MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**Powered Compression Devices/Lymphedema Pumps**
Policy Number	**1.01.17**
Category	**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, 04/23/20, 04/21/22, 06/22/23, 05/16/24, 12/19/24**
Current Effective Date	**12/19/24**
Archived Date	**N/A**
Archived Effective Date	**N/A**
Product Disclaimer	• *Services are contract dependent; 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.

****Note: State and Federal Mandates supersede criteria within this policy. See Policy Guidelines****

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 **ALL** of the following criteria are met:
   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;
      2. regular exercise;
      3. 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 in Policy Statement I. and **BOTH A** and **B** are met:
   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, powered compression devices have not been medically proven to be effective and are considered **investigational** for **ALL** of the following indications:
   A. Venous stasis ulcers;

B. Peripheral artery disease (e.g., intermittent claudication, ischemia, arterial insufficiency) (HCPCS code E0675);
C. Chest and/or trunk applications for lymphedema (HCPCS code E0656, E0657, E0670);
D. Neck or head applications for lymphedema;
E. A non-pneumatic compression pump or non-pneumatic sequential compression garment for any indication (e.g., Koya Dayspring, VenoWave) (HCPCS codes E0680, E0681, E0682, E0677, E0678, E0679, E0683).

IV. Repair and/or replacement of a **medically necessary** powered compression device and/or components (HCPCS codes E0650, E0651, E0652) not under warranty will be considered **medically appropriate** when the following criteria are met:
A. Physician documentation includes **ALL** of the following:
1. date of device implantation/initiation,
2. manufacturer warranty information, **and**
3. attestation that the patient has been compliant with the use of device and will continue to benefit from the use of device; **AND ONE OF THE FOLLOWING APPLY**:
B. Repair of the currently used device when **ALL** of the following are met:
1. it is no longer functioning adequately,
2. inadequate function interferes with activities of daily living, **and**
3. repair is expected to make the equipment fully functional (as defined by manufacturer); **or**
C. Replacement of the currently used device when the following are met:
1. it is no longer functioning adequately, **AND EITHER**
2. has been determined to be non-repairable, **or**
3. the cost of the repair is in excess of the replacement cost; **or**
D. Replacement of the currently used device when **BOTH** of the following are met:
1. there is documentation that a change in the patient's condition makes the present unit non-functional, **and**
2. improvement is expected with a replacement unit.

V. Repair or replacement of equipment damaged due to patient neglect, theft, abuse, or when another available coverage source is an option (e.g., homeowners, rental, auto, liability insurance, etc.) is **ineligible for coverage**.

VI. The replacement of properly functioning powered device and/or external components is considered **not medically necessary**. This includes, but is not limited to, replacement desired due to advanced technology or in order to make the device more aesthetically pleasing.

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 and Prophylactic Breast Cancer Risk-Reducing Mastectomy

Refer to Corporate Medical Policy #11.01.03 Experimental or Investigational Services

POLICY GUIDELINES

I. The Federal Women's Health and Cancer Right Act (WHRCA) of 1998, as well as the New York Insurance Law, mandates coverage of all stages of reconstructive surgery (including surgery and reconstruction of other breast to produce symmetrical appearance, chest wall reconstruction, prosthesis and treatment of physical complication following mastectomy such as lymphedema) for all group health plans, whether insured or self-funded, that provide medical and surgical benefits including mastectomies. Federal laws do not require a diagnosis of breast cancer (preventive mastectomies are also covered).

II. According to the New York State Insurance Laws for prostheses and physical complications of all stages of the mastectomy, including lymphedemas, while an issuer may perform a medical necessity review of these items or services, the issuer should use appropriate written clinical criteria and the most recent medical literature to determine medical necessity.

III. Medical documentation of **ALL** of the following criteria is required for consideration of a 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.

IV. 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.

V. 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.

DESCRIPTION

Lymphedema is the abnormal accumulation of lymph fluid in the subcutaneous tissues of an affected body part. There are two types of lymphedema, primary (a genetic abnormality that causes a malformation of the lymphatic system) and secondary (damage to the lymphatic system [e.g., surgery, radiation, traumatic injury]). Lymphedema commonly occurs in the arm or leg, but may occur in the breast, chest, head and neck, and genitals.

Lymphedema is considered to be incurable; however, it can be reversible in the early stages. Lymphedema is a condition that will progress if left untreated. Nonsurgical treatment focuses on decongestion and maintenance therapies (e.g., compression garments, exercise, pharmacological) to decrease the excess volume of the limb as much as possible and maintaining the limb at its smallest size.

Complete decongestive therapy (CDT) is the standard of care for stage II lymphedema; however, the optimal program has not been established (National Cancer Institute, 2024). CTD consists of skin care, manual lymphatic drainage (MLD) or self-administered manual lymphatic drainage (SMLD), and compression bandages. MLD is a massage-like technique that is performed by specially trained physical therapists and is an important component for achieving successful results with CDT; however, MLD alone is not recommended to attempt to achieve volume reduction. The Academy of Oncologic Physical Therapy of American Physical Therapy Association (APTA) issued guidelines recommending that modifying CDT, specifically shortening or omitting the MLD component, may yield similar results on long-term volume reduction (Grade B) (Davies et al., 2020).

The shortage of trained lymphedema therapists and the inconvenience of multiple clinic visits have encouraged the development of pneumatic compression devices that patients can use at home. 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

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 pressure 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 quality of life (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 devices provide outcomes equal or superior to standard pneumatic compression devices. One randomized, single-center, crossover study involving ten patients, which compared

the efficacy of the Flexitouch device to massage for treatment of lymphedema of the arm, was found in the literature (Wilburn et al., 2006). 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.

Pneumatic Compression for Venous or Arterial Insufficiency

There is insufficient evidence in the peer-reviewed literature to establish that intermittent pneumatic compression (IPC) improves outcomes in patients with chronic venous insufficiency (CVI), 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.

A Cochrane review updated by Nelson et al. (2014) addressed intermittent pneumatic compression pumps for treating venous leg ulcers. In a meta-analysis of 3 of the 5 trials evaluating the incremental benefit of pneumatic compression pumps over continuous compression alone, there was a significantly higher rate of healing with combined treatment. Two of these 3 trials were considered to have a high-risk of bias (e.g., not blinded, unclear allocation or concealment). There was a high degree of heterogeneity among trials, and findings from other RCTs were not pooled. Neither of the 2 trials comparing intermittent pneumatic compression with continuous compression plus stockings or bandages found statistically significant between-group differences in healing rates.

Alvarez et al. (2020) conducted a small RCT (n= 52) with large (>20 cm^2) chronic venous leg ulcers that compared intermittent pneumatic compression plus standard compression therapy (n=27) to standard compression therapy alone (n=25). Standard compression therapy consisted of multilayer compression bandages. Intermittent pneumatic compression therapy was performed for 1 hour twice daily. At 9 months, median time to wound closure was significantly shortened in the group receiving pneumatic compression (141 days vs. 211 days; p=.03). Wound pain relief was greater in the pneumatic compression group for the first 3 weeks of therapy, but pain relief was similar between groups at subsequent time points.

A meta-analysis by Xu and Li (2023) was retracted in August 2024 due to findings that the peer review and publishing process for the article were found to be manipulated.

To date, that most current clinical practice guideline on management of venous leg ulcers was published in 2014 from the Society for Vascular Surgery and the American Venous Forum (O'Donnell et al., 2014). The suggested recommendation (grade 2; level of evidence C) state that it is advantageous to use intermittent pneumatic compression (IPC) compared with no compression therapy, currently there is limited evidence to suggest that the addition of IPC to compression therapy offers benefit. In circumstances in which IPC is used, there is some evidence to suggest that proportion of ulcers healed (86% vs 61% at 6 months; p=.003) is improved with rapid compared with slow cycling. The theory that IPC promotes healing remains to be rigorously tested.

Pneumatic Compression Applied to the Chest and Trunk

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. 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.

Pneumatic Compression Applied to the Head and Neck

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 industries sponsored RTCs that demonstrate the use of Flexitouch for head and neck lymphedema did slightly decrease head and neck lymphedema.

Mayrovitz et al. (2018) conducted a functional usability study on 44 patients with head and neck lymphedema. Although participants reported comfortable use and feeling better after one treatment, this is a single-arm, single-treatment study that did not follow use of the therapy long-term in the home setting.

Ridner et al., (2021) conducted a randomized, wait-list controlled trial of 49 patients (control group [n=24] intervention group [n=19]). All patients had follow-up visits at 1, 4, and 8 weeks. Although patients in the intervention group reported improvement in perceived ability to control lymphedema; there was no statistically significant differences in function ($p=0.312$ to $p=0.615$) or in inflammatory biomarker ($p>0.10$) levels 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.

Non-Pneumatic Compression

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 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)	

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
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 **(E/I)**	Nonpneumatic sequential compression garment, trunk
E0678 (**E/I)**	Non-pneumatic sequential compression garment, full leg
E0679 **(E/I)**	Non-pneumatic sequential compression garment, half leg
E0680 **(E/I)**	Non-pneumatic compression controller with sequential calibrated gradient pressure
E0681 **(E/I)**	Non-pneumatic compression controller without calibrated gradient pressure
E0682 **(E/I)**	Non-pneumatic sequential compression garment, full arm
E0683 **(E/I)**	Nonpneumatic, nonsequential, peristaltic wave compression pump *(Effective 10/01/24)*

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) 280.6 for Pneumatic Compression Devices. Please refer to the following websites for Medicare Members: [http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=225&ncdver=1&bc=AgAAgAAAAAAA&] accessed 11/27/24.