

MEDICAL POLICY



SUBJECT: PNEUMATIC COMPRESSION DEVICES/LYPHHEDEMA PUMPS	EFFECTIVE DATE: 09/26/02 REVISED DATE: 10/23/03, 09/23/04, 10/27/05, 12/07/06, 02/28/08, 04/23/09, 08/27/09, 08/26/10, 02/27/12, 02/28/13, 02/27/14, 02/26/15, 02/25/16, 06/22/16, 06/22/17, 04/26/18
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<ul style="list-style-type: none">• <i>If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</i>• <i>If a commercial product, including an Essential Plan product, covers a specific service, medical policy criteria apply to the benefit.</i>• <i>If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.</i>	

POLICY STATEMENT:

- I. Based upon our criteria, both the non-segmental compression devices (HCPCS code E0650) and segmental compression devices with or without calibrated gradient pressure (HCPCS codes E0651, E0652) are **medically appropriate** for use in the home in the treatment of intractable proven lymphedema of the extremities when:
 - A. failure of a 4-week trial of conservative therapy which consists of:
 1. regular and compliant use of an appropriate compression bandage system or compression garment to provide adequate graduated compression; and
 2. manual lymphatic drainage and self-manual lymphatic drainage (MLD) for at least 30 minutes per day; and
 3. regular exercise; and
 4. elevation of limb; and
 - B. the patient has undergone a supervised training program and is able to show proficiency in using the device.
- II. Based upon our criteria, segmental compression devices with calibrated gradient pressure which include both a two-phase or multi-phase lymph preparation phase as well as drainage phase therapy devices (e.g., Flexitouch™ Device, Lymphapress Optimal) (HCPCS code E0652) are considered **medically appropriate** when the above criteria are met and:
 - A. a non-segment or segmental compression device has been shown to be ineffective AND
 - B. all of the criteria in Policy Statement I has been met.
- III. Based on our criteria, pneumatic compression devices (HCPCS codes E0650, E0651, E0652, E0675, E0676; [e.g., ACTitouch® device]) have not been medically proven to be effective and are considered **investigational** for the following indications:
 - A. venous stasis ulcers; or
 - B. peripheral artery disease (e.g., intermittent claudication, ischemia, arterial insufficiency); or
 - C. lower extremity and truncal edema due to obesity.

Refer to Corporate Medical Policy 1.01.51 Limb Pneumatic Compression Devices for Venous Thromboembolism Prophylaxis.

Refer to Corporate Medical Policy #10.01.01 regarding Breast Reconstruction Surgery.

Refer to Corporate Medical Policy #11.01.03 regarding Experimental and Investigational Services.

POLICY GUIDELINES:

- I. Medical documentation of all the following is required for consideration of a pneumatic compression device/ lymphedema pump:
 - A. The lymphedema is intractable (lymphedema which has been difficult to manage and nonresponsive to decongestive treatment). Documentation should include etiology, symptoms and objective findings, measurements establishing the severity of the condition, and the extent to which the lymphedema impairs function of the extremity causing pain and gross distention.
 - B. Previous less intensive treatments have been tried and found inadequate (e.g., leg/arm elevation, custom fabricated gradient pressure stockings or sleeves, and exercise); and

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- C. Appropriate physician oversight (e.g., instruction in the operation of the machine, amount of pressure to be used, the frequency and duration of use, and ongoing monitoring of use and response to treatment).
- II. Home use will be dependent upon the clinical response to treatment, including:
 - A. Change from pre-treatment to post-treatment limb volume measurements;
 - B. Ability to tolerate the treatment session parameters; and
 - C. Ability of the patient (or caregiver) to apply the device for continued use in the home.
- III. Durable Medical Equipment rider/coverage is required. (Except for a postmastectomy diagnosis in accordance with the Women’s Health and Cancer Rights Act).
- IV. The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION:

Lymphedema is the abnormal accumulation of lymph fluid in the subcutaneous tissues of an affected body part due to an obstruction of the lymphatic flow. Lymphedema is a relatively uncommon condition which may be due to:

- I. Surgical removal of lymph nodes,
- II. Post-radiation fibrosis,
- III. Scarring of lymphatic channels,
- IV. Onset of puberty (Milroy’s Disease),
- V. Congenital anomalies, or
- VI. Spread of malignant tumors to regional lymph nodes.

Lymphedema is considered to be incurable. Treatment focuses on decreasing the excess volume of the limb as much as possible and to maintain the limb at its smallest size.

Pneumatic compression devices/lymphedema pumps are devices which were developed to aid in the mobilization of lymph fluid from the extremity and to avoid the adverse consequences of uncontrolled lymphedema. These devices are often classified into three types: single compartment pumps; 2) multi-chamber devices with each chamber sequentially inflated but with fixed pressure in each; and 3) multi-chamber devices with sequential inflation and with manually calibrated pressure in each chamber.

Non-segmental compression pumps are the simplest type of pump and consist of a one boot or sleeve chamber that inflates and deflates during a single phase. Examples of these types pumps include the KCI Extremity pump 7000 and Huntleigh Flowpress.

Segmental compression pumps consist of three chambers which inflate sequentially with a fixed pressure during a single phase. Examples of these types pumps include the Flowtron® Hydroven FPR pump, KCI Extremity pump 7500, Lympha Press, Petite Basic™ 701A, and BioCompression Pump Model 2004.

Segmental compression pumps with calibrated, gradient pressure direct the lymph fluid from the extremity towards the body by decreasing the pressure in the chambers from the farthest part of the body to the closest in a single phase. The pressure can be changed or tailored in each individual chamber sleeve. These pumps can be equipped with two-phases, a preparatory phase, which acts similarly to manual decongestive therapy by using a light, variable pressure to prepare the trunk and extremity prior to draining the fluid from the affected extremity and a compression phase. The Flexitouch™ (Tactile Systems Technology, Inc) system is an example of a segmental compression pump with calibrated, gradient pressure and two-phases. This device received 510(k) approval from the FDA as a class II device under the name Biotouch™ Massage Therapy System. Another device by Tactile Systems Technology, Inc, is the ACTitouch® system which combines intermittent and sustained compression therapy in one easy-to-wear device for treatment of venous ulcers. The ACTitouch® system is designed to accommodate a wide range of leg shapes and sizes and can be worn under regular clothing and with most shoes. In sustained compression mode, the compact, lightweight device gives patients the

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freedom to stay active while experiencing the benefits of dual-compression therapy. The device inflates to preset pressures to ensure consistent, predictable compression, regardless of variations in sleeve application. To deliver effective compression throughout the day, the system monitors pressures every 30 minutes, adjusting the inflation in response to anatomic changes. The Lymphapress Optimal also has the capability to deliver Pretherapy™ based on the principles of manual lymph drainage. The Lympha Press Optimal Compression Therapy Device received FDA approval in 2008.

Home-based devices that deliver intermittent pneumatic compression have also been proposed to treat venous leg ulcers and intermittent claudication. These devices apply rapid and timed compression to the foot and calf which is proposed to move blood through deep veins at a high pulsatile rate and increase arterial blood flow.

The Women’s Health and Cancer Rights Act of 1998 mandated coverage for physical complications, including lymphedemas, of mastectomies for all contracts that provide medical and surgical benefits.

RATIONALE:

There is insufficient evidence in the peer-reviewed literature that segmental compression pumps with calibrated, gradient pressure two-phase lymph preparation and drainage therapy devices provide outcomes equal or superior to standard pneumatic compression devices. One randomized, single-center, crossover study involving 10 patients that compared the efficacy of the Flexitouch™ device to massage for treatment of lymphedema of the arm was found in the literature. The study was limited by small sample size, short duration of treatment and no comparison to standard pneumatic lymphedema pumps or complex lymphedema therapy. Another similar study compared pressure delivered to parts of the arm between a segmental compression pump and the Flexitouch device. Differences in delivered pressures between the two devices was observed, but no conclusion regarding the optimal pressure needed was made.

There is insufficient evidence in the peer-reviewed literature that edema in the lower extremities is a result of obstruction in the lymphatic system caused by obesity. However preliminary studies have shown that obese individuals are more likely to develop edema in the lower extremities. Additional studies are needed to determine the functional role of lymphatic vasculature in the obese patient.

There is insufficient evidence in the peer-reviewed literature that intermittent pneumatic compression(IPC) improves outcomes in patients with venous stasis ulcers and arterial insufficiency. Preliminary studies have proposed IPC improves exercise tolerance in a model of peripheral arterial insufficiency in part by enhancing blood flow to collateral-dependent tissues but further research is needed to validate use for these indications.

CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member’s subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

CPT: No code(s)

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<u>HCPCS:</u>	E0650	Pneumatic compressor, nonsegmental home model
	E0651	Pneumatic compressor, segmental home model without calibrated gradient pressure
	E0652	Pneumatic compressor, segmental home model with calibrated gradient pressure
	E0655	Nonsegmental pneumatic appliance for use with pneumatic compressor, half arm
	E0656	Segmental pneumatic appliance for use with pneumatic compressor, trunk
	E0657	Segmental pneumatic appliance for use with pneumatic compressor, chest

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E0660	Nonsegmental pneumatic appliance for use with pneumatic compressor, full leg
E0665	full arm
E0666	half leg
E0667	Segmental pneumatic appliance for use with pneumatic compressor, full leg
E0668	full arm
E0669	half leg
E0671	Segmental gradient pressure pneumatic appliance, full leg
E0672	full arm
E0673	half leg
E0675	Pneumatic compression device high pressure, rapid inflation./deflation cycle, for arterial insufficiency (unilateral or bilateral system)
E0676	Intermittent limb compression device (includes all accessories), not otherwise specified
ICD10: I89.0	Lymphedema, not elsewhere classified
I97.2	Postmastectomy lymphedema syndrome
Q82.0	Hereditary lymphedema

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KEY WORDS:

Flexitouch™, Lymphedema sleeve.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) and a Local Coverage Determination (LCD) for Pneumatic Compression Devices. Please refer to the following websites for Medicare Members:

NCD SITE:

<http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=225&ncdver=1&bc=AgAAgAAAAAAA&>

LCD SITE:

https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33829&ver=32&CntrctrSelected=137*1&Cntrctr=137&s=41&DocType=Active&bc=AggAAAIAlAAAA%3d%3d&