

# Protocol

## Pneumatic Compression Pumps for Treatment of Lymphedema and Venous Ulcers

(10118)

Medical Benefit	Effective Date: 04/01/14	Next Review Date: 01/15
Preauthorization	Yes	Review Dates: 02/07, 01/08, 11/08, 09/09, 09/10, 09/11, 01/12, 01/13, 01/14

*The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. **Preauthorization is required initially; if continued use is medically necessary after three months, preauthorization is required at least a second time.** 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.*

### Description

Pneumatic compression pumps are proposed as a treatment option for patients with lymphedema who have failed conservative measures, e.g., compression garments, manual massage. 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 design and complexity.

#### Background

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. Treatment includes mechanical measures (compression garments, bandaging, manual massage, pneumatic compression devices [i.e., lymphedema pumps]), drugs, or rarely, surgery.

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 in the case of patients who do not respond to these standard therapies.

Pneumatic compression pumps consist of pneumatic cuffs that are 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 different pneumatic compression pumps for treating lymphedema are available, with varying materials, design, degree of pressure, and complexity. There are three primary types of pumps as follows:

Single-chamber nonprogrammable pumps: These are the simplest pumps, consisting of a single chamber that is inflated at one time that applies uniform pressure.

Multichamber nonprogrammable pumps: These pumps have multiple chambers, ranging from two to twelve 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 manually adjust the pressure in individual compartments.

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

Pneumatic compression pumps may be used in lymphedema clinics or purchased or rented for home use; this Protocol addresses the home use of these pumps.

#### *Regulatory Status*

Several pneumatic compression pumps indicated for 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 (FDA) through the 510(k) process. Examples of devices with these indications that are intended for home or clinic/hospital use include the Compression Pump, Model GS-128 (Medmark Technologies, LLC, Perkasie, PA); the Sequential Circulator® (Bio Compression Systems, Inc., Moonachie, NJ); and the Lympha-Press® and Lympha-Press Optimal (Mego Afek, Israel), the Flexitouch™ system (Tactile Systems Technology, Inc.) and the PowerPress Unit Sequential Circulator (Hanuri Distribution, Inc., Chatsworth, CA).

Several pneumatic compression devices are cleared by the FDA 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, Inc.), CTU676(R) (Compression Technologies), and Recovery+™ (Pulsar Scientific).

#### *Related Protocol*

End-Diastolic Pneumatic Compression Boot as a Treatment of Peripheral Vascular Disease or Lymphedema

#### **Policy (Formerly Corporate Medical Guideline)**

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 compressive garments.

Single compartment or multichamber programmable lymphedema pumps applied to the limb are 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**

Pneumatic devices are **medically necessary** in the home setting for the treatment of lymphedema or for the treatment of chronic venous insufficiency with venous stasis ulcers in the following:

- A. Lymphedema-Primary or Secondary

If the patient has undergone a four-week trial of conservative therapy and the treating physician determines that there has been no significant improvement or if significant symptoms remain after the trial. The trial of conservative therapy must include use of an appropriate compression bandage system or compression garment, exercise, and elevation of the limb. The garment may be prefabricated or custom-fabricated but must provide adequate graduated compression.

B. Chronic Venous Insufficiency With Venous Stasis Ulcers

If the patient has one or more venous stasis ulcer(s) which have failed to heal after a six month trial of conservative therapy directed by the treating physician. The trial of conservative therapy must include a compression bandage system or compression garment, appropriate dressings for the wound, exercise, and elevation of the limb.

C. General Coverage Criteria

Pneumatic compression devices are **medically necessary** only when prescribed by a physician and when they are used with appropriate physician oversight, i.e., physician evaluation of the patient's condition to determine medical necessity of the device, assuring suitable instruction in the operation of the machine, a treatment plan defining the pressure to be used and the frequency and duration of use, and ongoing monitoring of use and response to treatment.

The only time that a segmented, calibrated gradient pneumatic compression device would be **medically necessary** is when the individual has unique characteristics that prevent them from receiving satisfactory pneumatic compression treatment using a non-segmented device in conjunction with a segmented appliance or a segmented compression device without manual control of pressure in each chamber.

Appliances used for pneumatic compression of the chest or trunk are considered **not medically necessary**.

### Benefit Application

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. When a patient meets the above medically necessary criteria for a pneumatic pump after the first three months, an approval must be obtained to continue treatment beyond three months by providing documentation of:

- Compliance by the patient's reported use of the device including frequency of use (e.g., three times a day) and length of time applied (e.g., 30 minutes)
- Effectiveness by edema measurements for lymphedema (circumferences along affected limb, volume measurement of limb, patient's weight) or for stasis ulcer by improvement in wound healing.

For general business, the existence of Legislative Mandates, such as Women's Health Care Reform Act which is regarding complications after a mastectomy, may impact whether a service could be considered not medically necessary or investigational.

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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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12. Sponsored by the Centre for Research & Implementation of Clinical Practice (U.K.). Two Pneumatic Compression Devices in the Treatment of Lower Extremity Lymphedema (ACE) (NCT01239160). Available online at: [www.clinicaltrials.gov](http://www.clinicaltrials.gov). Last accessed September, 2013.
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