PNEUMATIC COMPRESSION DEVICES IN THE HOME SETTING

Description: Pneumatic compression devices consist of an inflatable garment and an electrical pneumatic controller or pump that fills the garment with compressed air. The garment is intermittently inflated and deflated with cycle times and pressures to improve venous circulation and lymphatic drainage. This treatment is also referred to as intermittent pneumatic compression (IPC).

Pneumatic compression devices are used in the treatment of lymphedema, chronic venous insufficiency and prevention of venous thromboembolism after major surgery. These devices have also been proposed for use in the home setting in other situations, such as treatment of restless legs syndrome.

Many different pneumatic compression devices are available, with varying materials, design, and complexity. These devices are classified into three types:

- Non-segmented (single compartment) device;
- Segmented (multi-chamber) device with sequential inflation of each chamber and with fixed pressure (no manual control of pressure) in each chamber; and
- Segmented (multi-chamber) programmable device with sequential inflation and with manually calibrated pressure in each chamber.

Devices cleared by the Food and Drug Administration (FDA) for primary or adjunctive (e.g., post mastectomy) treatment of lymphedema include but are not limited to, the following:

- Compression Pump, Model GS-128 (Medmark Technologies, LLC., Perkasie, PA)
- Flexitouch® system (Tactile Systems Technology, Inc., Minneapolis, MN)
- Lympha-Press and Lympha-Press Optimal (Mego Afek, Israel)
Several pneumatic compression devices are cleared by the FDA for treatment of venous stasis ulcers. Examples include the Model GS-12, Lympha-press, Flexitouch, and PowerPress Unit listed above as well as Nanotherm™ (ThermoTek, Inc., Flower Mound, TX), the CTU676 device (Compression Technologies Unlimited, Lansing, MI) and Recovery+ (Pulsar Scientific LLC, Ludlow, MA).

FDA-cleared devices with indications that include prevention of DVT include, but are not limited to, the following:

- Venowave™ VW5 (Venowave Inc.; Stouffville, Ontario, Canada):
- ActiveCare+SFT® System (Medical Compression Systems LTD, Or Akiva, Israel)
- Restep® DVT System (Stortford Medical LLC, West Windsor, NJ)
- Kendall SCD™ 700 Sequential Compression System (Covidien, Mansfield, MA)

Definitions: **Lymphedema** is the swelling of subcutaneous tissues due to the accumulation of excessive lymph fluid. The accumulation of lymph fluid results from impairment to the normal clearing function of the lymphatic system and/or from an excessive production of lymph. Lymphedema is divided into two broad classes according to etiology. Primary lymphedema is a relatively uncommon, chronic condition which may be due to such causes as Milroy’s Disease or congenital anomalies. Secondary lymphedema, which is much more common, results from the destruction of or damage to formerly functioning lymphatic channels, such as surgical removal of lymph nodes or post radiation fibrosis, among other causes.

**Chronic venous insufficiency (CVI)** of the lower extremities is a condition caused by abnormalities of the venous wall and valves, leading to obstruction or reflux of blood flow in the veins. Signs of CVI include hyperpigmentation, stasis dermatitis, chronic edema, and venous ulcers.

**Venous thromboembolism (VTE)** refers to deep vein thrombosis (DVT) or pulmonary embolism (PE). Risk of DVT increases due to venous stasis of the lower limbs as a consequence of immobility during or after surgery. Patients who have major orthopedic surgery (such as total hip arthroplasty, total knee arthroplasty and hip fracture surgery) are at particularly high risk. While most DVTs are asymptomatic and generally resolve when mobility is restored, some acute DVTs can be associated with substantial morbidity. The most serious adverse consequence of an acute DVT is a PE, which
occurs when a DVT detaches and migrates to the lungs. Antithrombotic prophylaxis is recommended for patients undergoing major orthopedic surgery and for other surgical patients at increased risk of VTE. Specialty society guidelines recommend pharmacotherapy unless it is contraindicated.

Policy:

I. Lymphedema
The use of pneumatic compression devices may be considered MEDICALLY NECESSARY for the treatment of lymphedema in the home setting when ALL of the following criteria are met:
   A. The patient has undergone a four-week trial of conservative therapy which includes:
      1. Use of an appropriate compression bandage system or compression garment,
      2. Exercise, and
      3. Elevation of the limb;
      AND
   B. The treating physician determines that no significant improvement has occurred or significant symptoms remain following the four-week trial.

II. Chronic Venous Insufficiency
The use of pneumatic compression devices in the home setting may be considered MEDICALLY NECESSARY for the treatment of chronic venous insufficiency of the lower extremities when ALL of the following criteria are met:
   A. The patient has one or more venous stasis ulcers;
   AND
   B. The patient has undergone a trial of conservative therapy for a minimum of six months which includes ALL of the following:
      1. The use of an appropriate compression bandage system or compression garment,
      2. Appropriate dressings for the wound,
      3. Exercise, and
      4. Elevation of the limb.
      AND
   C. The treating physician determines that the venous stasis ulcer has failed to heal.

III. Post-Surgical Venous Thromboembolism (VTE) Prophylaxis
   A. The use of pneumatic compression devices in the home setting may be considered MEDICALLY NECESSARY in patients who have undergone surgery when ALL of the following criteria are met:
      1. The patient has undergone surgery that requires postsurgical VTE prophylaxis (e.g., major orthopedic surgery such as such a total hip arthroplasty, total knee arthroplasty or hip fracture repair);
      AND
2. The patient has a contraindication to pharmacologic anticoagulants, such as being at high-risk for bleeding. Risk factors for bleeding include:
   a. Bleeding disorder such as hemophilia
   b. Active liver disease
   c. Severe renal failure
   d. Previous major bleed (and previous bleeding risk similar to current risk)
   e. Concomitant antiplatelet agent
   f. History of or difficult-to-control surgical bleeding during the current operative procedure, extensive surgical dissection, and revision surgery.

B. Home use of pneumatic compression devices for post-surgical VTE prophylaxis is considered INVESTIGATIVE for all other indications.

IV. The use of pneumatic compression devices in the home setting is considered INVESTIGATIVE for all other indications, including but not limited to treatment of restless legs syndrome.

Coverage: Blue Cross and Blue Shield of Minnesota medical policies apply generally to all Blue Cross and Blue Plus plans and products. Benefit plans vary in coverage and some plans may not provide coverage for certain services addressed in the medical policies.

Medicaid products and some self-insured plans may have additional policies and prior authorization requirements. Receipt of benefits is subject to all terms and conditions of the member's summary plan description (SPD). As applicable, review the provisions relating to a specific coverage determination, including exclusions and limitations. Blue Cross reserves the right to revise, update and/or add to its medical policies at any time without notice.

For Medicare NCD and/or Medicare LCD, please consult CMS or National Government Services websites.

Refer to the Pre-Certification/Pre-Authorization section of the Medical Behavioral Health Policy Manual for the full list of services, procedures, prescription drugs, and medical devices that require Pre-certification/Pre-Authorization. Note that services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial of claims may result if criteria are not met.

Coding: The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

HCPCS:
E0650 Pneumatic compressor, non-segmental home model
E0651 Pneumatic compressor, segmental home model without calibrated gradient pressure
E0652 Pneumatic compressor, segmental home model with calibrated gradient pressure
E0655 Non-segmental 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 Non-segmental pneumatic appliance for use with pneumatic compressor, full leg
E0665 Non-segmental pneumatic appliance for use with pneumatic compressor, full arm
E0666 Non-segmental 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 Segmental pneumatic appliance for use with pneumatic compressor, integrated, 2 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 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

Policy History:

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Cross Reference: Cooling/Heating Devices Used in the Outpatient Setting, VII-14