MedStar Family Choice

ADMINISTRATIVE POLICY AND PROCEDURE		
Policy #:	**1419**	
Subject:	**Pneumatic Compression Devices for Lymphedema**	
Section:	**Medical Non-Pharmacy Protocols**	
Initial Effective Date:	**07/01/2017**	
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Historical Review Date(s):	**07/17**	
Responsible Parties:	**Medical Director**	
Responsible Department(s):	**Clinical Operations**	
Regulatory References:	**LCD L33829, NCD 280.6**	
Approved:	**AVP Clinical Operations**	**Chief Medical Officer**

Purpose: **It is the purpose of this policy to define the conditions under which pneumatic compression devices will be authorized.**

Scope: **MedStar Family Choice, Maryland**

Policy: **It is the policy of MedStar Family Choice to provide pneumatic compression devices when it is medically necessary as outlined in the criteria below.**

Background:

MedStar Family Choice will require prior authorization for pneumatic compression devices.

1. Requests for pneumatic compression devices should be forwarded along with the supporting clinical information in accordance with the MedStar Family Choice Prior Authorization Policy.

A. Medical Description/Background:
Lymphedema is defined as the accumulation of fluid and fibroadipose tissues due to disruption of lymphatic flow. Initial conservative therapy consists of general measures for self-care (e.g., self-monitoring, skin care, weight reduction/maintenance of ideal body weight, limb elevation); these are applicable to all stages of lymphedema. Varying levels of compression therapy (compression bandaging, compression garments, intermittent pneumatic compression) and physiotherapy (manual lymphatic drainage, complete decongestive therapy) are appropriate with the choice of the specific interventions depending upon the severity of the lymphedema.

Pneumatic compression pumps are proposed as a treatment option for patients with lymphedema who have failed conservative measures. (Conservative measures include weight reduction/maintenance of ideal body weight, limb elevation, exercise, use of an appropriate compression bandage/garment, physiotherapy to teach lymphatic drainage.) A variety of pumps are available. They can be single chamber (non-segmented) or multi-chamber (segmented) and have varying design and complexity. Pneumatic compression devices consist of an inflatable appliance (garment) for an arm, leg, trunk or chest 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 among devices.

There are three main types of pumps:

1. Single chamber (non-segmented) non-programmable compressor (pump) consist of a single outflow port on the compressor. The pressurized air from this single outflow port can be transmitted to an appliance (garment) that consists of a single segment or multiple segments. The parts of the garment inflate and deflate based on pressure and cycle times specified by the pump.

2. Multi-chamber (segmented) non-programmable pumps consist of multiple outflow ports on the pump. The pressurized air from each of the outflow ports is transmitted to corresponding segments on the appliance (garment). The segments of the garment are inflated sequentially and have a fixed pressure in each compartment. They either have the same pressure in each compartment or a pressure gradient, but they do not include the ability to manually adjust the pressure in individual compartments.

3. Multi-chamber (segmented) programmable pumps are similar to the above pumps except that it is possible to make manual adjustments in the pressure on at least three outflow ports. This allows an individually determined pressure to be delivered to a corresponding garment segment.

Generally, when a pneumatic compression pump is needed, a non-segmented or segmented compression device without manual control (non-programmable) is considered sufficient to treat most lymphedema.

B. Indications for Pneumatic Compression Devices:
    1. The use of single chamber (non-segmented) or multi-chamber (segmented) non-programmable pneumatic compression devices (coded as E0650 or E0651, respectively) for the treatment of lymphedema may be considered medically necessary when all of the following are met:
        a. A documented diagnosis of lymphedema as well as the cause of the lymphedema (e.g., surgical procedure, cancer, traumatic episodes, underlying condition that has interrupted normal lymphatic drainage of the extremity) and the date of onset of swelling.
        b. The member must have documented persistence over a period of at least six months of "chronic and severe" lymphedema as identified by the documented presence of at least one of the following findings:
            i. Marked hyperkeratosis with hyperplasia and hyperpigmentation
            ii. Papillomatosis cutis lymphostatica
            iii. Deformity of elephantiasis
            iv. Skin breakdown with persisting lymphorrhea
            v. Detailed measurements over time confirming the persistence of lymphedema with a history demonstrating the likely cause of the lymphedema
        c. The member must be under the care of a lymphedema specialist or program.
        d. There must be documentation of objective findings that establish the severity of the lymphedema.
            i. Circumferential measurement charts demonstrating significant asymmetrical swelling
            ii. Clinician determination of lymphedema Stage/Severity (Stage 0/Stage 1 and/or mild lymphedema do not meet criteria for a pneumatic compression device) [Clinical Stage as defined by The International Society of Lymphology]*
            iii. Documentation of the presence of lymphedema symptoms
        e. Clinical records must demonstrate the member has been compliant with a minimum of a four-week trial of conservative therapy. The trial of conservative therapy must include all of the following:
            i. Use of an appropriate compression bandage or compression garment to provide adequate graduated compression:
                1. Adequate compression is defined as sufficient pressure at the lowest pressure point to cause fluid movement and sufficient pressure across the gradient (from highest to lowest pressure point) to move fluid from distal to proximal. The compression used must not create a tourniquet effect at any point
                2. The garment may be prefabricated or custom-fabricated but must provide adequate graduated compression beginning with a minimum of 30mmHg distally.
            ii. Regular Exercise
            iii. Elevation of the limb
            iv. Manual lymphatic drainage with a lymphedema specialist

v. Self-manual lymphatic drainage for a least 30 minutes per day or documentation of why this is not possible

f. The treating physician/lymphedema specialist must determine that there has been no improvement with conservative therapy. Documentation for this must include all of the following:
    i. Detailed measurements obtained in the same manner and with reference to the same anatomic landmarks, prior to and at the conclusion of the various trials and therapy, with bilateral comparisons where appropriate.
    ii. The member has other complications such as severe fibrosis, recurrent cellulitis or skin breakdown.
    iii. Clinician determination from a provider experienced in lymphedema treatment that the patient is failing to achieve results from conservative therapies alone and has a medical need for pneumatic compression treatment.
    iv. At the end of the four-week trial, if there has been improvement, then a pneumatic compression device will not be approved. In cases where improvement occurred, the trial of conservative therapy must be continued with subsequent reassessment at four-week intervals. When no further improvement occurs and the coverage criteria above are still met, treatment with a pneumatic compression device may be considered medically necessary.
g. A lymphedema specialist must provide all treatment. All clinical notes and other documentation of the treatment must be submitted.
h. The trial of conservative therapy must be documented in the member's medical record before ordering any pneumatic compression device. The physician/nurse practitioner/physician assistant that is prescribing a pneumatic compression device must receive and review all reports of conservative treatment. In addition, the prescribing provider must sign and date these reports and state agreement or disagreement with the assessments and treatments. The signature date must be on or before the pneumatic compression device prescription date.

2. The use of single chamber or multi-chamber programmable pneumatic compression devices (i.e., manual control of the pressure in each chamber) (coded as E0652) may be considered medically necessary when all of the following are met:
    a. The member meets all of the requirements listed above for non-programmable pneumatic compression devices, and
    b. The member has failed a minimum of four weeks of regular, daily, multiple-hour home usage of a non-programmable pump (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. Documentation must demonstrate the non-programmable pump's level of effectiveness in treating the member's lymphedema, fibrosis and pain. Documentation must be provided by a lymphedema specialist. Documentation must include the following:
        i. Type/make/model of basic pump used.
        ii. Pressure settings and treatment plan.

iii. Dates and/or timeframe the pump was utilized (a minimum of a four week trial is necessary).
iv. Limb measurements before and throughout the pump trial to demonstrate level of effectiveness in treating the member's swelling.
v. Modifications made during the trial to address unique characteristics and treatment challenges.

c. The member must have extremity lymphedema extending onto the chest, trunk and/or abdomen which has remained unresponsive to all other therapies. The lymphedema must extend past the limits of a standard compression sleeve and the chest, trunk and/or abdominal lymphedema has failed to improve with four-week trial defined above. A PCD coded as E0652 used to treat lymphedema not extending onto the chest, trunk and/or abdomen will be considered not medically necessary.
d. Documents must justify why the member has a medical need for a programmable pneumatic compression device and how that will produce better results than the previously tried non-programmable pump.

3. There must be documentation of the ability of the member (or caregiver) to appropriately apply the device in the frequency prescribed for use in the home.

4. The use of programmable pneumatic compression devices will be considered not medically necessary in all other clinical situations.

5. The use of any pneumatic compression device for any disease process other than lymphedema or chronic venous insufficiency with venous stasis ulcers (see policy #1420) will be considered not medically necessary.

6. Pneumatic compression devices for the head and neck are not a covered benefit.

7. The use of any pneumatic compression device for any body part other than an extremity (arm or leg) will be considered not medically necessary and therefore not a covered benefit.

8. The use of any pneumatic compression device for lymphedema or edema of the chest, trunk or abdomen not associated with lymphedema of an extremity (arm or leg) will be considered not medically necessary and therefore not a covered benefit.

9. A pneumatic compression device coded as E0652 is not covered for the treatment of lymphedema of the extremities alone.

*International Society of Lymphology Clinical Stage:

Stage 0 – Lymphedema is a subclinical or latent condition where swelling is not evident. Most patients are asymptomatic, but some patients report a feeling of heaviness in the affected limb

Stage 1 – Lymphedema is characterized by the accumulation of fluid relatively high in protein content that decreases with limb elevation, usually within 24 hours. This is sometimes referred to as reversible edema.

Stage II – Lymphedema does not resolve with limb elevation alone. This reflects dermal fibrosis and as the fibrosis progresses, the limb may no longer pit.

Stage III – Lymphedema is characterized by lymphostatic elephantiasis.

Summary of Changes:	**07/24:** • Removed specific names for "Responsible Parties" and "Approved"; just using titles • Added measurements overtime to confirm persistent lymphedema • Removed counseling on weight reduction/maintenance • Clarified E0652 will not be approved if lymphedema does not extend to the chest, trunk, abdomen **07/23:** • Updated approved by to Carol Attia and Dr. Wills • Defined "unique characteristics" as per LCD L33829 **07/22:** • Clarified E0652 not covered without lymphedema extending onto chest, trunk, abdomen in Procedure B.2.d. • Added requirement of documentation of ability of member/caregiver to apply device in frequency prescribed, Procedure B.3. • Removed Dr. Toye from responsible parties. **07/21:** • Updated Responsible Departments from Utilization Management to Clinical Operations. • Added "Maryland" to scope. • Specified "Regular" in Section B. #1, e, ii • Section B. #8 added "A pneumatic compression device coded as E0652 is not covered for the treatment of lymphedema of the extremities alone". **12/20:** • Specified "extremity lymphedema" in Section B. #2d. • Renumbered and added content in Section B. #4-7.

	07/20: • Updated Section from Care Management to Medical Non-Pharmacy Protocols. **07/19:** • Removed "Maryland" from scope. • Edits made in A. 1, 2, and 3. • Removed B1, b.iv: persistent ulceration superimposed on chronic edema. • Section B5: added "and therefore not a covered benefit." **07/18:** • Removed DC Healthy Families and Alliance under Scope. • Modified Effective Date to Initial Effective Dates; added Historical Revision Dates and Revision Effective Dates; and added Historical Review Dates and Review Effective Dates. **07/17:** • New policy.