Policy Guidelines section. The following was added to the **When It Is Not Covered** section: "The use of active cooling devices with sequential or intermittent pneumatic compression is considered **not medically necessary** for all indications, including, but not limited to post operative care." References updated. (adn)
- 5/29/12 Related policies added. Specialty Matched Consultant Advisory Panel review 5/16/12. Summary statement added. HCPCS code E0675 added to Billing/Coding/Physician Documentation Information Section. No change to policy intent. (sk)

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Policy renamed: Pneumatic Compression Pumps for Treatment of Lymphedema and Venous Ulcers

- 11/27/12 Reference added. Title changed to Pneumatic Compression Pumps for Treatment of Lymphedema and Venous Ulcers. 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. Statement added that use of lymphedema pumps to treat venous ulcers is considered investigational. Medical Director review. Notification given 11/27/12. Policy effective 2/26/13. (sk)
- 5/28/13 Specialty Matched Consultant Advisory Panel review 5/15/13. HCPCS code E0670 added to Billing/Coding/Physician Documentation Information Section. No change to policy intent. (sk)
- 12/10/13 Reference added. “Applied to the limb” added to the first 2 covered policy statements and to the first non covered policy statement for clarification. In the statement on venous ulcers, “lymphedema pumps” changed to “pneumatic compression pumps”. Senior Medical Director review. (sk)
- 6/10/14 Specialty Matched Consultant Advisory Panel review 5/27/14. No change to policy intent. (sk)
- 10/28/14 Added the following statement to the Benefits Application section: “The DME supplier must meet eligibility and/or credentialing requirements as defined by the Plan to be eligible for reimbursement.” (mco)
- 11/11/14 Reference added. (sk)
- 7/1/15 Specialty Matched Consultant Advisory Panel review 5/27/15. Removed End Diastolic Pneumatic Compression Boot from list of related policies as it has been archived. (sk)
- 10/30/15 Policy Guidelines updated. Reference added. No change to Policy statement. (sk)
- 7/1/16 Specialty Matched Consultant Advisory Panel review 5/25/16. (sk)
- 6/30/17 Reference added. Policy Guidelines updated. Specialty Matched Consultant Advisory Panel review 5/31/17. (sk)
- 4/13/18 Reference added. (sk)
- 6/29/18 Specialty Matched Consultant Advisory Panel review 5/23/18. (sk)
- 7/16/19 Reference added. Specialty Matched Consultant Advisory Panel review 6/28/2019. (sk)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.