Policy Statement

Single-compartment or multichamber nonprogrammable lymphedema pumps applied to the limb may be considered medically necessary when either of the following criteria is met:

- Treatment of lymphedema post mastectomy (in accordance with the “Women's Health and Cancer Rights Act of 1998”)*
- The treatment of lymphedema that has failed to respond to conservative measures, including, but not limited to, elevation of the limb and use of compression garments, or manual lymph drainage

Single-compartment or multichamber programmable lymphedema pumps applied to the limb may be considered medically necessary when either of the following criteria is met:

- Treatment of lymphedema post mastectomy (in accordance with the “Women's Health and Cancer Rights Act of 1998”)*
- The treatment of lymphedema when both of the following criteria are met:
  - The individual is otherwise eligible for nonprogrammable pumps
  - There is documentation that the individual has unique characteristics that prevent satisfactory pneumatic compression with single-compartment or multichamber nonprogrammable lymphedema pumps (e.g., contractures, dermatitis, highly sensitive skin, significant scarring, ulcerations)

Single-compartment or multichamber lymphedema pumps applied to the limb are considered investigational in all situations not 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.

Continued use of a pneumatic compression pump may be considered medically necessary when documentation supports both of the following:

- Patient tolerance and compliance to the prescribed treatment plan
- Effectiveness of the pump as evidenced by decreased edema with pre- and post-treatment measurements and/or documented improvement in functional capacity

Note: Equipment may be rented for a period of 2 to 3 months before a request for continued use is made by the provider to establish effectiveness of device and patient compliance and tolerance to the prescribed treatment plan.

*Note: The Women's Health and Cancer Rights Act of 1998 mandates that a group health plan or group health insurance policy that provides medical and surgical benefits with respect to a mastectomy shall provide coverage for “prostheses and physical complications of all stages of mastectomy, including lymphedemas, in a manner determined in consultation with the attending physician and the patient.”
Policy Guidelines

Coding
Claims for lymphedema pumps are coded with 2 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 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

Multichamber 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

Multichamber 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
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.

Related Policies
- Bioimpedance Devices for Detection and Management of Lymphedema
- Noncontact Ultrasound Treatment for Wounds
- Targeted Phototherapy and Psoralen with Ultraviolet A for Vitiligo

Benefit Application
Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member’s contract benefits in effect at the
time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

**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 (FDA) 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 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), CTU676 devices (Compression Technologies), and Recovery+™ (Pulsar Scientific).

FDA product code: JOW

**Rationale**

**Literature Review**

A 1998 Blue Cross Blue Shield Association Technology Evaluation Center (TEC) Assessment, which informed the original review, concluded that pneumatic compression devices are efficacious to some degree but that it was not possible to estimate precisely the magnitude of this effect.  

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function- including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens, and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.
In the case of lymphedema, clinically relevant outcomes include symptoms, functional outcomes (e.g., range of motion), and quality of life (e.g., ability to conduct activities of daily living). Limb volume and limb circumference are also commonly reported outcomes.

Lymphedema—Pneumatic Compression Pumps Applied to the Limb Only
Clinical Context and Therapy Purpose

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.

The purpose of pneumatic compression pumps in patients who have lymphedema is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does the use of pneumatic compression pumps in patients who have lymphedema improve net health outcomes?

The following PICO was used to select literature to inform this review.

Patients
The relevant population of interest is patients with lymphedema. 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.

Interventions
The treatment being considered is the use of pneumatic lymphatic pumps. 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 3 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 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 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. Lymphedema therapists and physiatrists provide care.

**Comparators**
The following practices are currently being used to treat lymphedema; physiotherapy and manual lymphatic drainage. Lymphedema therapists and physiatrists provide care.

**Outcomes**
The general outcomes of interest are symptoms, change in disease status, functional outcomes and quality of life.

Lymphedema is a chronic condition, and follow-up of at least 6 weeks to 6 months would be desirable to assess outcomes.

**Study Selection Criteria**
Methodologically credible studies were selected using the following principles:

1. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
2. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
3. To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
4. Studies with duplicative or overlapping populations were excluded.

In 2010, the Agency for Healthcare Research and Quality published a technology assessment on the diagnosis and treatment of secondary lymphedema that included discussion of intermittent pneumatic compression pumps. In 2012, Oremus et al. identified 12 studies focusing on treatment of lymphedema with intermittent pneumatic compression 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 regarding types of lymphedema pumps used, comparison interventions (e.g., compression bandages, laser, massage), and intervention protocols. Statistically, intermittent pneumatic compression was 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.

Oremus et al (2012) published an updated systematic review of 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 intermittent pneumatic compression. Study findings were not pooled. According to reviewers, 2 RCTs found that intermittent pneumatic compression was superior to decongestive therapy or self-massage but 3 other RCTs failed to show that intermittent pneumatic compression was superior to another conservative treatment.

A systematic review by Shao et al (2014) 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 percentage of volume reduction with and without use of lymphedema pumps (mean difference, 4.51; 95% confidence interval, -7.01 to 16.03).

A 2015 RCT from Japan included 31 women with unilateral upper-extremity lymphedema after mastectomy. To be eligible; 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 randomized to decongestive physical therapy alone (n=15) or decongestive physical therapy plus intermittent pneumatic compression (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 post treatment and 1-month follow-up points, there were no statistically significant differences in groups for any outcomes, including arm circumference and dermal thickness of the arm and forearm.

Section Summary: Lymphedema–Pneumatic Compression Pumps Applied to the Limb Only
A number of RCTs have been published. Most published 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.

Lymphedema–Pneumatic Compression Pumps Applied to the Trunk and/or Chest as Well as Limb
Clinical Context and Therapy Purpose
The purpose of pneumatic compression pumps in patients who have lymphedema is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does the use of pneumatic compression pumps on the trunk and/or chest, as well as the limb, improve net health outcomes in patients who have lymphedema?

The following PICO was used to select literature to inform this review.

Patients
The relevant population of interest is patients with lymphedema. Lymphedema and its treatment are described in the first indication.

Interventions
The treatment being considered is the use of pneumatic lymphatic pumps on the trunk and/or chest, as well as the limb. Pneumatic compression pumps are described in the first indication. Pneumatic compression pumps may be used in lymphedema clinics, purchased, or rented for home use; home use is addressed herein. Lymphedema therapists and physiatrists provide care.

Comparators
The following practices are currently being used to treat lymphedema; physiotherapy and manual lymphatic drainage. Lymphedema therapists and physiatrists provide care.

Outcomes
The general outcomes of interest are symptoms, change in disease status, functional outcomes and quality of life.

Lymphedema is a chronic condition and follow-up of at least 6 weeks to 6 months would be desirable to assess outcomes.

Study Selection Criteria
Methodologically credible studies were selected using the principles described in the first indication.

Due to the U.S. Food and Drug Administration (FDA) approval of lymphedema pumps that treat the truncal area as well as the affected limb, researchers have assessed truncal clearance as part of lymphedema treatment. This literature review focuses on RCTs comparing pneumatic compression for patients who had 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 (2012) compared treatment using the Flexitouch system with treatment using the Bio Compression Systems Sequential Circulator. Participants had to have at least 5% edema volume in the upper-extremity at trial enrollment. A total of 36 women from 3 centers were
included, 18 in each group. Participants used the devices for home treatment for 1 hour daily for 12 weeks in addition to standard care (e.g., 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 (78%) of 36 participants. The authors reported on 4 key outcomes at 12 weeks: there was a statistically significant week by group interactions in 2 of these outcomes (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 there been statistical adjustments for multiple comparisons (i.e., if p<0.0125 had been used instead of p<0.05 to adjust for the 4 comparisons), none of the differences would have been statistically significant. The trial was limited by its small sample size, missing data on the local tissue water outcome, and unclear blinding of outcome assessment. Also, the volume of tissue reported (a primary outcome) is of less clinical significance than outcomes such as symptoms or functional status.

Ridner et al (2012) compared treatment using the Flexitouch system for an arm only versus arm, chest, and trunk therapy in women with breast cancer who had arm lymphedema. To be eligible, patients had to have a 2-cm difference in girth on the affected arm compared with the unaffected arm. Forty-seven 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. The final outcome assessment took place at the end of the 30-day treatment period. The trial lists 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).

Section Summary: Lymphedema—Pneumatic Compression Pumps Applied to the Trunk and/or Chest as Well as Limb
Two published RCTs have compared pneumatic compression treatment with and without truncal involvement. In 1 RCT, 2 of 4 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.

Pneumatic Compression Pumps Applied to Venous Ulcers
Clinical Context and Therapy Purpose
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.

The purpose of pneumatic compression pumps in patients who have venous ulcers is to provide a treatment option that is an alternative to or an improvement on existing therapies.
The question addressed in this evidence review is: Does the use of pneumatic compression pumps in patients who have venous ulcers improve net health outcomes?

The following PICO was used to select literature to inform this review.

**Patients**
The relevant population of interest is patients with venous ulcers. Venous ulcers, which occur most commonly on the medial distal leg, can develop in patients with chronic venous insufficiency when leg veins become blocked.

**Interventions**
The treatment being considered is the use of pneumatic lymphatic pumps. 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 3 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 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 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 wound care clinics, purchased, or rented for home use; home use is addressed herein. Wound care therapists, surgeons and physiatrists provide care.

**Comparators**
The following practices are currently being used to treat venous ulcers; local wound care and compression bandages or hosiery supplemented by conservative measures such as leg elevation.

Wound care therapists, surgeons, and physiatrists provide care.

**Outcomes**
The general outcomes of interest are symptoms, change in disease status, functional outcomes and quality of life.

Venous ulcers are a chronic condition and follow-up of at least 6 weeks to 6 months would be desirable to assess outcomes.

**Study Selection Criteria**
Methodologically credible studies were selected using the principles described in the first indication.

The analysis of venous ulcers focused on RCTs evaluating preferred outcomes for wound healing. Complete healing is generally considered the most clinically relevant outcome; a 50% reduction in wound area over time and time to heal are also considered acceptable outcomes.
A Cochrane review updated by Nelson et al (2014) addressed intermittent pneumatic compression pumps for treating venous leg ulcers. Reviewers 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 intermittent pneumatic compression regimens. In a meta-analysis, 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 (relative risk, 1.31; 95% confidence interval, 1.06 to 1.63). Two of these 3 trials were considered to have a high-risk of bias (e.g., not blinded, unclear allocation or concealment). There was a high degree of heterogeneity among trials, and findings from other RCTs were not pooled. Neither of the 2 trials comparing intermittent pneumatic compression with continuous compression plus stockings or bandages found statistically significant between-group differences in healing rates.

A RCT by Dolibog et al (2014) was published after the Cochrane review literature search. The trial included 147 patients with venous ulcers. It compared 5 types of compression therapy: intermittent pneumatic compression 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. Rates of complete healing at the end of treatment were similar in 3 of the treatment groups: 16 (57%) of 28 patients in the pneumatic compression group, 17 (57%) of 30 in the stockings group, and 17 (59%) of 29 in the multilayer bandage group. On the other hand, rates of healing were much lower in the other 2 groups: 5 (17%) of 30 in the 2-layer bandage group and 6 (20%) of 30 in the Unna boot group. In 2013, a pilot study by Dolibog et al, included in the Cochrane review, had similar findings.

Section Summary: Venous Ulcers
A Cochrane review of RCTs on pneumatic compression pumps for treating venous leg ulcers conducted a meta-analysis of 3 trials. This analysis 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.

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 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 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 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.

Supplemental Information
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:

“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.

U.S. Preventive Services Task Force Recommendations
Not applicable.

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.”
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

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<td>July 2020</td>
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NCT: national clinical trial.
*a Denotes industry-sponsored or cosponsored trial.

References

Documentation for Clinical Review

Please provide the following documentation (if/when requested):

Initial Request:
- History and physical and/or consultation notes including:
  - Reason pneumatic compression pump required
  - Office and progress notes for the past three months
  - Documentation of prior conservative treatment including type and duration
  - Documentation of individual’s characteristics preventing use of nonprogrammable pump (if requesting programmable pump)
- Treatment plan including estimated length of time device is needed (number of months)
- Prescription for pump and/or appliance

For continued use of a pneumatic compression pump (if applicable):
- Physician progress notes documenting response to initial treatment with the pump including:
  - Documentation of patient’s compliance and tolerance to treatment plan
  - Documentation of decreased edema with pre- and post-treatment measurements and/or documented improvement in functional capacity
- Prescription and/or recommended treatment plan including estimated length of time (in months) device is further required

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of codes does not constitute or imply member coverage or provider reimbursement.

MN/IE

The following services may be considered medically necessary in certain instances and investigational in others. Services may be considered medically necessary when policy criteria are met. Services may be considered investigational when the policy criteria are not met or when the code describes application of a product in the position statement that is investigational.

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<td>Pneumatic compressor, segmental home model without calibrated gradient pressure</td>
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Pneumatic Compression Pumps for Treatment of Lymphedema and Venous Ulcers

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<tr>
<td>Nonsegmental pneumatic appliance for use with pneumatic compressor, full leg</td>
<td>E0660</td>
<td></td>
</tr>
<tr>
<td>Nonsegmental pneumatic appliance for use with pneumatic compressor, full arm</td>
<td>E0665</td>
<td></td>
</tr>
<tr>
<td>Nonsegmental pneumatic appliance for use with pneumatic compressor, half leg</td>
<td>E0666</td>
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</tr>
<tr>
<td>Segmental pneumatic appliance for use with pneumatic compressor, full leg</td>
<td>E0667</td>
<td></td>
</tr>
<tr>
<td>Segmental pneumatic appliance for use with pneumatic compressor, full arm</td>
<td>E0668</td>
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</tr>
<tr>
<td>Segmental pneumatic appliance for use with pneumatic compressor, half leg</td>
<td>E0669</td>
<td></td>
</tr>
<tr>
<td>Segmental pneumatic appliance for use with pneumatic compressor, integrated, 2 full legs and trunk</td>
<td>E0670</td>
<td></td>
</tr>
<tr>
<td>Segmental gradient pressure pneumatic appliance, full leg</td>
<td>E0671</td>
<td></td>
</tr>
<tr>
<td>Segmental gradient pressure pneumatic appliance, full arm</td>
<td>E0672</td>
<td></td>
</tr>
<tr>
<td>Segmental gradient pressure pneumatic appliance, half leg</td>
<td>E0673</td>
<td></td>
</tr>
<tr>
<td>Pneumatic compression device, high pressure, rapid inflation/deflation cycle, for arterial insufficiency (unilateral or bilateral system)</td>
<td>E0675</td>
<td></td>
</tr>
<tr>
<td>Intermittent limb compression device (includes all accessories), not otherwise specified</td>
<td>E0676</td>
<td></td>
</tr>
</tbody>
</table>

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

<table>
<thead>
<tr>
<th>Effective Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/15/2007</td>
<td>BCBSA Medical Policy adoption</td>
</tr>
<tr>
<td>12/18/2009</td>
<td>Policy revision without position change</td>
</tr>
<tr>
<td>07/22/2011</td>
<td>Administrative Review</td>
</tr>
<tr>
<td>03/29/2013</td>
<td>Policy revision with position change</td>
</tr>
<tr>
<td>06/28/2013</td>
<td>Policy Guideline clarification</td>
</tr>
<tr>
<td>01/30/2015</td>
<td>Policy title change from Compression Therapy for Lymphedema and Venous Stasis Ulcers Policy revision with position change effective 3/30/2015</td>
</tr>
<tr>
<td>03/30/2015</td>
<td>Policy revision with position change</td>
</tr>
<tr>
<td>12/30/2016</td>
<td>Policy revision without position change</td>
</tr>
<tr>
<td>05/01/2017</td>
<td>Policy revision without position change</td>
</tr>
<tr>
<td>05/01/2018</td>
<td>Policy revision without position change</td>
</tr>
<tr>
<td>05/01/2019</td>
<td>Policy revision without position change</td>
</tr>
<tr>
<td>05/01/2020</td>
<td>Annual review. No change to policy statement. Literature review updated.</td>
</tr>
</tbody>
</table>

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and
effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member’s illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member’s health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member’s eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.