ADMINISTRATIVE POLICY AND PROCEDURE		
Policy#:	**1430**	
Subject:	**Non-Pneumatic Compression Devices for Lymphedema**	
Section:	**Medical Non-Pharmacy Protocols**	
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Responsible Parties:	**Lisa Speight, MD**	
Responsible Department(s):	**Clinical Operations**	
Regulatory References:	**CMS' First Biannual 2022 HCPCS Meeting (6/7/22)**	
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Purpose: It **is the purpose of this policy to define the conditions under which non-pneumatic compression devices will be authorized.**

Scope: **MedStar Family Choice, Maryland**

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

Background:

Med Star Family Choice will require prior authorization for non-pneumatic compression devices.

1. Requests for non-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.

Non-pneumatic compression devices are proposed as a treatment option for some patients with lymphedema, venous insufficiency and non-healing wounds 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 Non-pneumatic compression device is a segmental compression device that consists of a non-pneumatic segmental compressor controller, a liner and a compression garment. The compressor creates calibrated pressure that moves excess fluid from the distal to proximal portion of an extremity. The wearable compression garment allows the patient to remain mobile during treatment.

There are two main types of controllers:

- K1031 Non-pneumatic compression controller without calibrated gradient pressure (nonprogrammable)
- K1024 non-pneumatic compression controller with calibrated gradient pressure (programmable)

Generally, when a non- pneumatic compression pump is needed, a non-programmable controller is considered sufficient to treat most lymphedema.

B. Indications for Non-Pneumatic Compression Devices:

1. The use of non-pneumatic compression controller without calibrated gradient pressure (coded K1031) 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:
        1. Marked hyperkeratosis with hyperplasia and hyperpigmentation
        2. Papillomatosis cutis lymphostatica
        3. Deformity of elephantiasis
        4. Skin breakdown with persisting lymphorrhea
    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.
        1. Circumferential measurement charts demonstrating significant asymmetrical swelling
        2. 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]*
        3. 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:

        1. Use of an appropriate compression bandage or compression garment to provide adequate graduated compression:
            - 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
            - The garment may be prefabricated or custom-fabricated but must provide adequate graduated compression beginning with a minimum of 30mmHg distally.
        2. Regular Exercise
        3. Elevation of the limb
        4. Manual lymphatic drainage with a lymphedema specialist
        5. Self-manual lymphatic drainage for a least 30 minutes per day or documentation of why this is not possible
        6. Counseling on weight reduction/maintenance of ideal body

weight and how this affects lymphedema.

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:
    1. 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.
    2. The member has other complications such as severe fibrosis, recurrent cellulitis or skin breakdown.
    3. 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.
    4. At the end of the four-week trial, if there has been improvement, then a non-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 non-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 non-pneumatic compression device. The physician/nurse practitioner /physician assistant that is prescribing a non-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 non-pneumatic compression device prescription date.
i. The member must be ambulatory
j. Documentation of a medical reason why the patient must remain mobile during treatment must be provided. This must meet the COMAR definition of medical necessity. (COMAR 10.67.01.01(B))
    1. A non-pneumatic compression device allows the patient to remain mobile during treatment. This is different from pneumatic compression devices.

2. The use of non-pneumatic compression controller with calibrated gradient pressure (coded as K1024)) may be considered medically necessary when all of the following are met:
    a. The member meets all of the requirements listed above for a non-

pneumatic compression controller without calibrated gradient pressure
AND

b. The member has failed a minimum of four weeks of regular, daily, multiple-hour home usage of a non-pneumatic compression controller without calibrated gradient pressure (K1031) 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 this device'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:
    - Type/make/model of non-pneumatic compression controller used.
    - Pressure settings and treatment plan.
    - Dates and/or timeframe the device was utilized (a minimum of a four-week trial is necessary).
    - Limb measurements before and throughout the trial to demonstrate level of effectiveness in treating the member's swelling.
    - Modifications made during the trial to address unique characteristics and treatment challenges.
c. The member has unique characteristics that prevent satisfactory non-pneumatic compression without calibrated gradient pressure The only unique characteristics identified in the clinical literature that require the use of a device with calibrated gradient pressure are lymphedema extending onto the chest, trunk and/or abdomen which has remained unresponsive to all other therapies
d. Documents must justify why the member has a medical need for a compression controller with calibrated gradient pressure and how that will produce better results than the previously tried compression controller without calibrated gradient pressure.

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 non-pneumatic compression controller with calibrated gradient pressure will be considered not medically necessary in all other clinical situations.

5. The use of any non-pneumatic compression device for any disease process other than lymphedema or chronic venous insufficiency with venous stasis ulcers (see policy #1429) will be considered not medically necessary.

6. The use of any non-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.

7. The use of any non-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.

8. The use of a non-pneumatic compression device in any member with a history of any of the following conditions will not be approved as these are contraindications to using this device:

    - Pulmonary edema
    - Thrombophlebitis
    - Congestive heart failure
    - Deep vein thrombosis
    - Episodes of pulmonary embolism
    - Infections and inflammations
    - Uncontrolled systemic disease
    - Severe peripheral artery disease
    - Conditions in which increased venous and lymphatic return is undesirable

*International Society of Lymphology Clinical Stage:

Stage O - 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.

	07/23: • New policy.