

## Corporate Medical Policy

### Lymphedema Pumps-Sequential Pneumatic Compression Device

**File Name:** lymphedema\_pumps\_sequential\_pneumatic\_compression\_device  
**Origination:** 6/1994  
**Last CAP Review:** 10/2007  
**Next CAP Review:** Not applicable  
**Last Review:** 2/2011

**Active policy, no longer scheduled for routine literature review.**

#### Description of Procedure or Service

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Pneumatic compression pumps are proposed as a treatment option for patients with lymphedema who have failed conservative measures e.g., compression garments, manual massage. A variety of pumps are available; they can be single- or multichamber 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. Treatment includes mechanical measures (compression garments, bandaging, manual massage, pneumatic compression devices (i.e., lymphedema pumps), drugs, or rarely, surgery.

Lymphedema pumps consist of pneumatic cuffs that are 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 different pneumatic compression pumps for treating lymphedema are available, with varying materials, design, degree 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 that applies 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.

Recently, a new type of pump has been introduced, a 2-stage multichamber pump. One device of this type, the Flexitouch™ system (Tactile Systems Technology, Minneapolis, MN), has 27-32 chambers and includes 13 sequential treatment programs for different regions of the body. Treatment sessions consist of 2 phases, meant to simulate manual lymph drainage. The first phase is preparation of the affected area for drainage, which uses a proximal-to-distal gradient, and the second phase is drainage, which uses a distal-to-proximal gradient. The Flexitouch™ system includes a variety of garment types. For treating an upper extremity, chest and trunk garments are used in addition to the arm garment. When treating a lower extremity, a trunk garment is used with a calf-foot garment. This allows treatment of the truncal area in addition to the affected limb.

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Lymphedema pumps may be used in lymphedema clinics or purchased or rented for home use. This policy addresses the home use of lymphedema 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); and the Lympha-Press (Mego Afek, Israel). Device manufacturers generally have a line of products for different applications and to treat different affected areas of the body. A pump with another variation in pump design, the Flexitouch™ (Tactile Systems Technology, Inc.) was cleared by the FDA in 2006.

**\*\*\*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

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**Active policy, no longer scheduled for routine literature review.**

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

## Benefits Application

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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.

## When Lymphedema Pumps/Sequential Pneumatic Compression Devices are covered

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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).

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## When Lymphedema Pumps/Sequential Pneumatic Compression Devices are not covered

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For indications other than those cited above.

When the medical criteria and guidelines outlined above and in the Policy Guidelines (see below) are not met.

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

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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.

## Billing/Coding/Physician Documentation Information

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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.bcbsnc.com](http://www.bcbsnc.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, E0671, E0672, E0673*

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.

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## Scientific Background and Reference Sources

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Senior Director of Health Affairs

BCBSNC Matrix Program - Certificate Language

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

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Medical Policy Advisory Group 12/2/1999

Specialty Matched Consultant Advisory Panel - 10/2000

Medical Policy Advisory Group - 10/2000

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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>

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## Policy Implementation/Update Information

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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)
10/8/07	Additional information re: types of pneumatic compression devices added to " <b>Description</b> " section. Under " <b>When Covered</b> " 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 " <b>When not Covered</b> " section, deleted statement re: two phase lymph preparation and drainage therapy devices (e.g., Flexitouch® Lymphedema System) being not covered/investigational. Under " <b>Policy Guidelines</b> ", 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®

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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)

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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.