Pneumatic Compression Pumps for Treatment of Lymphedema and Venous Ulcers

Introduction

Swelling due to too much fluid in the arm or leg is called lymphedema. The usual treatment is raising the arm or leg or wearing an elastic compression garment, which applies gentle pressure to the limb. If the usual treatments don’t work, wearing an inflatable garment attached to a pump may be medically necessary. There are basically three kinds of garments and pumps. One type of garment consists of a single chamber and the pump pushes in a pre-set, non-calibrated amount of pressure. Another type of garment contains several chambers, and the pressure is non-calibrated but can be set to a single pressure that is sequentially sent to each of those chambers. The last type of garment and pump contains several chambers, and the pump can be calibrated to send each chamber a different amount of pressure. This policy describes when each of these different types of lymphedema pumps may be medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
# Policy Coverage Criteria

## Type of Pump | Medical Necessity
---|---
**Lymphedema pumps**  
- Single compartment  
  - Nonprogrammable  
  - Programmable  
- Multi-chamber  
  - Nonprogrammable  
  - Programmable  

Single-compartment or multichamber 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:

- The individual is otherwise eligible for nonprogrammable pumps

AND

- There is documentation that the individual has unique characteristics that prevent satisfactory pneumatic compression with single-compartment or multichamber nonprogrammable lymphedema pumps (eg, 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 2 policy statements.

## Type of Pump | Investigational
---|---
**Lymphedema pumps**  
- Pneumatic compression pumps  

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.
Documentation Requirements

For a nonprogrammable pump, the medical records submitted for review should include:

- Clinical documentation supporting that member has lymphedema which has failed to respond to conservative treatment such as limb elevation and use of compression garments

For a programmable pump, the medical records submitted for review should include:

- Clinical documentation supporting that member has lymphedema which has failed to respond to conservative treatment such as limb elevation and use of compression garments

AND

- Documentation that member has tried the nonprogrammable pump and it was not effective in relieving member's symptoms OR documentation indicating member has unique characteristics that prevent standard nonprogrammable pump from being effective (eg, significant scarring)

Coding

Claims for lymphedema pumps are coded with 2 HCPCS codes:

- One to describe the actual pump
- One to describe the appliance (ie, sleeve) that is put on the affected body part

Note: Pneumatic compression pumps may be used in lymphedema clinics or purchased or rented for home use. This policy addresses the home use of pneumatic compression pumps. For other indications see Related Policies.

The various types of pumps may be identified by HCPCS codes.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>E0650</td>
<td>Pneumatic compressor, nonsegmental home model</td>
</tr>
<tr>
<td>E0651</td>
<td>Pneumatic compressor, segmental home model without calibrated gradient pressure</td>
</tr>
<tr>
<td>E0652</td>
<td>Pneumatic compressor, segmental home model with calibrated gradient pressure</td>
</tr>
<tr>
<td>E0656</td>
<td>Segmental pneumatic appliance for use with pneumatic compressor, trunk</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>-------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>E0657</td>
<td>Segmental pneumatic appliance for use with pneumatic compressor, chest</td>
</tr>
<tr>
<td>E0670</td>
<td>Segmental pneumatic appliance for use with pneumatic compressor, integrated, 2 full legs and trunk</td>
</tr>
</tbody>
</table>

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## Related Information

### Benefit Application

Compliance may be an issue with lymphedema pumps, due to either lack of effectiveness or patient dissatisfaction with the pumping process itself. Therefore, the Company may consider requiring that a pump rented initially for a period of 1 to 2 months before purchase to confirm compliance.

### Evidence Review

### 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 (non-segmented) or multi-chamber (segmented) and have varying designs and complexity.
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 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 different pneumatic compression pumps are available for treating lymphedema, with varying materials, design, degree of pressure, and complexity. There are 3 primary types of pumps as follows:

- **Single-chamber nonprogrammable pumps:** These are the simplest pumps, consisting of a single chamber that is inflated at the same time to apply uniform pressure.

- **Multichamber nonprogrammable pumps:** These pumps have multiple chambers, ranging from 2 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 manually adjust the pressure in individual compartments.

- **Single-chamber or multichamber programmable pumps:** These 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.

**Summary of Evidence**

For individuals who have lymphedema who failed to respond to conservative therapy and who receive pneumatic compression pumps applied only to the limb, 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 of the RCTs were rated as moderate-to-high quality by an Agency for Healthcare Research and Quality review, and about half reported significant improvement 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 and who receive pneumatic compression pumps applied to trunk and/or chest as well as the limb, the evidence includes 2 RCTs comparing treatment with and without truncal involvement. Relevant outcomes are symptoms, change in disease status, functional outcomes, and quality of life. In 1 RCT, 2 of 4 key outcomes were significantly better with truncal treatment than without. This trial was limited by a small sample size, failure to adjust statistically for multiple primary outcomes, and use of intermediate outcomes (eg, amount of fluid removed) rather than health outcomes (eg, 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 only the affected limb. 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 3 trials found significantly higher healing rates with lymphedema pumps plus continuous compression than with continuous compression alone; however, 2 of the 3 trials were judged to be at high risk of bias. Moreover, the 2 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.

**Ongoing and Unpublished Clinical Trials**

A currently unpublished trial that might influence this review is listed in Table 1.

**Table 1. Summary of Key Trials**

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT01239160a</td>
<td>Two Pneumatic Compression Devices in the Treatment of Lower Extremity Lymphedema (ACE)</td>
<td>262</td>
<td>Jul 2018</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

a Denotes industry-sponsored or cosponsored trial.

**Practice Guidelines and Position Statements**

*Society for Vascular Surgery and American Venous Forum*

The 2014 joint guidelines from the Society for Vascular Surgery and the American Venous Forum on the management of venous ulcers included the following statement on pneumatic compression:\(^{11}\):

> We suggest use of intermittent pneumatic compression when other compression options are not available, cannot be used, or have failed to aid in venous leg ulcer healing after prolonged compression therapy. [GRADE - 2; LEVEL OF EVIDENCE - C]
**International Union of Phlebology**

A 2013 consensus statement from the International Union of Phlebology indicated that primary lymphedema could be managed effectively by a sequenced and targeted management program based on a combination of decongestive lymphatic therapy and compression therapy. Treatment should include compression garments, self-massage, skin care, exercises, and if desired, pneumatic compression therapy applied in the home.

**Medicare National Coverage**

A 2002 national coverage determination for pneumatic compression devices by the Centers for Medicare & Medicaid Services has stated the following:

A. **Lymphedema**

...Pneumatic compression devices are covered in the home setting for the treatment of lymphedema 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**

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.

Pneumatic compression devices are covered in the home setting for the treatment of CVI of the lower extremities only if the patient has one or more venous stasis ulcer(s) which have failed to heal after a 6 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.

**Regulatory Status**

Several pneumatic compression pumps, indicated for primary or adjunctive treatment of primary or secondary (eg, post-mastectomy) 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:

- 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)
- 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 of devices for this indication include:

- The Model GS-128
- The Lympha-Press
- The Flexitouch
- The PowerPress Unit
- Nanotherm™ (ThermoTek)
- CTU676 devices (Compression Technologies)
- Recovery+™ (Pulsar Scientific)

FDA product code: JOW.
References


<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
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<tr>
<td>09/01/98</td>
<td>Add to Durable Medical Equipment Section - New medical policy.</td>
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<tr>
<td>04/04/00</td>
<td>Replace Policy - Scheduled review; no criteria changes</td>
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<tr>
<td>10/08/02</td>
<td>Replace Policy - Policy reviewed without literature review; new review date only.</td>
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<tr>
<td>08/12/03</td>
<td>Replace Policy - Policy reviewed; Medicare language added; no criteria changes.</td>
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<td>05/26/06</td>
<td>Update Scope and Disclaimer - No other changes.</td>
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<td>04/10/07</td>
<td>Replace Policy - Policy updated with literature review; no change in policy statement. Codes updated.</td>
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<td>05/13/08</td>
<td>Replace Policy - Policy updated with literature search; no change in policy statement. Rationale and References updated; status changed from AR to BC.</td>
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<td>01/13/09</td>
<td>Replace Policy - Policy updated with literature search; no change to the policy statement. References added; codes added (E0656 and E0657, effective 1/1/09).</td>
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<td>09/14/10</td>
<td>Replace Policy - Policy updated with literature review through May 2010; references 2-8 added. Title changed to “Pneumatic Compression Pumps for Lymphedema” (previously entitled, “Lymphedema Pumps.”) “Non-programmable” has been added to the first policy statement and “elastic garments” has been changed to “compression garments”. Programmable pumps have been changed to medically necessary if criteria are met; a new policy statement has been added that two-phase multi-chamber pumps are investigational.</td>
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<td>05/10/11</td>
<td>Replace Policy - Policy reviewed with literature search on pneumatic compression pumps for treating truncal areas. No change in policy statements. Reference 2 has been added; others renumbered. Coding of pumps clarified.</td>
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<td>08/24/12</td>
<td>Update Coding Section – ICD-10 codes are now effective 10/01/14.</td>
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<tr>
<td>12/11/12</td>
<td>Replace Policy. Policy reviewed with literature search through August 2012. Title changed to Pneumatic Compression Pumps for Treatment of Lymphedema and Venous Ulcers. Statement on two-phase pumps deleted. Clarification added to first policy statement (when other conservative measures, have been tried but have failed to improve the patient’s condition. Statement added that 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 lymphedema pumps to treat venous ulcers is considered investigational. References 1, 4, 8-10 and 13 added; other references renumbered or removed. HCPCS code E0665 and ICD-10 codes added.</td>
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<tr>
<td>01/10/13</td>
<td>Coding update. HCPCS code E0670, effective 1/1/13, added to policy.</td>
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<td>03/15/13</td>
<td>Update Related Policies. Add 1.01.525.</td>
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<tr>
<td>12/09/13</td>
<td>Replace policy. The words “Applied to the limb” added to the first 3 policy statements for clarification. In the statement on venous ulcers, “lymphedema pumps” changed to “pneumatic compression pumps”. Policy reviewed with literature search through</td>
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</table>

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<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>August 16, 2013. References 7 and 11 added; other references renumbered/removed. Policy statements revised as noted. HCPCS codes E0655 – E0673 removed from policy (minus E0656, E0657 &amp; E0670); these address the sleeves and the policy addresses the pumps only.</td>
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<td>01/30/14</td>
<td>Update Related Policies. Change title to 2.01.82.</td>
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<tr>
<td>02/13/14</td>
<td>Update Related Policies. Change title to 1.01.525.</td>
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<tr>
<td>05/19/14</td>
<td>Update Related policies. Remove 2.02.17 as it was archived.</td>
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<td>11/20/14</td>
<td>Annual Review. Added Benefit Application statement that The Company may require rental before purchase to ensure compliance with use of the device. Policy reviewed with literature review through July 25, 2014. References 4 and 11-13 added; others renumbered/removed. Policy statements unchanged. HCPCS codes E0650, E0651, E0655, E0665-E0669, E0671-E0673 removed; these relate to another policy.</td>
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<tr>
<td>11/10/15</td>
<td>Annual Review. Policy updated with literature review through August 10, 2015; references 5 and 11 added. Policy statements unchanged.</td>
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<tr>
<td>02/01/16</td>
<td>Coding update. Added E650 and E0651.</td>
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<td>08/01/16</td>
<td>Annual Review, approved July 12, 2016. Policy updated with literature review. No change in policy statement.</td>
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<tr>
<td>03/24/17</td>
<td>Policy moved into new format; no change to policy statements.</td>
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<tr>
<td>04/01/18</td>
<td>Updated Related Policies; removed 2.01.82 as it has been archived.</td>
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<tr>
<td>05/01/18</td>
<td>Annual Review, approved April 18, 2018. Policy updated with literature review through January 2018; no references added. Policy statements unchanged.</td>
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U.S. Department of Health and Human Services
200 Independence Avenue SW, Room S09F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

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Daytoy a Pakadaa ket naglaon iti Napateg nga Impormacion. Daytoy a pakadaa mabalin nga adda ket naglaon iti napateg nga impormacion maiyanggep iti aplikasyon wong coverage baa baa Premera Blue Cross. Daytoy ket mabalin dagiti importante a petsa iti daytoy a pakadaa. Mabalin nga adda rumbeng nga aramideng nga addition sakbayan dagiti partikular a naituding nga adda tidaw tapon mapagtailayadoy ti coverage ti salun-año wong tulong kadagiti gastos. Adda karbenganyo a mangala iti daytoy nga impormacion ken tulong iti bukody a pagasasan nga awan ti bayadanyo. Tumawag ti numero nga 800-722-1471 (TTY: 800-842-5357).

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