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Department of Origin: Integrated Healthcare Services	**Effective Date:** 05/17/24
Approved by: Medical Policy Quality Management Subcommittee	**Date Approved:** 12/05/23
Clinical Policy Document: DMEPOS, Pneumatic Compression Devices and Heat/Cold Therapy Units	**Replaces Effective Clinical Policy Dated**: 12/12/23
Reference #: MC/D006	**Page:** 1 of 7

PURPOSE:
The intent of this clinical policy is to ensure services are medically necessary.

Please refer to the member's benefit document for specific information. To the extent there is any inconsistency between this policy and the terms of the member's benefit plan or certificate of coverage, the terms of the member's benefit plan document will govern.

POLICY:
Benefits must be available for health care services. Health care services must be ordered by a provider. Health care services must be medically necessary, applicable conservative treatments must have been tried, and the most cost-effective alternative must be requested for coverage consideration.

GUIDELINES:
Medical Necessity Criteria – Must satisfy any of the following: I - IV

I. Request for pneumatic compressor, non-segmental home model or segmental home model without calibrated gradient pressure (HCPCS: E0650, E0651) - must satisfy any of the following: A or B

A. Lymphedema - must satisfy all of the following: 1 - 3
1. Member is under the care of a *lymphedema/vascular specialist or program*; and

2. Member has chronic, severe lymphedema - as evidenced by any of the following clinical findings: a - e
   a. Marked hyperkeratosis w/ hyperplasia and hyperpigmentation; or
   b. *Papillomatosis cutis lymphostatica*; or
   c. *Elephantiasis*; or
   d. Skin breakdown with persisting *lymphorrhea*; or
   e. Detailed measurements over time confirming the persistence of the lymphedema.

3. There is no significant improvement after a 4-week trial of conservative management (ie, Complex Decongestive Therapy [CDT]) of all the following: a - c
   a. Regular and compliant use of a prefabricated or custom-fabricated compression bandage system or compression garment that provides adequate graduated compression, starting with a minimum of 30 mmHg distally; and
   [Note: Trial of compression bandage or garment is not required for truncal edema.]
   b. Exercise program from the *lymphedema specialist*; and
   c. Elevation of the limb.

B. Chronic venous insufficiency (CVI) – must satisfy all the following: 1 - 4
1. Member is under the care of a *lymphedema/vascular specialist or program*; and

2. Edema in the affected lower extremity; and

3. One or more venous stasis ulcers; and

4. The ulcer has failed to heal after a six-month trial of conservative management of all the following: a - d
   a. Regular and compliant use of a prefabricated or custom-fabricated compression bandage system or compression garment that provides adequate graduated compression, starting with a minimum of 30 mmHg distally; and
   b. Exercise; and
   c. Elevation of the limb; and
   d. Appropriate wound care for the ulcer.

II. Request for pneumatic compressor, segmental home model with calibrated gradient pressure - (E0652) must satisfy any of the following: A or B

A. Lymphedema - must satisfy all the following: 1 - 5
   1. Member is under the care of a *lymphedema/vascular specialist or program*; and

   2. Member has chronic, severe lymphedema - as evidenced by any of the following clinical findings: a - e
      a. Marked hyperkeratosis w/ hyperplasia and hyperpigmentation; or
      b. *Papillomatosis cutis lymphostatica*; or
      c. *Elephantiasis*; or
      d. Skin breakdown with persisting *lymphorrhea*; or
      e. Detailed measurements over time confirming the persistence of the lymphedema.

   3. There is no significant improvement after a 4-week trial of conservative management (CDT) of all the following: a - c
      a. Regular and compliant use of a prefabricated or custom-fabricated compression bandage system or compression garment that provides adequate graduated compression, starting with a minimum of 30 mmHg distally; and
      b. Exercise; and
      c. Elevation of the limb.

   4. The lymphedema extends onto the chest, trunk, and/or abdomen (ie, extends past the limits of a standard compression sleeve); and

   5. Documentation supports no significant improvement after a 4-week trial including all the following: a - e
      a. Regular, daily, multiple-hour home usage of pneumatic compression treatment using a non-segmental compressor or a segmental compressor without calibrated gradient pressure (E0650 or E0651) after careful, in-person fitting, training and supervision by a technician who is skilled in and who regularly and successfully uses the appliance provided (CDT); and
      b. Manual lymphoid drainage (where available) and self-manual lymphatic drain (MLD) for at least 30 minutes per day (CDT); and
      c. Evaluation of diet and implementation of any necessary change; and
      d. Medications as appropriate, eg, diuretics; and
      e. Correction (where possible) of anemia and/or hyponatremia.

[Note: A trial of E0650 or E0651 is not required when there is specific documentation of a rare clinical circumstance that prevents effective pneumatic compression treatment using a device without

calibrated pressure contracture that may require reduced pressure in a localized area, such as extensive scarring or contracture.]

B. *Chronic venous insufficiency (CVI)* – must satisfy all the following: 1 - 4
   1. Edema in the affected lower extremity; and

   2. One or more venous stasis ulcers; and

   3. The ulcer has failed to heal after a six-month trial of conservative management of all the following: a - d
      a. Regular and compliant use of a prefabricated or custom-fabricated compression bandage system or compression garment that provides adequate graduated compression, starting with a minimum of 30 mmHg distally; and
      b. Exercise; and
      c. Elevation of the limb; and
      d. Appropriate wound care for the ulcer

   4. Documentation supports no significant improvement after a 4-week trial of a non-segmental compressor or a segmental compressor without calibrated gradient pressure (E0650 or E0651) after careful, in-person fitting, training and supervision by a technician who is skilled in and who regularly and successfully uses the appliance provided.

[Note: A trial of E0650 or E0651 is not required when there is specific documentation of a rare clinical circumstance that prevents effective pneumatic compression treatment using a device without calibrated pressure contracture that may require reduced pressure in a localized area, such as extensive scarring or contracture.]

III. Request for pneumatic compression device, high pressure, rapid inflation/deflation cycle for peripheral arterial disease/arterial insufficiency (E0675) - can be allowed for treatment of peripheral artery disease in members that might otherwise require surgical treatment of the arterial insufficiency.

IV. Request for intermittent limb compression device (including all accessories), not otherwise specified (E0676) – can be allowed for prevention of deep vein thrombosis in an outpatient setting or upon discharge from an inpatient setting

NOT ROUTINELY COVERED:
A 2-phase lymph preparation and drainage therapy device (eg, Flexitouch Device, Tactile Systems Technology, Minneapolis, MN; LymphaPress Optimal, Lympha Press USA, Manalapan, NJ) is considered non-standard, as it is equally effective to standard segmented pneumatic compression devices with calibrated gradient pressure.

The ACTitouch Adaptive Compression Therapy System is considered non-standard, as it is equally effective to standard segmented pneumatic compression devices without calibrated gradient pressure.

Devices that deliver heat and/or cold compression therapy are not covered. Therapy administered with these devices has not been proven to be any more effective than traditional delivery of heat/cold and compression (eg, heating pads, ice packs, compression wraps), and therefore these devices are considered convenience items.

EXCLUSIONS (not limited to):
Refer to member's Certificate of Coverage or Summary Plan Description

The following are considered investigative (see Investigative List): I – III

I. Active Cooling Therapy for cryoanalgesia are considered investigative (see Investigative List). Including, but not limited to, Aqua Relief System®, AutoChill, BioCryo® Cold Compression System, Game Ready® units with attached cooled systems, IceMan, NanoTherm, Prothermo, and Vascutherm.

II. Pneumatic compressor, segmental home model with calibrated gradient pressure used to treat lymphedema that does not extend onto the chest, trunk and/or abdomen

III. Non-pneumatic compression controller with sequential calibrated gradient pressure for treatment of lymphedema. Investigative device includes, but is not limited to: Dayspring system by Koya

DEFINITIONS:
Activities of Daily Living (ADL):
Activities related to personal self-care and independent living, which include eating, bathing, dressing, transferring, walking/mobility, and toileting/continence

Chronic venous insufficiency (CVI):
A condition of the lower limbs that occurs when the walls and valves of the veins are not working effectively, leading to blocking or reflux (backflow) of blood in the veins. This makes it difficult for the blood to return to the heart. Signs of CVI include discolored or inflamed skin, chronic swelling, and venous ulcers (sores).

Elephantiasis:
The enlargement and hardening of limbs or body parts due to tissue swelling. It is characterized by edema, hypertrophy, and fibrosis of skin and subcutaneous tissues, due to obstruction of lymphatic vessels. It may affect the genitalia. The term elephantiasis is often used in reference to parasitic worm infections, but may refer to a variety of diseases where parts of a person's body swell to massive proportions.
Lymphedema/vascular specialist or program:
Completed training as defined by the National Lymphedema Network Position Statement on Training of Lymphedema Therapists (May 2010) Available at: https://lymphnet.org/position-papers

Lymphorrhea
An escape of lymph onto the surface of the skin from ruptured, torn, or cut lymphatic vessels.

Papillomatosis cutis lymphostatica:
A benign, usually asymptomatic and underreported condition resulting from primary lymphedema or damage of lymphatic vessels due to diabetes

BACKGROUND:
Pneumatic compression devices (PCD) are classified as segmental or non-segmental, depending on whether distinct segments of devices can be inflated sequentially.

PCDs consist of an inflatable garment for the arm or leg and an electrical pneumatic pump that fills the garment with compressed air. The garment is intermittently inflated and deflated with cycle times and pressures that vary between devices.

A non-segmental pneumatic compressor (E0650) is a device which has a single outflow port on the compressor. The fact that the air from the single tube may be transmitted to a sleeve/appliance with multiple compartments or segments (E0671-E0673) does not affect the coding of the compressor.

A segmental pneumatic compressor (E0651, E0652) is a device which has multiple outflow ports on the compressor which lead to distinct segments on the appliance which inflate sequentially.

A segmental device without calibrated gradient pressure (E0651) is one in which either:
(a) the same pressure is present in each segment; or
(b) there is a predetermined pressure gradient in successive segments but no ability to individually set or adjust pressures in each of several segments.
In an E0651 device the pressure is usually set by a single control on the distal segment.

A segmental device with calibrated gradient pressure (E0652) is characterized by a manual control on at least three outflow ports which can deliver an individually determined pressure to each segmental unit. The fact that the tubing and/or appliance are capable of achieving a pressure gradient does not classify the compressor as E0652 because this is not a calibrated gradient pressure.

Segmental gradient pressure pneumatic appliances (E0671-E0673) are appliances/sleeves which are used with a non-segmental pneumatic compressor (E0650) but which achieve a pressure gradient through the design of the tubing and/or air chambers.

Pneumatic pumps can consist either of static uni-compartmental pumps where an equal amount of pressure is applied throughout the edematous limb, or a sequential pump which essentially attempts to “wring out” the edema by graded compression from distal to proximal. Due to the short cycles of pressure, higher pressures can be applied compared to the static pumps. Pressures higher than the systolic blood pressure are avoided; pressures up to 80 to 90 mm Hg are typical.

At this point sequential pumps (such as the Lymphapress or the Wright linear sequential pump) appear to be more commonly used than static pumps. The Lymphapress device is composed of a series of overlapping cells that apply a sequential pattern of compression moving distally to proximally along the affected limb. Using this strategy, higher levels of pressure can be applied compared to other uni-compartmental devices which apply the same degree of pressure along the entire limb. The Lymphapress device seems to be effective in acutely decreasing lymphedema, and many patients have purchased this device for home use.

Newer, advanced pneumatic compression devices with additional features that the more "traditional" type of pumps have been developed. A two-stage multichamber programmable pneumatic compression device operates in two separate phases. These devices are proposed to be based on the principles of manual lymph drainage (treat the proximal areas first, which is theorized to prepare the distal areas for drainage). The first phase is a "preparatory" phase, followed by the treatment or drainage phase, which utilizes light variable pressure to drain the fluid/ blood from the distal treatment areas. The second phase may be controlled by multiple programmable options. Examples of this type of pump include, but may not be limited to, the Flexitouch or LymphaPress Optimal.

The Flexitouch Device (Tactile Systems Technology, Minneapolis, MN) is a 2-phase lymph preparation and drainage therapy device. The device consists of an electronic controller unit and garments which are

worn on the trunk and upper and lower affected extremities and connected to the controller unit by tubing harnesses. The garment consists of 32 inflatable chambers that sequentially inflate and deflate at 1 to 3 second intervals, according to 1 of the 13 pre-programmed treatment patterns selected. Chamber pressure and treatment times can be adjusted. The manufacturer states that device's sequential action evacuates lymph from the trunk and extremities and drains it into the venous system. The garments are made from stretch material and are fitted with Velcro enclosures, so custom fitting of garments is not required. There are no published studies comparing the effectiveness of this 2-phase lymph preparation and drainage therapy device to standard segmental pneumatic compression devices.

The ACTitouch Adaptive Compression therapy system is another more recently developed pump device. It combines intermittent pneumatic compression with a sustained gradient pressure. It may be used when stationary or when ambulating (walking).

Prior Authorization: Yes, per network provider agreement.

CODING:
CPT® or HCPCS - See guidelines

REFERENCES:
1. Integrated Healthcare Services Process Manual: UR015 Use of Medical Policy and Criteria
2. Clinical Policy: Coverage Determination Guidelines MP/C009
3. Clinical Policy: Durable Medical Equipment, Prosthetics, Orthotics and Supplies MP/D004
4. Mehrara B. Clinical staging and conservative management of peripheral lymphedema. (Topic 738, Version 50.0; last update 11/16/22) In: Collins KA, Vora SR, ed. *UpToDate*. Waltham, Mass.: UpToDate; 2023. www.uptodate.com. Accessed 10-27-23.
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PreferredOne Community Health Plan
PO Box 59052
Minneapolis, MN 55459-0052
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

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You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

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U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

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ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສັຽຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ 1.800.940.5049 (TTY: 763.847.4013).

ማስታወሻ: የሚናገሩት ቋንቋ አማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፣ በነጻ ሊያግዝዎት ተዘጋጀተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ 1.800.940.5049 (መስማት ለተሳናቸው: 763.847.4013).

ဟသူဉ်ဟ်သး– နမ့ါကတိၤ ကညီ ကျိာ်အယိ, နမၤန့ါ ကျိာ်အတ၊်မၤစၢၤလၢ တလၢာ်ဘူဉ်လၢာ်စ့ၤ နီတမံၤဘဉ်သ့နှဉ်လီၤ. ကိး 1.800.940.5049 (TTY: 763.847.4013).

ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1.800.940.5049 (TTY: 763.847.4013).

ប្រយ័ត្ន៖ បើសិនជាអ្នកនិយាយ ភាសាខ្មែរ, សេវាជំនួយផ្នែកភាសា ដោយមិនគិតឈ្នួល គឺអាចមានសំរាប់បំរើអ្នក។ ចូរ ទូរស័ព្ទ 1.800.940.5049 (TTY: 763.847.4013)។

ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 1.800.940.5049 (رقم هاتف الصم والبكم: 763.847.4013).

ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1.800.940.5049 (TTY: 763.847.4013).

주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1.800.940.5049 (TTY: 763.847.4013). 번으로 전화해 주십시오.

PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa 1.800.940.5049 (TTY: 763.847.4013).