MEDICAL POLICY DRAFT

MEDICAL POLICY DETAILS	
Medical Policy Title	**~~Pneumatic~~ Powered Compression Devices/Lymphedema Pumps**
Policy Number	**1.01.17**
Category	**~~Equipment/ Supplies~~ Contract Clarification**
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, 6/xx/23**
Current Effective Date	**~~4/21/22~~ 10/xx/23**
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.*~~ • ***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 (including Medicare HMO-Dual Special Needs Program (DSNP) 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.*** • ***If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.***

*****Note: This policy does not address compression devices for prevention of venous thrombosis.*****

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~~ **powered** 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) **(HCPCS code E0675);** or
   C. ~~Lower extremity and truncal edema due to obesity;~~ **Chest and/or trunk applications for lymphedema (HCPCS code E0656, E0657, E0670);** or
   D. Neck or head applications for lymphedema; or
   E. A non-pneumatic compression pump or non-pneumatic sequential compression garment for any indication (e.g., Koya Dayspring) (HCPCS codes K1024, K1025, K1031, K1032, K1033, E0677).

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~~ **powered** 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. **Segmental pumps that have a calibrated gradient pressure feature are typically used only in patients who require limited pressure to be applied to a specific area (e.g., significant scars, the presence of contracture or pain caused by the clinical condition).** 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 **limited** 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.

There is insufficient evidence in the peer-reviewed literature that pneumatic compression pumps applied to the chest and/or trunk as well as the limb provide improvement beyond that provided by treating the affected limb only. There have been few RCTs studying the treatment of the chest and/or trunk along with the effected upper extremity. One such study by Ridner et al, 2012 compared pneumatic compression therapy on the trunk, chest, and arm to treating the arm only (control group) in the setting of lymphedema. Each group was comprised of 21 participants who had a history of breast cancer with stage II lymphedema. The Flexitouch System was used for both groups at home for 30 days. The authors found there was no statistically significant differences in these outcomes between the groups. A statistically significant reduction in bioelectrical impedance and arm circumference within both of the groups was achieved; however, there was no statistically significant difference in

reduction between groups. These findings indicate that both configurations are effective, but that there may be no added benefit to pneumatic treatment of the trunk and/ or chest for arm lymphedema. Further research is indicated in a larger sample size.

There is insufficient evidence in the peer-reviewed literature supporting the use of pneumatic devices for head and neck lymphedema associated with head and neck cancer. The literature is limited to a few industry sponsored RCTs that demonstrate the use of Flexitouch for head and neck lymphedema did slightly decrease head and neck lymphedema compared to the control group (n=24) while at the same time increasing pain in the intervention group (n=19) for the duration of the study period (Ridner, et al. 2021). No statistically significant differences in function were observed between groups for the eight week study duration. Low compliance was noted with only one participant documented using the device the prescribed about of time. Further studies are needed to evaluation pneumatic compression for head and neck lymphedema with larger, more diverse study populations.

In 2021 The U.S. Food and Drug Administration granted Class II 510K substantial equivalence approval for marketing for two non-pneumatic compressible limb devices: Dayspring, a sequential calibrated gradient pressure device, and Dayspring Lite, a sequential gradient pressure device without calibration. These devices are comprised of a powered smart controller and a wearable garment for the affected extremity. The custom garment is embedded with flex frames shape memory that contract and relax to reduce edema and minimize interference with activities of daily living. Koya has garments for upper extremities, lower extremities and a new HCPC code for a trunk garment. There is no specialty society guidance for these devices. There are a few manufacturer-sponsored trials published by Rockson SG, et al. in 2022. The first compared the nonpneumatic Koya Dayspring to an advanced pneumatic compression device (Flexitouch) in treating breast cancer related lymphedema in the upper extremity in a multicenter, randomized, crossover study of 52 individuals. The mean reduction in edema volume was reported to be 64.6% in the Dayspring device group and 27.7% in the control group. However, it should be noted there was a significant difference in reported compliance between groups, with 95.6% of Dayspring subjects complying with the 60-minute per day therapy and only 49.8% of the control group subjects complying. The second trial by Rockson et al., 2022 was a non-randomized, open-label study of the safety and effectiveness of the Koya Dayspring for lower limb lymphedema. The 24 participants utilized the Koya Dayspring lower leg garment for one hour a day and were encouraged to continue to exercise and move around while wearing the device over 12 weeks. The primary endpoints were measured with a Quality of Life (QOL) questionnaire and measured change in lower limb volume. Only 18 participants completed the study, results showed an improvement in QOL by 8% and a reduction in lower limb edema by 39.4% compared to baseline of using no compression pump before the start of the study. This study had a small sample size and no control group. While these results are promising, additional larger, well-designed, and conducted long-term studies are needed to establish the role of nonpneumatic compression therapy for lymphedema in standard treatment regimens.

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.*
- ***Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).***

CPT Codes

Code	Description
No code(s)	

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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 **(E/I)**	Segmental pneumatic appliance for use with pneumatic compressor, trunk
E0657 **(E/I)**	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
E0670 (E/I)	**Segmental pneumatic appliance for use with pneumatic compressor, integrated, two full legs and trunk (effective 01/01/2013)**
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 **(E/I)**	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	**Nonpneumatic sequential compression garment, trunk (effective 04/01/2023)**
K1024 **(E/I)**	Nonpneumatic compression controller with sequential calibrated gradient pressure
K1025 **(E/I)**	Nonpneumatic sequential compression garment, full arm
K1031 (E/I)	**Nonpneumatic compression controller without calibrated gradient pressure (effective 04/01/2022)**
K1032 (E/I)	**Nonpneumatic sequential compression garment, full leg (effective 04/01/2022)**
K1033 (E/I)	**Nonpneumatic sequential compression garment, half leg (effective 04/01/2022)**

ICD10 Codes

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

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*Key Article

KEY WORDS

Flexitouch, Lymphedema sleeve, **Koya Dayspring**.

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&