

Protocol

Pneumatic Compression Pumps for Treatment of Lymphedema and Venous Ulcers

(10118)

Medical Benefit		Effective Date: 01/01/17	Next Review Date: 11/19
Preauthorization	No	Review Dates: 02/07, 01/08, 11/08, 09/09, 09/10, 09/11, 01/12, 01/13, 01/14, 11/14, 11/15, 11/16, 11/17, 11/18	

Preauthorization is not required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

Populations	Interventions	Comparators	Outcomes
Individuals: • With lymphedema who failed to respond to conservative therapy	Interventions of interest are: • Pneumatic compression pumps applied to limb only	Comparators of interest are: • Conservative therapy (e.g., exercise, compression therapy, elevation) • Manual lymphatic drainage • Complete decongestive therapy	Relevant outcomes include: • Symptoms • Change in disease status • Functional outcomes • Quality of life
Individuals: • With lymphedema who failed to respond to conservative therapy	Interventions of interest are: • Pneumatic compression pumps applied to trunk and/or chest as well as limb	Comparators of interest are: • Conservative therapy (e.g., exercise, compression therapy, elevation) • Manual lymphatic drainage • Complete decongestive therapy • Pneumatic compression pump applied to limb only	Relevant outcomes include: • Symptoms • Change in disease status • Functional outcomes • Quality of life
Individuals: • With venous ulcers	Interventions of interest are: • Pneumatic compression pumps	Comparators of interest are: • Medication therapy • Continuous compression (e.g., stockings, bandages)	Relevant outcomes include: • Symptoms • Change in disease status • Morbid events • Quality of life

DESCRIPTION

Pneumatic compression pumps are proposed as a treatment for patients with lymphedema who have failed conservative measures. They are also proposed to supplement standard care for patients with venous ulcers. A variety of pumps are available; they can be single chamber (nonsegmented) or multichamber (segmented) and have varying designs and complexity.

SUMMARY OF EVIDENCE

For individuals who have lymphedema who failed to respond to conservative therapy who receive pneumatic compression pumps applied to limb only, the evidence includes randomized controlled trials (RCTs) and systematic reviews of RCTs. Relevant outcomes are symptoms, change in disease status, functional outcomes, and quality of life. Most RCTs were rated as moderate-to-high quality by an Agency for Healthcare Research and Quality review, and about half reported significant improvements with pumps compared with conservative care. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have lymphedema who failed to respond to conservative therapy who receive pneumatic compression pumps applied to trunk and/or chest as well as a limb, the evidence includes two RCTs comparing treatment with and without truncal involvement. Relevant outcomes are symptoms, change in disease status, functional outcomes, and quality of life. In one RCT, two of four key outcomes were significantly better with truncal involvement than without. This trial was limited by small sample size, failure to adjust statistically for multiple primary outcomes, and use of intermediate outcomes (e.g., amount of fluid removed) rather than health outcomes (e.g., functional status, quality of life). The other RCT did not find statistically significant differences between groups for any of the efficacy outcomes. The available evidence does not demonstrate that pumps treating the trunk or chest provide incremental improvement beyond that provided by pumps treating the affected limb only. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have venous ulcers who receive pneumatic compression pumps, the evidence includes several RCTs and a systematic review of RCTs. Relevant outcomes are symptoms, change in disease status, morbid events, and quality of life. A meta-analysis of three trials found significantly higher healing rates with lymphedema pumps plus continuous compression than with continuous compression alone; however, two of the trials were judged to be at high risk of bias. Moreover, the two trials comparing lymphedema pumps with continuous compression did not find significant between-group differences in healing rates. The evidence is insufficient to determine the effects of the technology on health outcomes.

POLICY

Single-compartment or multi-chamber *nonprogrammable* lymphedema pumps applied to the limb may be considered **medically necessary** for the treatment of lymphedema that has failed to respond to conservative measures such as elevation of the limb and use of compression garments.

Single-compartment or multichamber *programmable* lymphedema pumps applied to the limb may be considered **medically necessary** for the treatment of lymphedema when:

1. The individual is otherwise eligible for nonprogrammable pumps; and
2. There is documentation that the individual has unique characteristics that prevent satisfactory pneumatic compression with single-compartment or multichamber nonprogrammable lymphedema pumps (e.g., significant scarring).

Single compartment or multichamber lymphedema pumps applied to the limb are considered **investigational** in all situations other than those specified above in the first two policy statements.

The use of lymphedema pumps to treat the trunk or chest in patients with lymphedema limited to the upper and/or lower limbs is considered **investigational**.

The use of pneumatic compression pumps to treat venous ulcers is considered **investigational**.

MEDICARE ADVANTAGE

For Medicare Advantage a pneumatic compression device (a non-segmented pneumatic compressor or a segmented device without calibrated gradient pressure) is **medically necessary** for both primary and secondary chronic and severe lymphedema when all of the following three requirements are met:

1. The member has a diagnosis of lymphedema as defined above, and
2. The member has persistence of chronic and severe lymphedema as identified by the documented presence of at least one of the following clinical findings:
 - Marked hyperkeratosis with hyperplasia and hyperpigmentation,
 - Papillomatosis cutis lymphostatica,
 - Deformity of elephantiasis,
 - Skin breakdown with persisting lymphorrhea,
 - Detailed measurements over time confirming the persistence of the lymphedema with a history evidencing a likely etiology, and
3. In addition to this documented persistence, the lymphedema is then documented to be unresponsive to other clinical treatment over the course of a required four-week trial (see Medicare Advantage Policy Guidelines for trial guidelines).

For Medicare Advantage a pneumatic compression device (a non-segmented pneumatic compressor or a segmented device without calibrated gradient pressure) is **medically necessary** for the treatment of chronic venous insufficiency with venous stasis ulcers (CVI) of the lower extremities only if the patient has all of the following:

- Edema in the affected lower extremity
- One or more venous stasis ulcer(s)
- The ulcer(s) have failed to heal after a six-month trial of conservative therapy directed by the treating physician. (See Medicare Advantage Policy Guidelines for trial guidelines.)

For Medicare Advantage a pneumatic compression device (a segmented device with calibrated gradient pressure) is **medically necessary** for the treatment of lymphedema extending onto the chest, trunk and/or abdomen when all of the following are met:

- The member has lymphedema of an extremity as defined above
- The criteria for a non-segmented pneumatic compressor or a segmented device without calibrated gradient pressure are met
- The member has lymphedema extending onto the chest, trunk and/or abdomen that extends past the limits of a standard compression sleeve, and the chest, trunk and/or abdominal lymphedema has failed to improve with a four-week trial. (See Medicare Advantage Policy Guidelines for trial guidelines.)

MEDICARE ADVANTAGE POLICY GUIDELINES**FOUR-WEEK TRIAL FOR LYMPHEDEMA**

A four-week trial of conservative therapy demonstrating failed response to treatment is required. The four-week trial of conservative therapy must include all of the following:

- Regular and compliant use of an appropriate compression bandage system or compression garment to provide adequate graduated compression
 - Adequate compression is defined as (1) sufficient pressure at the lowest pressure point to cause fluid movement and (2) 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 starting with a minimum of 30 mm Hg distally

- Regular exercise
- Elevation of the limb

SIX-MONTH TRIAL FOR CVI

A six-month trial of conservative therapy demonstrating failed response to treatment is required. The six-month trial of conservative therapy must include all of the following:

- Compliant use of an appropriate compression bandage system or compression garment to provide adequate graduated compression
 - Adequate compression is defined as (1) sufficient pressure at the lowest pressure point to cause fluid movement and (2) 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 starting with a minimum of 30 mm Hg distally
- Medications as appropriate (e.g., diuretics and/or other treatment of congestive failure, etc.)
- Regular exercise
- Elevation of the limb
- Appropriate wound care for the ulcer (including sharp debridement where appropriate)

FOUR-WEEK TRIAL FOR LYMPHEDEMA EXTENDING ONTO THE CHEST, TRUNK AND/OR ABDOMEN

A four-week trial of conservative therapy demonstrating failed response to treatment with a non-segmented pneumatic compressor or a segmented device without calibrated gradient pressure is required. The four-week trial of conservative therapy must include all of the following:

- At least four weeks of regular, daily, multiple-hour home usage of the non-segmented pneumatic compressor or the segmented device without calibrated gradient pressure after careful, in-person fitting, training and supervision by a technician who is skilled in and who regularly and successfully uses the appliance provided
- Compliant use of an appropriate compression bandage system or compression garment to provide adequate graduated compression
 - Adequate compression is defined as (1) sufficient pressure at the lowest pressure point to cause fluid movement and (2) 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 starting with a minimum of 30 mm Hg distally
- Regular exercise
- Elevation where appropriate
- Manual lymphatic drainage (where available) and self-manual lymphatic drainage (MLD) for at least 30 minutes per day
- Evaluation of diet and implementation of any necessary change
- Medications as appropriate (e.g., diuretics and/or other treatment of congestive failure, etc.)
- Correction (where possible) of anemia and/or hypoproteinemia

POLICY GUIDELINES

For all business, when medical necessity criteria are met, a rental trial of three months is required as opposed to initial purchase due to known compliance issues related to lack of effectiveness or patient dissatisfaction with the pumping process. An approval must be obtained to continue treatment beyond three months.

BACKGROUND

LYMPHEDEMA AND VENOUS ULCERS

Lymphedema is an abnormal accumulation of lymph fluid in subcutaneous tissues or body cavities resulting from obstruction of lymphatic flow. Lymphedema can be subdivided into primary and secondary categories. Primary lymphedema has no recognizable etiology, while secondary lymphedema is related to a variety of causes including surgical removal of lymph nodes, postradiation fibrosis, scarring of lymphatic channels, or congenital anomalies. Conservative therapy is the initial treatment for lymphedema and includes general measures such as limb elevation and exercise as well as the use of compression garments and compression bandaging. Another conservative treatment is manual lymphatic drainage, a massage-like technique used to move edema fluid from distal to proximal areas. Manual lymphatic drainage is performed by physical therapists with special training. Complete decongestive therapy is a comprehensive program that includes manual lymphatic drainage in conjunction with a range of other conservative treatments. Rarely, surgery is used as a treatment option.

Venous ulcers, which occur most commonly on the medial distal leg, can develop in patients with chronic venous insufficiency when leg veins become blocked. Standard treatment for venous ulcers includes compression bandages or hosiery supplemented by conservative measures such as leg elevation. Pneumatic compression pumps are proposed as a treatment for venous ulcers, especially for patients who do not respond to these standard therapies.

Treatment

Pneumatic compression pumps consist of pneumatic cuffs connected to a pump. They use compressed air to apply pressure to the affected limb. The intention is to force excess lymph fluid out of the limb and into central body compartments in which lymphatic drainage should be preserved. Many pneumatic compression pumps are available for treating lymphedema, with varying materials, designs, degrees of pressure, and complexity. There are three primary types of pumps as follows.

Single chamber nonprogrammable pumps: They are the simplest pumps, consisting of a single chamber that is inflated at one time to apply uniform pressure.

Multichamber nonprogrammable pumps: They have multiple chambers, ranging from two to 12 or more. The chambers are inflated sequentially and have a fixed pressure in each compartment. They can either have the same pressure in each compartment or a pressure gradient, but they do not include the ability to adjust the pressure manually in individual compartments.

Single- or multichamber programmable pumps: They are similar to the pumps described above except that it is possible to adjust the pressure manually in the individual compartments and/or the length and frequency of the inflation cycles. In some situations, including patients with scarring, contractures, or highly sensitive skin, programmable pumps are generally considered the preferred option.

Pneumatic compression pumps may be used in lymphedema clinics, purchased, or rented for home use; home use is addressed herein.

REGULATORY STATUS

Several pneumatic compression pumps, indicated for the primary or adjunctive treatment of primary or secondary (e.g., postmastectomy) lymphedema, have been cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process. Examples of devices with these indications intended for home or clinic/hospital use include the Compression Pump, Model GS-128 (MedMark Technologies); the Sequential Circulator® (Bio Compression Systems); the Lympha-Press® and Lympha-Press Optimal (Mego Afek); the Flexitouch™ system (Tactile Medical, formerly Tactile Systems Technology); and the Powerpress Unit Sequential Circulator (Neomedic).

Several pneumatic compression devices have been cleared by the Food and Drug Administration for treatment of venous stasis ulcers. Examples include the Model GS-128, Lympha-Press, Flexitouch®, and Powerpress Unit (listed above) as well as NanoTherm™ (ThermoTek), CTU676 devices (Compression Technologies), and Recovery+™ (Pulsar Scientific).

Food and Drug Administration product code: JOW

RELATED PROTOCOLS

Autologous Platelet-Derived Growth Factors for Wound Healing and Other Non-Orthopedic Conditions

Bioimpedance Devices for Detection and Management of Lymphedema

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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