Medical Policy

BlueCross BlueShield of Kansas
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Title: Pneumatic Compression Pumps for Treatment of Lymphedema and Venous Ulcers (for Home Use)

See Also: *Outpatient Use of Limb Pneumatic Compression Devices for Venous Thromboembolism Prophylaxis*

Professional
Original Effective Date: June 7, 2013
Revision Date(s):
Current Effective Date: June 7, 2013

Institutional
Original Effective Date: July 8, 2013
Revision Date(s):
Current Effective Date: July 8, 2013

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DESCRIPTION

Pneumatic compression pumps are proposed as a treatment option for patients with lymphedema who have failed conservative measures e.g., compression garments, manual massage. They are also proposed to supplement standard care for patients with venous ulcers. A variety of pumps are available; they can be single- or multichamber and have varying design and complexity.

Background

Lymphedema is an abnormal accumulation of lymph fluid in subcutaneous tissues or body cavities resulting from obstruction of lymphatic flow. Lymphedema can be subdivided into primary and secondary categories. Primary lymphedema has no recognizable etiology, while secondary lymphedema is related to a variety of causes including surgical removal of lymph nodes, postradiation fibrosis, scarring of lymphatic channels, or congenital anomalies. Treatment includes mechanical measures (compression garments, bandaging, manual massage, pneumatic compression devices (i.e., lymphedema pumps), drugs, or rarely, surgery.

Venous ulcers, which occur most commonly on the medial distal leg, can develop in patients with chronic venous insufficiency when leg veins become blocked. Standard treatment for venous ulcers includes compression bandages or hosiery supplemented by conservative measures such as leg elevation. Pneumatic compression pumps are proposed as a treatment for venous ulcers, especially in the case of patients who do not respond to these standard therapies.

Pneumatic compression pumps consist of pneumatic cuffs that are connected to a pump. They use compressed air to apply pressure to the affected limb. The intention is to force excess lymph fluid out of the limb and into central body compartments in which lymphatic drainage should be preserved. Many different pneumatic compression pumps for treating lymphedema are available, with varying materials, design, degree of pressure, and complexity. There are three primary types of pumps as follows:

- Single-chamber nonprogrammable pumps: These are the simplest pumps, consisting of a single chamber that is inflated at one time that applies uniform pressure.
- Multichamber nonprogrammable pumps: These pumps have multiple chambers, ranging from 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)

POLICY

A. Single compartment or multichamber nonprogrammable lymphedema pumps may be considered **medically necessary** for the treatment of lymphedema that has failed to respond to conservative measures, such as elevation of the limb, exercise and use of compression garments.

B. Single compartment or multichamber programmable lymphedema pumps 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).

C. The use of lymphedema pumps is considered **medically necessary** for the treatment of leg venous stasis ulcers which have failed to heal after 6 months of conservative therapy (compression bandages or garments, appropriate dressings, exercise and leg elevation).

D. Single compartment or multichamber lymphedema pumps are considered **experimental / investigational** in all situations other than those specified above in the first two policy statements.

E. 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 **experimental / investigational**.

RATIONALE

Lymphedema

The literature review addresses two main questions: the efficacy and safety of pneumatic compression pumps compared to alternative treatments for lymphedema and the relative efficacy of different types of pumps. Due to the FDA-approval of lymphedema pumps that treat the truncal area in addition to the affected limb, there has recently been interest in the evidence on truncal clearance as part of lymphedema treatment. The updated literature searches did not identify any comparative studies that examined whether treating the truncal area in addition to the affected limb improves the outcomes of pneumatic compression pump treatment more than only treating the limb.

In 2010, the McMaster University Evidence-based Practice Center, under contract with the Agency for Healthcare Research and Quality (AHRQ), published a technology assessment on diagnosis and treatment of secondary lymphedema that included discussion of pneumatic compression pumps. (2) The authors, Oremus and colleagues, identified a total of 10 studies; 6 moderate-to-high-quality randomized controlled trials (RCTs), 2 low-quality RCTs, and 2 observational studies. There was a high degree of heterogeneity between studies: 7 types of lymphedema pumps were used, pumps were compared to 6 different alternative interventions (including compression bandages, laser, and massage), and 5 studies used pumps in combination with other interventions. Six trials compared the addition of massage, including manual lymphatic drainage (a specialized type of massage performed by a trained therapist), to more conservative treatments such as bandaging or physical therapy. Five of the 6 studies included women with arm lymphedema after breast cancer treatment. Only 1 of these 5 studies found that massage led to greater reduction in arm volume than more conservative therapy. The sixth trial, which addressed lymphedema after ankle surgery, found significantly greater reduction in volume when manual lymph drainage massage was added to standard physical therapy versus physical therapy alone. Due to the relatively small number of studies and high degree of variability in study design, the authors concluded that there was insufficient evidence to determine whether any type of intermittent pneumatic compression (IPC) device and sleeve was more effective than another type.

In 2012, Oremus and colleagues published an updated systematic review on conservative treatments for secondary lymphedema. (3) The authors identified a total of 36 English-language studies, 30 of which were RCTs and 6 were observational studies. Six RCTs evaluated intermittent pneumatic compression. Study findings were not pooled. The authors reported that 2 RCTs showed that IPC was superior to decongestive therapy or self-massage but 3 other RCTs failed to show that IPC was superior to a different type of conservative treatment of lymphedema. In addition, the authors identified 1 RCT comparing types of IPC devices. This study, Pilch et al. 2009 (see description below (4)) found that a 3-chamber IPC sleeve was superior to a 1-chamber sleeve for reducing edema.

Representative RCTs using FDA-cleared devices are described below:

Lymphedema pumps compared to alternative treatment

In 2002, Szuba and colleagues published an article that evaluated the Biocompression Systems Sequential Circulator lymphedema pump, a 4-chamber device, in 2 RCTs conducted in the U.S. among women with breast cancer. (5)

Study 1: The study evaluated initial treatment of women with unilateral lymphedema (an increase of at least 20% in the volume of the swollen arm compared to the normal arm) who had completed cancer therapy at least 12 weeks earlier. Twelve women were randomly assigned to 10 days of outpatient treatment with decongestive lymphatic therapy (a multidisciplinary approach consisting of manual lymph drainage, compression bandaging, and massage) plus use of a lymphedema pump 30 minutes a day at 40-50 mm Hg, and 11 were randomly assigned to decongestive lymphatic therapy alone. At the 2-week follow-up, there was a statistically significant greater reduction in volume of the edematous arm in the group assigned to pump use (45%) compared to the nonpump group (26%), $p<0.05$. The difference in volume reduction between groups was not significantly different at 40 days at the end of Phase II; there was a mean reduction of 30% in the pump group and 27% in the nonpump group.

Study 2: The study included women who had received a course of decongestive lymphatic therapy at least 1 month and less than 1 year prior to enrollment. Twenty-seven women were randomly assigned; the average duration of lymphedema was 60 months, and the average time from surgery was 114 months. Thirty days of self-administered conservative therapy alone (i.e., lymphatic massage and use of a compression garment) was compared to conservative therapy plus 60 minutes per day of lymphedema pump use. Patients assigned to use lymphedema pumps were supplied with a device for home use. After 1 month of treatment, patients could cross-over to the other intervention. The authors did not report the number of patients in each treatment group but stated that 25 women completed the study and 2 voluntarily withdrew. During the month of treatment that included pump use, there was a mean volume reduction in the affected limb of 86 mL; there was no apparent effect of treatment order. In contrast, during the month of self-administered conservative treatment alone, there was a mean increase in volume of 33 mL. There were no adverse responses to maintenance treatment with the lymphedema pump; in study 1, the authors reported that only 1 of 11 patients experienced headache and a modest increase in blood pressure during pump use.

In 2006, Wilburn and colleagues published a pilot randomized crossover study in 10 women with breast-cancer-associated lymphedema of the arm (at least 10% increased volume in the affected limb) after initial treatment with intensive decongestive physical therapy. (6) Women were assigned, in random order, to self-administered treatment with the Flexitouch™ or massage, 1 hour daily for 14 days; they then switched to the other treatment. There was a washout phase of 1 week before each treatment period during which patients used only a compression garment. The difference in arm volume was significantly greater after treatment with the Flexitouch™ (mean decrease of 207 mL) than after self-massage (mean increase of 52 mL), $p=0.007$. The authors state that the positive response to the Flexitouch™ device in this preliminary trial warrants additional testing in larger studies.

Comparison between lymphedema pumps and/or protocols

A 2009 RCT by Pilch and colleagues, in Poland, compared lymphedema pumps in terms of number of chambers and cycle times. (4) Fifty-seven women with lymphedema of the arm following breast cancer treatment were randomly assigned to 1 of 4 treatments: 1) one-to-one cycle of compression and interval (90s: 90s) with a single chamber sleeve (n=17); 2) one-to-one cycle of compression and interval (90s: 90s) with a 3-chamber sleeve (n=9); 3) three-to-one cycle of compression and interval (45s: 15s) with a single chamber sleeve (n=11); or 4) three-to-one cycle of compression and interval (45s: 15s) with a 3-chamber sleeve (n=20). Patients in all groups received 25 intermittent pneumatic compression treatments, performed 5 days a week for 5 weeks. Two models of Flowtron pumps (Huntleigh Healthcare, UK) were used. (These pumps appear to be FDA-cleared for prevention of deep vein thrombosis.) The mean percent edema post-treatment was 29% in group 1, 35% in group 2, 34% in group 3, and 28% in group 4. Overall, there was not a significant difference among groups. However, percent edema was significantly lower in group 3 (45s cycle with a 3-compartment sleeve) than group 4 (45s cycle with a single compartment sleeve) (p=0.040).

Two industry-sponsored RCTs were published in 2012 that included women with breast cancer who had documented post-surgical upper-extremity lymphedema. Fife and colleagues compared treatment with the Flexitouch™ system to the Biocompression Systems Sequential Circulator. (7) 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 hour per day for 12 weeks in addition to standard care e.g. wearing compression garments. The Biocompression Systems device utilized an arm garment only whereas the Flexitouch device utilized three garments and treated the full upper extremity (arm, chest and 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.

Key outcomes at the end of the 12-week treatment period are as follows:

	Flexitouch	Sequential Circulator	p-value
Affected arm volume (ml)	2,952 ± 724	3,013 ± 773	0.141
Edema volume (ml)	438 ± 344	537 ± 293	0.050
Edema volume (%)	18.2 ± 14.0	21.0 ± 10.7	0.047
Local tissue water (TDC*)	33.8 ± 7.6	33.5 ± 6.6	0.049

*TDC: arm tissue dielectric constant

At the p<0.05 level, there was a statistically significant difference in edema volume and tissue water at 12 weeks between groups, favoring treatment with the Flexitouch system. If the p-value was adjusted for the 2 primary outcome variables (edema volume and local tissue water) or the 4 reported outcome variables, differences would not be statistically different. The study was limited by its small sample size, missing data on the local tissue water outcome and unclear blinding of outcome assessment. Also, the outcomes reported were primarily volume of fluid removed, which is an intermediate outcome. It is unclear whether the difference in volume of fluid removed would translate to clinically meaningful differences in symptoms, functional status, and/or quality of life.

Ridner and colleagues conducted an RCT comparing treatment with the Flexitouch™ system of the arm-only versus the arm, chest and trunk in women with breast cancer who had arm lymphedema. (8) To be eligible for participation, there needed to have a 2 cm difference in girth on the affected arm compared to the unaffected arm. A total of 47 patients were enrolled; 5 patients were withdrawn in the course of the study, leaving n=21 in each treatment group. Participants completed training in using the device and were observed in the laboratory to insure they used proper technique; the remainder of the sessions were conducted at home. Patients in the experimental group (arm, chest and trunk treatment) were told to perform 30 daily sessions of 1-hour each; patients in the control group (arm-only) were told to perform 30 daily treatments of 36 minutes each. Final outcome assessment took place at the end of the 30-day treatment period. The authors did not report whether the staff members that assessed objective outcomes were blinded to the patient's treatment group. 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 the end of the study was 10.0 in the experimental group and 6.0 in the control group (p=0.145).

Venous ulcers

A 2011 Cochrane review addressed intermittent pneumatic compression pumps for treating venous leg ulcers. (9) The review identified a total of 7 RCTs. Four trials compared pneumatic compression pumps plus compression bandages or stockings to compression bandages or stockings only, 1 trial compared compression pumps to wound dressings only and 1 trial compared two intermittent pneumatic compression regimens. The trial comparing pumps to wound dressings, which was not blinded, found a significantly greater rate of wound healing with compression treatment. However, the more relevant comparison intervention is continuous compression provided by bandages or stockings. The 4 trials with this comparison had sample sizes ranging from 22 to 53. Blinding was unclear in 3 of the studies and the fourth was not blinded. In a pooled analysis of 3 of the 4 trials, there was not a statistically significant difference in the number of healed ulcers in the group receiving intermittent pneumatic compression or compression bandaging or stockings only, risk ratio (RR): 1.09 (95% confidence interval [CI]: 0.91-1.30). The fourth trial found a significantly higher healing rate in the pump group than the compression bandage/stocking group; in this trial, the rate of healing with compression bandages/stockings was particularly low.

This evidence is insufficient to conclude whether lymphedema pumps improve healing of venous ulcers. Overall, there are few trials that reported on the most relevant clinical comparisons i.e., pneumatic compression as an adjunct to optimal wound care compared to optimal wound care alone. In many studies, it is difficult to ascertain whether optimal wound care was provided in the control group and whether enrolled patients had failed optimal wound care prior to enrollment in the study. The available studies do not consistently show that intermittent pneumatic compression improves ulcer healing. Moreover, many of the studies have methodological limitations such as a lack of blinding or a failure to report on complete ulcer healing. The literature is characterized by a high degree of heterogeneity among studies in the types of pumps used, the protocols for pneumatic compression, the comparison groups, and control interventions. The pumps used in the trials varied and some were older devices used in the 1980s and 1990s. This creates challenges in classifying the types of devices used. Moreover, it is difficult to compare the pumps in the trials to currently available lymphedema pumps since all but

1 of the studies were published at least 10 years ago and some were from the late 1980s / early 1990s.

Ongoing Clinical Trials

Two Pneumatic Compression Devices in the Treatment of Lower Extremity Lymphedema (ACE) (NCT01239160)(10): This multicenter single-blind randomized trial will compare the efficacy of two types of lymphedema pumps in 262 patients with lower limb lymphedema. Patients are randomized to use a pump without calibrated compression (Hydroven PFR) or a pump with calibrated compression (Flexitouch System). The primary endpoint is limb volume reduction after 12 weeks of treatment, with the outcome at 24 weeks included as a secondary endpoint. The trial is sponsored by the Centre for Research and Implementation of Clinical Practice in the U.K. and Tactile Technologies. The expected date of completion is December 2013.

Summary

The available evidence from randomized controlled trials suggests that use of pneumatic compression pumps may be effective at reducing limb volume in patients with lymphedema who fail to respond to conservative therapy. There is insufficient evidence from comparative trials that one type of pump is more effective than another for lymphedema patients. Therefore, nonprogrammable lymphedema pumps are considered medically necessary and programmable pumps are considered medically necessary only for patients unable to use the standard pumps. There is insufficient evidence that treating the truncal area in addition to the limb affected by lymphedema improves the outcomes of pneumatic compression pump treatment more than only treating the limb. Therefore, 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.

There is insufficient evidence that pneumatic compression pumps enhances healing of venous ulcers compared to standard compression techniques e.g., bandaging. There are few RCTs on this topic and the existing studies do not consistently show benefit; a meta-analysis of 3 studies did not find a significant benefit of pneumatic compression pumps for ulcer healing. Thus, lymphedema pumps for the treatment of venous ulcers is considered investigational.

Practice Guidelines and Position Statements

A 2009 consensus statement from the International Union of Phlebology stated that sequential pneumatic compression is an effective treatment for primary lymphedema and is particularly useful in situations in which lymphedema is best treated by physical passive therapy e.g., elderly and disabled patients. (11)

A 2009 technology assessment report by the McMaster University Evidence-based Practice Center for AHRQ had the following conclusions regarding treatment of secondary lymphedema (3): "...there was no evidence concerning the optimal criteria to initiate or stop treatment. While the studies suggested that most treatments did reduce the size of the lymphatic limb, there was too much heterogeneity in terms of treatments, inclusion and exclusion criteria, and treatment protocols to suggest the optimality of one type of treatment over another. Despite the multiplicity of inclusion and exclusion criteria, the studies did not contain reports of treatment benefits in any subgroup of patients." The report did not have specific recommendations on use of lymphedema pumps.

In 2001, Health Canada issued breast cancer treatment guidelines that included information on management of lymphedema related to breast cancer. (12) Recommendations include encouraging long-term consistent use of compression garments and offers practical advice on skin care, exercise, and body weight. The guideline states that one trial demonstrated a trend in favor of pneumatic compression pumps and that further randomized trials are needed to determine whether pneumatic compression provides additional benefit beyond that offered by compression garments.

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.

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. 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.

CPT/HCPCS

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

- Claims for lymphedema pumps are coded with a pair of HCPCS codes: one to describe the actual pump (E0650, E0651, E0652) 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) is used in conjunction with any of the following appliances: E0655, E0660, E0665, E0666.
  - *Multichamber pumps*
    E0651 (Pneumatic compressor, segmental home model without calibrated gradient pressure) may be used with any of the following appliance codes: E0656, E0657, E0667, E0668, E0669.
  - *Multichamber programmable pumps*
    E0652 (Pneumatic compressor, segmental home model with calibrated gradient pressure) may be used with any of the following appliance codes: E0671, E0672, E0673.

ICD-9 Diagnoses
457.0 Postmastectomy lymphedema syndrome
457.1 Other noninfectious lymphedema
757.0 Hereditary edema of legs

ICD-10 Diagnoses (Effective October 1, 2014)
I97.2 Postmastectomy lymphedema syndrome
I89.0 Lymphedema, not elsewhere classified
Q82.0 Hereditary lymphedema

REVISIONS

06-07-2013	Policy added to the bcbsks.com web site.
	Effective for Institutional providers 30 days after the Revision Date, 07-08-2013.

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