Pneumatic Compression Pumps for Treatment of Lymphedema and Venous Ulcers

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.

OBJECTIVE

The objective of this evidence review is to evaluate the impact of pneumatic compression pumps on net health outcomes in patients with lymphedema or venous ulcers.

POLICY STATEMENT

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:

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 2 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.

**BENEFIT APPLICATION**

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

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

**FDA 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.

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.
RATIONALE

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 RCTs and systematic reviews of RCTs. The relevant outcomes are symptoms, change in disease status, functional outcomes, and QOL. 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. The relevant outcomes are symptoms, change in disease status, functional outcomes, and QOL. 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 (eg, amount of fluid removed) rather than health outcomes (eg, functional status, QOL). 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. The relevant outcomes are symptoms, change in disease status, morbid events, and QOL. 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 three 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.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Society for Vascular Surgery and American Venous Forum

The joint guidelines from the Society for Vascular Surgery and the American Venous Forum (2014) 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 consensus statement from the International Union of Phlebology (2013) 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.12 Treatment should include compression garments, self-massage, skin care, exercises, and, if desired, pneumatic compression therapy applied in the home.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

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A national coverage determination for pneumatic compression devices by the Centers for Medicare & Medicaid Services (2002) 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.

REFERENCES


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**POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
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<tbody>
<tr>
<td>December 2011</td>
<td>New policy</td>
<td>Policy title changed to add “and Venous Ulcers”, Deleted statement on two-phase pumps, statement added that use of lymphedema pumps to treat the trunk or chest in patients with lymphedema limited to upper and/or lower limbs is considered investigational. Use of lymphedema pumps to treat venous ulcers is considered investigational. References updated.</td>
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<tr>
<td>December 2012</td>
<td>Replace policy</td>
<td>Policy reviewed with literature. “Applied to the limb” added to the first 3 policy statements for clarification. References 7, and 11 added; other references renumbered or removed.</td>
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<tr>
<td>December 2013</td>
<td>Replace policy</td>
<td>Policy reviewed with literature search, no change to policy statements. References 4, 11-13 added.</td>
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<tr>
<td>December 2014</td>
<td>Replace policy</td>
<td>Policy updated with literature review through August 10, 2015; references 5 and 11 added. Policy statements unchanged.</td>
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<tr>
<td>March 2017</td>
<td>Replace policy</td>
<td>Policy updated with literature review through January 8, 2018; no references added. Policy statements unchanged except “not medically necessary” corrected to “investigational” due to FDA 510k approval in the following statements: lymphedema pumps to treat the trunk or chest in patients with lymphedema limited to the upper and/or lower limbs and the use of lymphedema pumps to treat venous ulcers is considered investigational.</td>
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<tr>
<td>June 2018</td>
<td>Replace policy</td>
<td>Policy updated with literature review through January 6, 2019; no references added. Policy statements unchanged.</td>
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<tr>
<td>June 2019</td>
<td>Replace policy</td>
<td>Policy updated with literature review through January 6, 2019; no references added. Policy statements unchanged.</td>
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