Pneumatic Compression Pumps for Treatment of Lymphedema and Venous Ulcers

Policy Number: 1.01.18  Last Review: 1/2017
Origination: 10/2000  Next Review: 1/2018

Policy
Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for pneumatic compression pumps when it is determined to be medically necessary because the criteria shown below are met.

When Policy Topic is covered
Single compartment or multi-chamber non-programmable 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 multi-chamber programmable lymphedema pumps applied to the limb may be considered medically necessary for the treatment of lymphedema when:

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

When Policy Topic is not covered
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.
**Considerations**

Claims for lymphedema pumps are coded for with a pair of HCPCS codes: one to describe the actual pump and one to describe the appliance (i.e., sleeve) that is put on the affected body part. The various different types of pumps may be distinguished by HCPCS codes.

*Single compartment pumps:*
- E0650: Pneumatic compressor, nonsegmental home model
  
  The above code (E0650) is used in conjunction with any of the following appliances:
  - E0655: Nonsegmental pneumatic appliance for use with pneumatic compressor, half arm
  - E0660: Nonsegmental pneumatic appliance for use with pneumatic compressor, full leg
  - E0665: Nonsegmental pneumatic appliance for use with pneumatic compressor, full arm
  - E0666: Nonsegmental pneumatic appliance for use with pneumatic compressor, half leg

*Multi-chamber pumps:*
- E0651: Pneumatic compressor, segmental home model without calibrated gradient pressure
  
  The above code (E0651) may be used with any of the following appliance codes:
  - E0656: Segmental pneumatic appliance for use with pneumatic compressor, trunk
  - E0657: Segmental pneumatic appliance for use with pneumatic compressor, chest
  - E0667: Segmental pneumatic appliance for use with pneumatic compressor, full leg
  - E0668: Segmental pneumatic appliance for use with pneumatic compressor, full arm
  - E0669: Segmental pneumatic appliance for use with pneumatic compressor, half leg

*Multi-chamber programmable pumps:*
- E0652: Pneumatic compressor, segmental home model with calibrated gradient pressure
  
  The above code (E0652) may be used with any of the following appliance codes:
  - E0671: Segmental gradient pressure pneumatic appliance, full leg
  - E0672: Segmental gradient pressure pneumatic appliance, full arm
  - E0673: Segmental gradient pressure pneumatic appliance, half leg

**Description of Procedure or Service**

<table>
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<tr>
<th>Populations</th>
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<tr>
<td>Individuals:</td>
<td>Interventions of interest are:</td>
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<td>Relevant outcomes include:</td>
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<td>• With lymphedema</td>
<td>• Pneumatic compression</td>
<td>• Conservative therapy (eg,</td>
<td>• Symptoms</td>
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<td>elevation)</td>
<td>• Change in disease status</td>
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<td>Pumps Applied to Limb</td>
<td>Decongestive Therapy/Complete Decongestive Therapy</td>
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<td>Individuals:</td>
<td>Interventions of Interest Are:</td>
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<td>Relevant Outcomes Include:</td>
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<td>• With Lymphedema</td>
<td>• Conservative Therapy (e.g., Exercise, Compression Therapy, Elevation)</td>
<td>• Symptoms</td>
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<td>• Pneumatic Compression Pumps Applied to Trunk, Chest, and Limb</td>
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<td>• Other Pneumatic Compression Pumps</td>
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<td>• Pneumatic Compression Pump Applied to Limb</td>
<td>• Pneumatic Compression Pump Applied to Limb</td>
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Pneumatic compression pumps are proposed as a treatment option 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 design and complexity.

The evidence on pneumatic compression pumps applied to the limb for patients with lymphedema includes randomized controlled trials (RCTs) and systematic reviews of RCTs. Relevant outcomes are symptoms, change in disease status, functional outcomes, and quality of life. The majority of these 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 qualitatively that the technology results in a meaningful improvement in the net health outcome.

The evidence on pneumatic compression pumps applied to the trunk, chest, and limb for patients with lymphedema 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 involvement than without. This trial was limited by a small sample size, lack of adjusting the p value for multiple primary outcomes, and use of intermediate outcomes (e.g., amount of fluid removed), rather than health outcomes such as functional status or 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 for the limb.
by pumps treating the affected limb only. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence on pneumatic compression pumps for patients with venous ulcers includes several RCTs and a systematic review of RCTs. Relevant outcomes are symptoms and change in disease status. The systematic review conducted a meta-analysis of 3 trials. This analysis found a significantly higher healing rate with lymphedema pumps plus continuous compression versus continuous compression alone; however, 2 of the 3 trials were judged to have a high risk of bias. Moreover, the 2 trials comparing lymphoma pumps and 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.

**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 compression garments, drugs, bandaging, manual lymphatic drainage and pneumatic compression devices (ie, lymphedema pumps). Comprehensive decongestive therapy combines manual drainage, bandaging, exercises and skin care, and may also include compression garments, dietary recommendations and/or breathing exercises. 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 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 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- 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 policy 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., Moonarchie, 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(TM) (ThermoTek, Inc.), CTU676(R) (Compression Technologies), and Recovery+(TM) (Pulsar Scientific)

**Rationale**
The evidence review was created in 1998 and was based on a TEC Assessment that concluded pneumatic compression devices are efficacious to some degree but that it was not possible to estimate precisely the magnitude of this effect.1 Beginning in 2010, the evidence review has been updated regularly with searches of the MEDLINE database. Most recently, the literature was reviewed through August 10, 2015. Following is a summary of the key literature to date.

Assessment of efficacy for therapeutic interventions involves a determination of whether the intervention improves health outcomes. The optimal study design for a therapeutic intervention is a randomized controlled trial (RCT) that includes clinically relevant measures of health outcomes. Intermediate outcome measures, also known as surrogate outcome measures, may also be adequate if there is an established link between the intermediate outcome and true health outcomes. Nonrandomized comparative studies and uncontrolled studies can sometimes
provide useful information on health outcomes, but are prone to biases such as selection bias (eg, noncomparability of treatment groups) and observation bias (eg, the placebo effect).

In the case of lymphedema, clinically relevant outcomes include symptoms, functional outcomes (eg, range of motion) and quality of life (eg, ability to conduct activities of daily living). Limb volume and limb circumference are also commonly reported outcomes.

**Lymphedema**

**Lymphedema Pumps Compared With Alternative Treatment**

In 2010, the McMaster University Evidence-based Practice Center, under contract with the Agency for Healthcare Research and Quality, published a technology assessment on diagnosis and treatment of secondary lymphedema that included discussion of intermittent pneumatic compression (IPC) pumps. The authors, Oremus et al, identified 12 studies focusing on treatment of lymphedema with IPC pumps. Seven studies were moderate- to high-quality RCTs, 3 were low-quality RCTs, and 2 were observational studies. There was a high degree of heterogeneity between studies in terms of types of lymphedema pumps used, comparison interventions (eg compression bandages, laser, massage), and intervention protocols. IPC was statistically significantly better than the comparison treatment in 4 studies, worse in 1 study (vs laser), and no different in 5 studies. Most studies assessed change in arm volume or arm circumference.

In 2012, Oremus et al published an updated systematic review on conservative treatments for secondary lymphedema. They identified 36 English-language studies on a variety of treatments, 30 of which were RCTs and 6 were observational studies. Six RCTs evaluated IPC. Study findings were not pooled. According to the review, 2 RCTs found that IPC was superior to decongestive therapy or self-massage but 3 other RCTs failed to show that IPC was superior to another conservative treatment.

A 2014 systematic review by Shao et al addressed pneumatic compression pumps for treatment of breast cancer–related lymphedema. They identified 7 RCTs; most compared decongestive lymphatic therapy alone with decongestive lymphatic therapy plus lymphedema pump therapy. A pooled analysis of data from the 3 RCTs suitable for meta-analysis did not find a statistically significant difference in the percent of volume reduction with and without use of lymphedema pumps (mean difference, 4.51; 95% confidence interval [CI], -7.01 to 16.03).

A 2015 RCT from Japan included 31 women with unilateral upper-extremity lymphedema after mastectomy. To be eligible for participation, patients had to have experienced at least a 10% increased volume in the affected limb or more than 2 cm difference in circumference between limbs. Patients were randomly assigned to decongestive physical therapy alone (n=15) or decongestive physical therapy plus IPC (n=16). Pneumatic compression was delivered using a pump marketed in Japan (Mark II Plus) and was applied for 45 minutes after manual
lymphatic drainage. Both groups underwent 5 weekly sessions for 3 weeks (a total of 15 sessions). At the immediate posttreatment and 1 month follow-up points, there were no statistically significant differences in groups in any outcomes including arm circumference and dermal thickness of the arm and forearm.

**Lymphedema Pumps Treating the Trunk or Chest**

Due to U.S. Food and Drug Administration approval of lymphedema pumps that treat the truncal area as well as the affected limb, there has recently been interest in the evidence on truncal clearance as part of lymphedema treatment. The literature review focused on RCTs comparing pneumatic compression for patients with lymphedema with and without treatment of the trunk or chest. Two RCTs were identified; both were industry-sponsored, published in 2012, and included women with breast cancer who had documented postsurgical upper-extremity lymphedema.

Fife et al compared treatment with the Flexitouch™ system and the Bio Compression Systems Sequential Circulator. Participants needed to have at least 5% edema volume in the upper extremity at the time of study enrollment. A total of 36 women from 3 centers were included, 18 in each group. Participants used the devices for home treatment for 1 h/d for 12 weeks in addition to standard care (eg, wearing compression garments). The Bio Compression Systems device used an arm garment only, whereas the Flexitouch device used 3 garments and treated the full upper extremity (arm, chest, truncal quadrant). Outcome assessment was conducted by experienced lymphedema therapists; blinding was not reported. Edema outcomes were available for all participants and local tissue water analysis for 28 of 36 (78%) of participants. The authors reported 4 key outcomes at 12 weeks. There were statistically significant week by group interactions in 2 of these (edema volume reported as a percent, p=0.047; tissue water, p=0.049), both favoring treatment with the Flexitouch system. Groups did not differ significantly on the other 2 outcomes (affected arm volume at 12 weeks, p=0.141; edema volume reported in milliliters, p=0.050). Moreover, had the p value been adjusted for multiple comparisons (ie, if p<0.0125 had been used instead of p<0.05 to adjust for the 4 comparisons), none of the differences would be statistically significant. The study was limited by its small sample size, missing data on the local tissue water outcome and unclear blinding of outcome assessment. Also, volume of tissue reported, a primary outcome, is of less clinical significance than outcomes such as symptoms or functional status.

Ridner et al compared treatment with the Flexitouch™ system of the arm-only versus the arm, chest, and trunk in women with breast cancer who had arm lymphedema. To be eligible for participation, patients needed to have a 2-cm difference in girth on the affected arm compared with the unaffected arm. A total of 47 patients were enrolled; 5 patients withdrew during the study, leaving 21 in each treatment group. Participants completed training in using the device and were observed in the laboratory to ensure they used proper technique; the remainder of the sessions was conducted at home. Patients in the experimental group (arm, chest, trunk treatment) were told to perform a 1-hour session daily for 30 days; patients in the control group (arm only) were told to perform a 36-
minute session daily for 30 days. Final outcome assessment took place at the end of the 30-day treatment period. The authors did not report whether the staff members who assessed objective outcomes were blinded to the patient treatment groups. There were no statistically significant differences between groups in efficacy outcomes. For example, change in the volume of the affected arm was -2.66 mL in the experimental group and -0.38 mL in the control group (p=0.609). In addition, the mean number of symptoms reported at 30 days was 10.0 in the experimental group and 6.0 in the control group (p=0.145).

**Venous Ulcers**

A Cochrane review by Nelson et al, updated in 2014, addressed IPC pumps for treating venous leg ulcers. The review identified 9 RCTs. Five trials compared pneumatic compression pumps plus continuous compression with continuous compression alone, 2 trials compared compression pumps with continuous compression (stockings or bandages), 1 trial compared compression pumps with wound dressings only, and 1 trial compared 2 IPC regimens. In a meta-analysis of 3 of the 5 trials evaluating the incremental benefit of pneumatic compression pumps over continuous compression alone, there was a significantly higher rate of healing with combined treatment (risk ratio, 1.31; 95% CI, 1.06 to 1.63). Two of these 3 trials were considered to have a high risk of bias (eg, not blinded, had unclear allocation concealment). There was a high degree of heterogeneity among trials, and findings from other RCTs were not pooled. Neither of the 2 trials comparing IPC with continuous compression plus stockings or bandages found statistically significant between-group differences in healing rates.

A 2014 RCT by Dolibog et al was published after the Cochrane review literature search. The trial included 147 patients with venous ulcers. It compared 5 types of compression therapy: IPC using a 12-chamber Flowtron device, stockings, multilayer bandages, 2-layer bandages, and Unna boots. All patients received standard drug therapy; the compression interventions lasted 2 months. The rate of complete healing at the end of treatment was similar in 3 of the treatment groups: 16 of 28 patients (57%) in the pneumatic compression group, 17 of 30 (57%) in the stockings group, and 17 of 29 (59%) in the multilayer bandage group. On the other hand, rates of healing were much lower in the other 2 groups: 5 of 30 (17%) in the 2-layer bandage group and 6 of 30 (20%) in the Unna boot group. A 2013 pilot study by Dolibog et al included in the Cochrane review, had similar findings.

**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>
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<tbody>
<tr>
<td>Ongoing</td>
<td>NCT01239160&lt;sup&gt;a&lt;/sup&gt; Two Pneumatic Compression Devices in the Treatment of Lower Extremity Lymphedema (ACE)</td>
<td>262</td>
<td>Jul 2016</td>
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</table>

NCT: national clinical trial.

<sup>a</sup> Denotes industry-sponsored or cosponsored trial.
Summary of Evidence
The evidence on pneumatic compression pumps applied to the limb for patients with lymphedema includes randomized controlled trials (RCTs) and systematic reviews of RCTs. Relevant outcomes are symptoms, change in disease status, functional outcomes, and quality of life. The majority of these 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 qualitatively that the technology results in a meaningful improvement in the net health outcome.

The evidence on pneumatic compression pumps applied to the trunk, chest, and limb for patients with lymphedema 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 involvement than without. This trial was limited by a small sample size, lack of adjusting the p value for multiple primary outcomes, and use of intermediate outcomes (eg, amount of fluid removed), rather than health outcomes such as functional status or 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.

The evidence on pneumatic compression pumps for patients with venous ulcers includes several RCTs and a systematic review of RCTs. Relevant outcomes are symptoms and change in disease status. The systematic review conducted a meta-analysis of 3 trials. This analysis found a significantly higher healing rate with lymphedema pumps plus continuous compression versus continuous compression alone; however, 2 of the 3 trials were judged to have a high risk of bias. Moreover, the 2 trials comparing lymphoma pumps and 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.

Practice Guidelines and Position Statements
A 2013 consensus statement from the International Union of Phlebology stated that primary lymphedema can 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.

U.S. Preventive Services Task Force Recommendations
Not applicable.
Medicare National Coverage
A 2002 National Coverage Determination for Pneumatic Compression Devices (280.6) 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


**Billing Coding/Physician Documentation Information**

**E0650** Pneumatic compressor, nonsegmental home model

**E0651** Pneumatic compressor, segmental home model without calibrated gradient pressure

**E0652** Pneumatic compressor, segmental home model with calibrated gradient pressure

**E0655** Nonsegmental pneumatic appliance for use with pneumatic compressor, half arm

**E0656** Segmental pneumatic appliance for use with pneumatic compressor, trunk

**E0657** Segmental pneumatic appliance for use with pneumatic compressor, chest

**E0660** Nonsegmental pneumatic appliance for use with pneumatic compressor, full leg

**E0665** Nonsegmental pneumatic appliance for use with pneumatic compressor, full arm

**E0666** Nonsegmental pneumatic appliance for use with pneumatic compressor, half leg

**E0667** Segmental pneumatic appliance for use with pneumatic compressor, full leg

**E0668** Segmental pneumatic appliance for use with pneumatic compressor, full arm

**E0669** Segmental pneumatic appliance for use with pneumatic compressor, half leg

**E0671** Segmental gradient pressure pneumatic appliance, full leg

**E0672** Segmental gradient pressure pneumatic appliance, full arm

**E0673** Segmental gradient pressure pneumatic appliance, half leg

**ICD-10 Codes**

**I89.0** Lymphedema, not elsewhere classified

**I97.2** Postmastectomy lymphedema syndrome

**Q82.0** Hereditary lymphedema
**Additional Policy Key Words**

N/A

**Policy Implementation/Update Information**

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<th>Date</th>
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<tr>
<td>10/1/01</td>
<td>Policy statement revised to indicate multichamber programmable pumps are not medically necessary.</td>
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<tr>
<td>10/1/02</td>
<td>Policy statement revised to indicate remove multichamber programmable pumps from the policy. Policy statement added that sequential pumps may be considered medically necessary for lymphedema. Other uses would be considered not medically necessary.</td>
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<td>Policy updated to indicate the use of pneumatic compression devices in the home following outpatient surgery is considered investigational.</td>
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<td>Policy statement regarding use following outpatient surgery was deleted. This topic is covered in policy 1.01.28 Outpatient Use of Limb Pneumatic Compression Devices for Venous Thromboembolism Prophylaxis.</td>
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<td>“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”.</td>
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<td>Removed Pneumatic compression devices for treatment of peripheral arterial occlusive disease/arterial insufficiency are considered investigational.</td>
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<td>No policy statement changes.</td>
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