MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**Pneumatic Compression Devices/Lymphedema Pumps**
Policy Number	**1.01.17**
Category	**Equipment/ Supplies**
Original Effective Date	**09/26/02**
Committee Approval 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, 04/25/19, 4/23/20, 4/21/22**
Current Effective Date	**4/21/22**
Archived Date	**N/A**
Archived Effective Date	**N/A**
Product Disclaimer	• *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *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.*

POLICY STATEMENT

I. Based upon our criteria and assessment of the peer-reviewed literature, both non-segmental compression devices (HCPCS code E0650) and segmental compression devices with or without calibrated gradient pressure (HCPCS codes E0651, E0652), are considered **medically appropriate** for use in the home in the treatment of intractable proven lymphedema of the extremities when:
   A. The patient has failed a four-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 the affected 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 and assessment of the peer-reviewed literature, segmental compression devices with calibrated gradient pressure which include therapy devices with both a two-phase or multi-phase lymph preparation phase, as well as a drainage phase (e.g., Flexitouch Plus Device, Lymphapress Optimal Plus) (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 have been met.

III. Based on our criteria and assessment of the peer-reviewed literature, pneumatic compression devices (e.g., ACTitouch device) (HCPCS codes E0650, E0651, E0652, E0675, E0676) 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.

IV. Replacement pneumatic compression devices (HCPCS codes E0650, E0651, E0652) are considered medically appropriate when:
   A. Physician documentation that the patient has been compliant with use of the device and will continue to benefit from use of the device;
   B. The device is out of warranty; and
   C. The device is malfunctioning.

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

Refer to Corporate Medical Policy #10.01.01 Breast Reconstruction Surgery.

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

POLICY GUIDELINES

I. Medical documentation of all of the following criteria is required for consideration of a pneumatic compression device/ lymphedema pump:
   A. The lymphedema is intractable (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
   C. Appropriate physician oversight (e.g., instruction in the operation of the machine, amount of pressure to be used, frequency and duration of use, and ongoing monitoring of use and response to treatment) has been provided.

II. Approval for 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 of the patient 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. Per the manufacturer's user guide (Tactile Medical, Minneapolis, MN), the Flexitouch and Flexitouch plus pneumatic compression devices have a two-year warranty for the controller and a five-year warranty for the garments and garment accessories. The average expected controller lifetime is five years.

IV. The member's subscriber contract or rider thereto must provide benefits for durable medical equipment, except in connection with a postmastectomy diagnosis, in accordance with the Women's Health and Cancer Rights Act.

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 maintaining the limb at its smallest size.

Pneumatic compression devices/lymphedema pumps are devices 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: 1) 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 single boot or sleeve chamber that inflates and deflates during a single phase. Examples of this type of pump include the KCI Extremity pump 7000 and Huntleigh Flowpress.

Segmental compression pumps consist of three chambers that inflate sequentially with a fixed pressure during a single phase. Examples of this type of pump 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 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 federal Women's Health and Cancer Rights Act of 1998 mandates coverage for physical complications, including lymphedemas, of mastectomies under all plans that provide medical and surgical benefits.

RATIONALE

There has been variability about the best diagnostic modality and treatment strategy for lymphedema. The American Venous Forum (AVF) created a working group to address questions related to risk factors, diagnosis and evaluation, and treatment of lymphedema to develop a consensus statement regarding the current practice for the diagnosis and treatment of lymphedema. (Lurie, et al. 2022). Sequential pneumatic compression (SPC) should be recommended as part of a multidisciplinary therapeutic treatment program that includes manual decongestive therapy, compression, and skin care for more advanced stage of lymphedema. Consensus for use of SPC for all stages of lymphedema is mixed. There is limited evidence to demonstrate its benefit for less severe lymphedema compared to inelastic compression of various forms. Currently there is no Grade A or Level 1 evidence supporting any treatment for lymphedema, included pneumatic compression, for reduction and/or maintenance of swelling. Ninety-two percent of the panel agreed that SPC should be recommended for lymphedema patients; 34% strongly agreed. Only 62% agreed that sequential pneumatic compression should be used for treatment of early stages of lymphedema; 38% disagreed and 2% strongly disagreed. There is data to demonstrate that advanced pneumatic compressions devices with calibrated gradient pressure are superior to simpler devices. SPC devices are well tolerated and are associated with a reduction in limb girth and cellulitis and improved QoL in patients with cancer and non-cancer associated lymphedema of the upper and lower extremities. However, the studies are limited by variations in the stage of lymphedema of the participants, presence of ulcers, treatment regimens, and compliance rate.

There is insufficient evidence in the peer-reviewed literature that segmental compression pumps with calibrated, gradient pressure two-phase lymph preparation and drainage therapy device**s** provide outcomes equal or superior to standard pneumatic compression devices. One randomized, single-center, crossover study involving 10 patients, which 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 were observed, but no conclusion regarding the optimal pressure needed was made.

There is insufficient evidence in the peer-reviewed literature to establish 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 to establish that intermittent pneumatic compression (IPC) improves outcomes in patients with venous stasis ulcers and arterial insufficiency. Preliminary studies have proposed that 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

- *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 Codes

Code	Description
No code(s)	

HCPCS Codes

Code	Description
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
E0660	Nonsegmental pneumatic appliance for use with pneumatic compressor, full leg
E0665	Nonsegmental pneumatic appliance for use with pneumatic compressor, full arm
E0666	Nonsegmental pneumatic appliance for use with pneumatic compressor, half leg
E0667	Segmental pneumatic appliance for use with pneumatic compressor, full leg
E0668	Segmental pneumatic appliance for use with pneumatic compressor, full arm
E0669	Segmental pneumatic appliance for use with pneumatic compressor, half leg

Code	Description
E0671	Segmental gradient pressure pneumatic appliance, full leg
E0672	Segmental gradient pressure pneumatic appliance, full arm
E0673	Segmental gradient pressure pneumatic appliance, 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
E0677 **(E/I)**	Non-pneumatic sequential compression garment, trunk (effective 04/01/23)
K1024	Non-pneumatic compression controller with sequential calibrated gradient pressure (Effective 10/01/21)
K1025	Non-pneumatic sequential compression garment, full arm. (Effective 10/01/21)

ICD10 Codes

Code	Description
I89.0	Lymphedema, not elsewhere classified
I97.2	Postmastectomy lymphedema syndrome
Q82.0	Hereditary lymphedema

REFERENCES

Desai SS and Shao M. Superior clinical, quality of life, functional, and health economic outcomes with pneumatic compression therapy for lymphedema. Ann Vasc Surg. 2020 Feb;63:298-306.

*Feist WR, et al. Problems with measuring compression device performance in preventing deep vein thrombosis. Throm Res 2011 Sep;128(3):207-9.

Finane A, et al. Review of the evidence of lymphedema treatment effect. Am J Phys Med Rehabil 2015 Jun;94(6):483-98.

*Geerts WH, et al. Prevention of venous thromboembolism: the seventh ACCP Conference on antithrombotic and thrombolytic therapy. Chest 2004;126(Supp1 3):338S-400S.

Grada AA, et al. Lymphedema: diagnostic work up and management. J Am Acad Dermatol 2017 Dec;77(6):995-1006.

Grada AA, et al. Lymphedema: pathophysiology and clinical manifestations. J Am Acad Dermatol 2017 Dec;77(6):1009-1020.

Gutiérrez C, et al. Longitudinal effects of a novel advanced pneumatic compression device on patient-reported outcomes in the management of cancer-related head and neck lymphedema: A preliminary report. Head Neck. 2020 Aug;42(8):1791-1799.

*Haslett ML, et al. Evaluating the effectiveness of a compression sleeve in managing secondary lymphedema. J Wound Care 2002 Nov;11(10):401-4.

*Hassell a, et al. A retrospective study of the effects of the lymphapress pump on lymphedema in a pediatric population. Lymphol 2001 Dec;34(4):156-65.

*Kakkos SK, et al. Combined intermittent pneumatic leg compression and pharmacological prophylaxis for prevention of venous thromboembolism in high-risk patients. Cochrane Database Syst Rev 2016 Sep 7; 9(9):CD005258.

Karaca-Mandic P, et al. The cutaneous, net clinical, and health economic benefits of advanced pneumatic compression devices in patients with lymphedema. JAMA Dermatol 2015 Nov 1;15(11):1187-93.

Lurie F, et al. The American Venous Forum, American Vein and Lymphatic Society and the Society for Vascular Medicine expert opinion consensus on lymphedema diagnosis and treatment.

Lurie F and Schwartz M. Patient-centered outcomes of a dual action pneumatic compression device in comparison to compression stockings for patients with chronic venous disease. J Vasc Surg Venous Lymphat Disord. 2017 Sep;5(5):699-706.

Maldonado TS, et al. Assessment of quality of life changes in patients with lower extremity lymphededema using an advanced pneumatic compression device at home. J Vasc Surg Venous Lymphat Disord 2021 May; 9(3);745-752.

Mayrovitz HN, et al. Usability of advanced pneumatic compression to treat cancer-related head and neck lymphedema: a feasibility study. Head Neck 2018 Jan;40(1):137-143.

Mehrara BJ, et al. Lymphedema and obesity: is there a link? Plast Reconstr Surg 2014;134(1):154e-60e.

*Naccarato M, et al. Physical methods for preventing deep vein thrombosis in stroke. Cochrane Database Syst Rev 2010 Aug 4;(8):CD001922.

National Cancer Institute. Lymphedema (PDQ) supportive care – health professionals. CancerNet. Updated 08/28/19. [http://www.cancer.gov/cancertopics/pdq/supportivecare/lymphedema/healthprofessional] accessed 3/17/22.

Nelson EA, et al. Intermittent pneumatic compression for treating venous leg ulcers. Cochrane Database Syst Rev. 2014 Feb 16;(2):CD001899.

O'Malley E, et al. Obesity-related chronic lymphoedema-like swelling and physical function. QJM 2015 Mar;108(3):183-7.

*Oremus M, et al. Diagnosis and treatment of secondary lymphedema. Technology Assessment Report. Project ID: LYMT0908. May 28 , 2010. McMaster University Evidence-based Practice Center under contract to the Agency for Healthcare Research and Quality.

Shao Y, Qi K, Zhou QH, et al. Intermittent pneumatic compression pump for breast cancer-related lymphedema: a systematic review and meta-analysis of randomized controlled trials. Oncol Res Treat 2014;37(4):170-4.

Tastaban E, et al. Role of intermittent pneumatic compression in the treatment of breast cancer-related lymphoedema: a randomized controlled trial. Clin Rehabil 2020 Feb;34(2):220-228.

Wang Y, et al. Current views on the function of lymphatic vasculature in health and disease. Genes Dev 2010;24:2115-26.

Yüksel A, et al. Management of lymphedema. Vasa 2016;45(4):283-91.

*Key Article

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&ContrId=389&ver=42&ContrVer=1&CntrctrSelected=389*1&Cntrctr=389&s=41&DocType=1&bc=AAQAAAIAAAAA&