Pneumatic Compression Devices in the Home Setting

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DESCRIPTION

Note: This document addresses pneumatic compression devices for postsurgical use in the home care setting only.

- *This document **excludes** any reviews for pneumatic compression devices in the outpatient or inpatient facility setting.*

Pneumatic compression devices consist of an inflatable garment and an electrical pneumatic pump that fills the garment with compressed air. The garment is intermittently inflated and deflated with cycle times and pressures that vary between devices. The devices are proposed as a treatment option for patients with lymphedema who have failed conservative measures, to supplement the standard of care for patients with venous ulcers or as prophylaxis for a postsurgical venous thromboembolism. A variety of pumps are available; they can be single chamber (non-segmented) or multi-chamber (segmented) and have varying design and complexity.
There are three primary types of pumps:

- **Single chamber (non-segmented) non-programmable pumps**: These are the simplest pumps, consisting of single chamber that is inflated at one time that applies uniform pressure. (E0650)
- **Multi-chamber (segmented) non-programmable 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 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. (E0651)
- **Single or multi-chamber programmable pumps or self-calibrating pumps:** These are similar to the pumps described except it is possible to make manual adjustments in the pressure in the individual compartment and/or the length and frequency of the inflation cycles. (E0652)

In general, a non-segmented or segmented compression device without manual control is considered sufficient to meet the needs of the individual. Typically, the only time a segmented, calibrated gradient pressure device would be indicated is when the individual has contractures or extensive scarring that prevents them from receiving satisfactory treatment from a non-segmented or segmented device without manual control due to safety concerns. This policy addresses various conditions for which pneumatic compression devices have been investigated for use.

Chronic Venous Insufficiency (CVI) 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.

Conservative measures for the treatment of venous stasis ulcers includes a compression bandage system/garment, appropriate dressings for the wounds, exercise, and elevation of the affected limb.

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, post-radiation 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. Pneumatic

compression pumps are proposed as a treatment for patients with lymphedema who have failed conservative measures.

Pneumatic compression pumps are also proposed to supplement standard care for 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. Standard treatment for venous ulcers includes compression bandages or hosiery supplemented by conservative measures such as leg elevation.

Pneumatic compression pumps may be used in lymphedema or wound care clinics, purchased, or rented for home use; home use is addressed herein. Pneumatic compression pumps consist of pneumatic cuffs connected to a pump. These pumps 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, with varying materials, designs, degrees of pressure, and complexity. There are 3 primary types of pumps. Single chamber nonprogrammable pumps are the simplest pumps, consisting of a single chamber that is inflated at 1 time to apply uniform pressure. Multichamber nonprogrammable 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 adjust the pressure manually in individual compartments. Single- or multi-chamber programmable pumps 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.

Postsurgical Home Use of Limb Compression Devices for Venous Thromboembolism (VTE) Prophylaxis

Antithrombotic prophylaxis is recommended for surgical patients at moderate-to-high risk of postoperative venous thromboembolism (VTE), including deep vein thrombosis and pulmonary embolism, based on the surgical procedure and/or patient characteristics. For some types of surgery (e.g., major orthopedic surgery), there is a particularly high-risk of VTE due to the nature of the procedure and the prolonged immobility during and after surgery. Common patient risk factors include increasing age, prior VTE, malignancy, pregnancy, and significant comorbidities. Increased risk of bleeding is a contraindication to anticoagulation as are adverse events and allergic reactions. Limb compression devices have been used as an adjunct or alternative to anticoagulation in the home setting for patients in the postoperative period as a method to reduce VTEs.

Pneumatic Compression Pumps Applied to Venous Ulcers

Clinical Context and Therapy Purpose

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 improve the net health outcome in patients who have venous ulcers?

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

Populations

The relevant population of interest is patients with venous ulcers.

Interventions

The therapy being considered is the use of pneumatic lymphatic pumps.

Comparators

The following practices are currently being used to treat venous ulcers: medication therapy and continuous compression (e.g., stockings, bandages).

Outcomes

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

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 following principles:

To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;

In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.

To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic Review

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 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 (relative risk, 1.31; 95% CI, 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.

Randomized Controlled Trials

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.

Alvarez et al. (2020) conducted an RCT in 52 patients with large (>20 cm^2) chronic venous leg ulcers that compared intermittent pneumatic compression plus standard compression therapy (n=27) to standard compression therapy alone (n=25). Standard compression therapy consisted of multilayer compression bandages. Intermittent pneumatic compression therapy was performed for 1 hour twice daily. At 9 months, median time to wound closure was significantly shortened in the group receiving pneumatic compression (141 days vs. 211 days; p=.03). Wound pain relief was greater in the pneumatic compression group for the first 3 weeks of therapy, but pain relief was similar between groups at subsequent time points.

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: Venous Ulcers:
For individuals who have venous ulcers who receive pneumatic compression pumps, the evidence includes 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 that the technology results in an improvement in the net health outcome.

Calibrated/Programmable Pneumatic Compression Devices
One randomized, single-center, crossover study involving 10 patients that compared the efficacy of the Flexitouch™ device to massage for treatment of lymphedema of the arm was found in the literature. The study was limited by small sample size, short duration of treatment and no comparison to standard pneumatic lymphedema pumps or complex lymphedema therapy. Another similar study compared pressure delivered to parts of the arm between a segmental compression pump and the Flexitouch™ device. Differences in delivered pressures between the two devices was observed, but no conclusion regarding the optimal pressure needed was made.

Summary of Evidence: Calibrated/Programmable Pneumatic Compression Devices
The literature has failed to prove that with certainty the non-programmable pumps are inferior to programmable compression, and programmable compression should only be utilized for those physically unable to utilize the non-programmable pneumatic compression devices. There is no consensus in the scientific literature on optimal pump selection and use. The scientific evidence supporting the use of pneumatic pumps as a solitary treatment modality for lymphedema is extremely limited and of poor quality. The evidence to support calibrated over non-calibrated pumps is insufficient in proving otherwise.

Lymphedema of the Chest/Trunk as well as Limb
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 were statistically significant week by group interactions in 2 of these outcomes (edema volume reported as a percent, p=.047; tissue water, p=.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=.141; edema volume reported in milliliters, p=.050). Moreover, had there been statistical adjustments for multiple comparisons (ie, if p<.0125 had been used instead of p<.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 were 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 trialists 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=.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=.145)

Summary of Evidence: Lymphedema of the Chest/Trunk as well as Limb
Two published RCTs have compared pneumatic compression treatment with and without truncal involvement. In one 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.

Although the impact of arm/extremity lymphedema has been well studied and documented, very little attention has been focused on the impact of trunk (truncal) and chest edema. There is insufficient evidence that treating the truncal/chest area in addition to the limb affected by lymphedema improves the outcomes of pneumatic compression pump therapy more than only treating the limb. There is insufficient evidence to determine that treating the truncal/chest area in addition to the limb affected by

lymphedema improves the outcomes of pneumatic compression pump therapy more than only treating the limb. Further research is indicated and clinically meaningful reductions in truncal girth should also be defined.

Lymphedema–Pneumatic Compression Pumps Applied to the Head and Neck

Clinical Context and Therapy Purpose
The purpose of pneumatic compression pumps applied to the head and neck in patients who have lymphedema who failed to respond to conservative therapy 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 head and neck improve the net health outcome in patients who have lymphedema who failed to respond to conservative therapy?

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

Populations
The relevant population of interest is patients with lymphedema who failed to respond to conservative therapy.

Interventions
The therapy being considered is the use of pneumatic lymphatic pumps on the head and neck.

Comparators
The following practices are currently being used to treat lymphedema: conservative therapy (e.g., range of motion exercises, compression therapy), manual lymphatic drainage, and complete decongestive therapy.

Outcomes
The general outcomes of interest are symptoms, change in disease status, functional outcomes (e.g., range of motion), and quality of life (e.g., ability to conduct activities of daily living). The Lymphedema Symptom Intensity and Distress Survey-Head and Neck is a patient-reported tool that captures symptom intensity and distress.

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:

To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;

In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.

To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

Studies with duplicative or overlapping populations were excluded.

Review of Evidence
This literature review focuses on RCTs evaluating pneumatic compression for patients with head and neck lymphedema. One RCT was identified that evaluated the feasibility and efficacy of an advanced pneumatic compression device, which was industry-sponsored. Additional uncontrolled preliminary observational studies have been published, which have reported improvements in symptoms and function with use of advanced pneumatic compression devices for head and neck lymphedema secondary to head and neck cancer.

Lymphedema of the Head and Neck
(2021) Ridner et al. reported Eligible patients had completed treatment for head and neck cancer (HNC), were disease free, and had lymphedema at enrollment. Participants were randomized to wait-list lymphedema self-management (standard of care) or lymphedema self-management plus the use of the advanced pneumatic compression device (APCD) twice a day. Safety (CTCAE V4.0) and feasibility were primary endpoints; secondary endpoints included efficacy measure by objective examination and patient reported outcomes (symptoms, quality of life, function), adherence barriers, and satisfaction. Assessments were conducted at baseline and weeks 4 and 8. Forty-nine patients were enrolled (wait-list n = 25; intervention n = 24). In total, forty-three patients completed the study. No device-related Serious Adverse Events were reported. Most patients used the APCD once per day, instead of the prescribed twice per day, citing time related factors as barriers to use. APCD use was associated with significant improvement in perceived ability to control lymphedema ($p = 0.003$) and visible external swelling (front view $p < 0.001$, right view $p = 0.004$, left $p = 0.005$), as well as less reported pain.

This trial supports the safety and feasibility of the APCD for the treatment of secondary lymphedema in head and neck cancer patients. Results demonstrated some improvements in patient-reported outcomes and swelling, but adherence was low, with only 1 patient using the pneumatic compression treatment device twice daily as prescribed. *Further investigation in larger studies and those that compare against the gold standard comparator of complete decongestive therapy are needed to determine efficacy of this treatment approach.*

(2020) Gutiérrez, C. et al. noted head and neck cancer survivors (n = 205) prescribed with an at-home Flexitouch head and neck advanced pneumatic compression device (APCD) completed pretreatment and posttreatment self-reported assessments addressing efficacy, function, and symptoms. Participant average age was 60 years with 74% male. Pre-post

responses for ≥25 days of use were assessed via the non-parametric Wilcoxon Signed Rank test. Analysis revealed statistically significant improvement in all symptoms and all function items ($P < 0.00001$). Compliance with prescribed therapy (at least 30 minutes daily) was high with 71% of participants reporting daily use and 87% reporting overall satisfaction.

Studied parameters, such as ability to perform activities of daily living and functional improvements in swallowing and breathing and high compliance rate demonstrated statistically significant positive changes from pre- to post-device use. Our findings suggest the potential utility of at-home use of this device in contributing to improved quality of life in this patient population and provide a rationale for a subsequent randomized controlled trial to objectively assess improvement in symptoms with the use of a head and neck APCD.

Section Summary: Lymphedema–Pneumatic Compression Pumps Applied to Head and Neck
One RCT has evaluated pneumatic compression treatment for head and neck lymphedema. The trial evaluated the feasibility, adherence, and safety of the intervention. Results demonstrated some improvements in patient-reported outcomes and swelling, but adherence was low, with only 1 patient using the pneumatic compression treatment device twice daily as prescribed. Further investigation in larger studies and those that compare against the gold standard comparator of complete decongestive therapy are needed to determine efficacy of this treatment approach.

Summary of Evidence: Lymphedema of the Head and Neck
Based on the peer reviewed medical literature the role of head and neck pneumatic compression therapy in the treatment of lymphedema is lacking, the clinical effectiveness of these devices cannot be determined and their role in the management of lymphedema has not been established and further research is indicated. Clinical guidelines fail to include pneumatic compression devices within this management. There is insufficient evidence that treating the truncal/chest area in addition to the limb affected by lymphedema improves the outcomes of pneumatic compression pump therapy more than only treating the limb.

Lymphedema–Pneumatic Compression Pumps Applied to the Limb Only
Clinical Context and Therapy Purpose
The purpose of pneumatic compression pumps applied to the limb only is to provide a treatment option that is an alternative to or an improvement on existing therapies for patients with lymphedema who failed to respond to conservative therapy.

The question addressed in this evidence review is: Does the use of pneumatic compression pumps applied to the limb only improve the net health outcome in patients with lymphedema who failed to respond to conservative therapy?

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

Populations
The relevant population of interest is patients with lymphedema who have failed to respond to conservative therapy.

Interventions
The therapy being considered is the use of pneumatic compression pumps applied to limb only.

Comparators
The following practices are currently being used to treat lymphedema: conservative therapy (e.g., exercise, compression therapy, elevation), manual lymphatic drainage, and complete decongestive therapy.

Outcomes
The general outcomes of interest are symptoms, change in disease status, 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 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:

To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;

In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.

To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

Studies with duplicative or overlapping populations were excluded.

Review of Evidence
(2020) Tastaban et al conducted an RCT in 76 patients with unilateral arm lymphedema related to breast cancer. Patients received complex decongestive treatment alone (n=38) or complex decongestive treatment plus intermittent pneumatic compression (n=38). Intermittent pneumatic compression was delivered for 30 minutes. All patients received complex decongestive treatment, which consisted of skin care, manual lymphatic drainage, compression bandaging, and exercise. Patients received 20 sessions of therapy over the course of 4 weeks. Both groups saw decreases in excess volume after 4 weeks, but between-group differences were not significant (percent reduction in excess volume,

54.6% with intermittent pneumatic compression vs. 49.6% without; p=.140). Symptoms of heaviness and tightness were significantly lower among patients who received intermittent pneumatic compression, as assessed by visual analog scale scores (heaviness, 2.0 vs. 3.0; p=.024; tightness, 2.0 vs. 2.5; p=.048).

(2015) A 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.

(2014) A systematic review by Shao et al. addressed pneumatic compression pumps for treatment of breast cancer-related lymphedema. The authors 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 [CI], -7.01 to 16.03).

(2012) Oremus et al. published an updated systematic review of conservative treatments for secondary lymphedema. The authors 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, 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.

Summary of Evidence: Lymphedema of the Limb Only
The evidence on pneumatic compression pumps applied to the limb for patients with lymphedema includes randomized controlled trials (RCTs) and systemic 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 the technology results in meaningful improvement in the net health outcome.

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 applied to the trunk and/or chest as well as the limb in patients who have lymphedema who failed to respond to conservative therapy 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 the net health outcome in patients who have lymphedema who failed to respond to conservative therapy?

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

Populations

The relevant population of interest is patients with lymphedema who failed to respond to conservative therapy.

Interventions

The therapy being considered is the use of pneumatic compression pumps on the trunk and/or chest, as well as the limb.

Comparators

The following practices are currently being used to treat lymphedema: conservative therapy (e.g., exercise, compression therapy, elevation), manual lymphatic drainage, complete decongestive therapy, and pneumatic compression pump applied to the limb only.

Outcomes

The general outcomes of interest are symptoms, change in disease status, 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 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:

To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;

In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.

To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

Studies with duplicative or overlapping populations were excluded.

Review of Evidence
Due to the 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.

Randomized Controlled Trials
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 were statistically significant week by group interactions in 2 of these outcomes (edema volume reported as a percent, p=.047; tissue water, p=.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=.141; edema volume reported in milliliters, p=.050). Moreover, had there been statistical adjustments for multiple comparisons (i.e., if p<.0125 had been used instead of p<.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 were 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 trialists 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=.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=.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.

Post-Surgical Use of Pneumatic Compression Devices to Control Pain and Swelling

(2017) Murgier et al. conducted a prospective case-control study of the Game Ready device, comparing 43 individuals (27 men, 16 women) recovering from revision total knee arthroplasty; the control group (n=19) was treated with a cold pack applied intermittently (4 hours daily), while the Game Ready group was treated with 2, 8-hour cycles in 30-minute off-on increments. While the main outcome was the reduction of total blood loss, a secondary outcome was postoperative pain, as measured by visual analog score 3 days postsurgery. Patients using the Game Ready device showed decreased blood loss compared with the control group (260 mL vs. 465 mL; $p<0.05$), as well as an improvement in postoperative pain (visual analog score, 1 vs. 3; $p<0.05$). Limitations included the possibility of a type II error due to the specialized surgical unit where the study was performed; additional limitations (e.g., variability of results, concerns about patients' comorbidities) affected the study's secondary outcomes. The authors concluded that, overall, the cryopneumatic device aided patients' recovery from revision total knee arthroplasty but additional prospective randomized trials would be needed to confirm results.

(2018) Noyes et al published a RCT comparing continuous cryotherapy (CC) (Polar Care) and standard ice packs (plain ice, ICE) as a means of improving postoperative pain

control for patients undergoing a primary or revision shoulder arthroplasty procedure. Forty patients (20 in each group), from 30 to 90 years old, were randomly assigned to the 2 treatments. V isual analog pain scores were similar for both the CC and ICE groups preoperatively (5.9 vs. 6.8; p=0.121) and postoperatively at 24 hours (4.2 vs. 4.3; p=0.989), 3 days (4.8 vs. 4.7; p=0.944), 7 days (2.9 vs. 3.3; p=0.593), and 14 days (2.5 vs. 2.7; p=0.742). Continuous cryotherapy and ICE did not differ significantly in the number of morphine equivalents of pain medication postoperatively at 24 hours (43 vs. 38 mg; p=0.579), 3 days (149 vs. 116 mg; p=0.201), 7 days (308 vs. 228 mg; p=0.181), or 14 days (431 vs. 348 mg; p=0.213). The visual analog score for quality of sleep was not different between CC and ICE postoperatively at 24 hours (5.1 vs. 4.3; p=0.382), 3 days (5.1 vs. 5.3; p=0.601), 7 days (6.0 vs. 6.7; p=0.319), or 14 days (6.5 vs. 7.2; p=0.348). The study was limited by patient compliance not being measured objectively, all patients receiving a single-shot interscalene block, and final outcomes not being evaluated.

(2015) Kraeutler et al. compared the Game Ready shoulder wrap with standard icing in a RCT of 46 patients who had undergone rotator cuff repair or subacromial decompression. The average age at the time of surgery was 55.4 years in the compressive cryotherapy intervention group (n=25) and 55.8 years in the control group (n=21; p=0.91). Patients were instructed to apply the cryotherapy every other hour for the first 3 days and 2 to 3 times a day until the follow-up visit at 7 to 10 days. In the immediate postoperative week (days 0-7), participants used diaries to document pain level using a visual analog score (no pain to extreme pain) twice per day. They also reported use of pain medication (converted to morphine equivalent dosage). Analysis of patient diaries showed no significant differences in average pain, worst pain, and morphine equivalent dosage between the 2 groups on any day during the week after surgery. Post hoc power analysis showed that 13 patients per group would provide sufficient power to detect a 25 mm (out of 100 mm) difference in visual analog scores between the 2 groups. Trial limitations included a small sample size (noting that 11 [19%] enrolled patients were excluded due to noncompliance), lack of blinding, potential recall bias due to the use of patient-reported diaries, and uncertainty whether the correct usage of cryotherapy was followed.

(2012) In a multicenter RCT, Su et al compared 280 total knee arthroplasty patients treated with the Game Ready cryopneumatic device or with ice packs plus static compression. On hospital discharge, the treatments were given at the same application cycle of 1 hour on and 30 minutes off. Compliance rates were similar for the 2 groups. Blinded evaluation of 187 patients (67% of patients had complete evaluations) found no significant difference between the groups in visual analog score for pain, range of motion, 6-minute walk test, Timed Up & Go test, or knee girth under this more typical icing regimen. Narcotic consumption decreased from 680 to 509 mg morphine equivalents over the first 2 weeks (14 mg less per day), and patient satisfaction increased with the cryopneumatic device.

(2012) Waterman et al reported on a RCT of the Game Ready device in 36 patients who had anterior cruciate ligament reconstruction. Patients were instructed to use ice or the

cryopneumatic device for 30 minutes at least 3 times a day and return to the clinic at 1, 2, and 6 weeks postoperatively. Compliance during the first 2 weeks did not differ significantly between groups (100% for Game Ready vs. 83% for icing). The primary outcome measure (visual analog pain score) differed at baseline, limiting interpretation of the results. There were no significant differences between the groups for knee circumference, the Lysholm Knee Score, 36-Item Short-Form Health Survey, or Single Assessment Numerical Evaluation scores. A greater percentage of patients treated with the Game Ready device discontinued narcotic use by 6 weeks (83% vs. 28%).

Summary of Evidence: Post-Surgical Use of Pneumatic Compression Devices to Control Pain and Swelling
Note*: Cooling devices are considered a non-covered benefit refer to the member's benefit document.*

Based on the review of the medical literature regarding the use of pneumatic compression devices in post-surgical management to help reduce pain and swelling (which may be combined with circulating cooling device, which is considered a non-covered benefit, see the member's benefit document) the evidence includes several RCTs and a case-control study. The randomized controlled trials (RCTs) produced no significant reduction in pain or medication use compared with standard of care. Trial limitations included small sample size, lack of blinding and patient non-compliance. Further randomized controlled trials are warranted to include larger sample sizes, blinding and patient compliance. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Moderate-to-High Postsurgical Risk of Venous Thromboembolism and No Contraindication to Pharmacologic Prophylaxis

Populations
The relevant population of interest are individuals with a moderate-to-high postsurgical of VTE and no contraindication to pharmacologic prophylaxis

Interventions
The therapy being considered is the home use of a limb compression device as an adjunct to anticoagulation.

Comparators
Comparators of interest include no outpatient venous prophylaxis or other methods of mechanical prophylaxis. Treatment includes conventional therapy.

Outcomes
The general outcomes of interest are overall survival, symptoms, and morbid events.

The existing literature evaluating home use of a limb compression device as an adjunct to anticoagulation as a treatment for moderate-to-high postsurgical risk of VTE and no

contraindication to pharmacologic prophylaxis has varying lengths of follow-up. While studies described below all reported at least 1 outcome of interest, longer follow-up was necessary to fully observe outcomes.

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

To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;

In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.

To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

Studies with duplicative or overlapping populations were excluded.

Review of Evidence
This section focuses on evidence that post-discharge use of limb compression devices (commonly referred to in the literature as intermittent pneumatic compression [IPC] devices) in addition to pharmacologic agents provide an incremental benefit to the net health outcome compared with pharmacologic agents alone. The ideal study design to address patients with moderate-to-high postsurgical risk of VTE and no contraindication to pharmacologic prophylaxis is a superiority RCT comparing VTE prophylaxis consisting of pharmaceutical agents plus home use of limb compression devices with pharmacologic agents alone. No RCTs with this study design were identified for patients discharged after major orthopedic surgery or other types of major surgery. There are, however, RCTs and meta-analyses of RCTs comparing medication plus compression devices with medication alone in surgical patients in the hospital setting. These studies may not permit inferences to the post-discharge home setting, however, they are briefly summarized for informational purposes below.

Review of Evidence: Postsurgical Home Use of Limb Compression Devices for Venous Thromboembolism (VTE) Prophylaxis
For individuals who have a moderate-to-high postsurgical risk of VTE and a contraindication to pharmacologic prophylaxis who receive home use of an IPC device, there are no RCTs assessing the incremental benefit of home use of an IPC device. A few meta-analyses of RCTs have compared VTE prophylaxis with an IPC device to no prophylaxis in surgical patients in the hospital setting, and 1 RCT evaluated the feasibility of post-discharge home use of an IPC. Relevant outcomes are overall survival, symptoms, morbid events, and treatment-related morbidity.

To draw inferences about the benefit of limb compression devices post-discharge in these patients, the feasibility of home use should be considered. An unblinded RCT by Sobieraj-Teague et al. (2012) compared the use of a portable battery-operated IPC device with usual care alone in patients undergoing cranial or spinal neurosurgery. All patients were also prescribed graduated compression stockings and 20% to 25% used anticoagulants. Patients were evaluated at 9 days post surgery, and those discharged earlier were permitted to use an IPC device at home (median duration of hospitalization, 4 days). Patients who used the IPC device post-discharge received home visits at least daily to optimize compliance. Three (4%) of 75 patients in the IPC group and 14 (19%) of 75 patients in the usual care group developed VTE; the difference between groups was statistically significant (p=0.008). Among evaluable patients in the IPC group, 23.3% were continuous users, 53.4% were intermittent users, and 23.3% discontinued use (this includes both inpatient and outpatient use). The mean duration of IPC device use was 6.6 days. Findings would suggest that in-home use of IPC devices is feasible with adequate post-discharge planning and support.

Summary of Evidence:
For individuals who have a moderate-to-high postsurgical risk of VTE and no contraindication to pharmacologic prophylaxis who receive home use of an intermittent pneumatic compression (IPC) device as an adjunct to anticoagulation, there are no RCTs assessing the incremental benefit of home use of an IPC device. Multiple meta-analyses of RCTs have compared medication plus an IPC device with medication alone in surgical patients in the hospital setting. Relevant outcomes are overall survival, symptoms, morbid events, and treatment-related morbidity. Results of these meta-analyses suggest that in-hospital addition of an IPC device to pharmacologic management improves VTE prophylaxis. Limitations of these meta-analyses include not distinguishing between asymptomatic and symptomatic deep vein thrombosis; sparse data on pulmonary embolism; and results generally not stratified by patient risk or specific intervention(s). Moreover, these trials do not permit inferences to the post-discharge home setting, since the post-discharge setting differs in important respects from the hospital setting. Discharged patients tend to be healthier than those in the hospital. Factors such as treatment consistency, duration, and application errors in use differ in the home. The evidence is insufficient to determine the technology results in an improvement in the net health outcome.

Moderate-to-High Postsurgical Risk of Venous Thromboembolism and a Contraindication to Pharmacologic Prophylaxis

Clinical Context and Therapy Purpose
The purpose of home use of a limb compression device is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as no outpatient venous prophylaxis or other methods of mechanical prophylaxis, in patients with a moderate-to-high postsurgical risk of VTE and a contraindication to pharmacologic prophylaxis.

The question addressed in this evidence review is: Does the use of limb compression devices in the home setting reduce the risk of VTE in the postsurgical period?

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

Populations
The relevant population of interest are individuals with a moderate-to-high postsurgical risk of VTE and a contraindication to pharmacologic prophylaxis.

Interventions
The therapy being considered is the home use of a limb compression device.

Comparators
Comparators of interest include no outpatient venous prophylaxis or other methods of mechanical prophylaxis. Treatment includes conventional therapy.

Outcomes
The general outcomes of interest are overall survival, symptoms, morbid events, and treatment-related morbidity.

The existing literature evaluating home use of a limb compression device as a treatment for moderate-to-high postsurgical risk of VTE and a contraindication to pharmacologic prophylaxis has varying lengths of follow-up. While studies described below all reported at least 1 outcome of interest, longer follow-up was necessary to fully observe outcomes.

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

To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;

In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.

To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

Studies with duplicative or overlapping populations were excluded.

Review of Evidence
This section addresses whether a post discharge limb compression device (commonly referred to in the literature as an IPC device) use in moderate-to-high risk patients with a contraindication to pharmacologic prophylaxis improves the net health outcome compared with no post-discharge VTE prophylaxis. The ideal study design is an RCT

comparing limb compression devices with no prophylaxis after hospital discharge. However, there may be ethical and practical barriers to conducting such a study, especially in higher-risk patients. Alternatively, a network meta-analysis could indirectly compare outcomes of limb compression device use with no VTE prophylaxis. One RCT of post-discharge use in patients with contraindication to pharmacologic prophylaxis was identified. Briefly summarized below are data from inpatients comparing limb compression device use to no prophylaxis.

Systematic Reviews

A few meta-analyses of RCTs have compared IPC devices to no prophylaxis in the hospital setting. Populations include surgical and nonsurgical patients, including critically ill patients in a medical or surgical intensive care unit (ICU). Commonly reported outcomes include the occurrence of DVT and PE. As with the meta-analyses reviewed above, there was heterogeneity of participants and interventions. Studies using a no prophylaxis control group might have included lower-risk patients and some studies involving higher-risk patients also included pharmacologic prophylaxis across groups. Overall, findings from meta-analyses suggest that the in-hospital addition of an IPC device improves VTE prophylaxis over no prophylaxis, especially for the prevention of DVT; 2 of the 3 meta-analyses also saw statistically significant reductions in the incidence of PE.

Randomized Controlled Trials

To draw inferences about the benefit of limb compression devices post-discharge in these patients, the feasibility of home use should be considered. An unblinded RCT by Sobieraj-Teague et al. (2012) compared the use of a portable battery-operated IPC device with usual care alone in patients undergoing cranial or spinal neurosurgery. All patients were also prescribed graduated compression stockings and 20% to 25% used anticoagulants. Patients were evaluated at 9 days postsurgery, and those discharged earlier were permitted to use an IPC device at home (median duration of hospitalization, 4 days). Patients who used the IPC device post-discharge received home visits at least daily to optimize compliance. Three (4%) of 75 patients in the IPC group and 14 (19%) of 75 patients in the usual care group developed VTE; the difference between groups was statistically significant (p=.008). Among evaluable patients in the IPC group, 23.3% were continuous users, 53.4% were intermittent users, and 23.3% discontinued use (this includes both inpatient and outpatient use). The mean duration of IPC device use was 6.6 days. Findings would suggest that in-home use of IPC devices is feasible with adequate post-discharge planning and support.

Section Summary: Moderate-to-High Postsurgical Risk of Venous Thromboembolism and a Contraindication to Pharmacologic Prophylaxis

For individuals who have a moderate-to-high postsurgical risk of VTE and a contraindication to pharmacologic prophylaxis who receive home use of an IPC device, there is 1 RCT assessing the evaluated the feasibility of post-discharge home use of an IPC incremental benefit of home use of an IPC device. A few meta-analyses of RCTs have compared VTE prophylaxis with an IPC device to no prophylaxis in surgical

patients in the hospital setting, and 1 RCT evaluated the feasibility of post-discharge home use of an IPC. Relevant outcomes are overall survival, symptoms, morbid events, and treatment-related morbidity. Results from meta-analyses suggest that in-hospital use of an IPC device improves VTE prophylaxis over no prophylaxis. Limitations include heterogeneity of participants and interventions; studies using a no prophylaxis control group might have included lower risk patients and some studies involving higher risk patients also included pharmacologic prophylaxis across groups. Nonetheless, the inference is supported that in patients with a contraindication to pharmacologic prophylaxis, post-discharge use of an IPC device is superior for VTE prophylaxis compared with no prophylaxis. A study of the post discharge use of an IPC device combined with home visits showed that home use is feasible. With post discharge planning and support, home use of an IPC device in moderate-to-high risk patients who have a contraindication to pharmacologic prophylaxis is likely to improve VTE prevention.

For individuals who have a moderate-to-high postsurgical risk of VTE and a contraindication to pharmacologic prophylaxis who receive home use of an IPC device, there are no RCTs assessing the incremental benefit of home use of an IPC device. Meta-analyses of RCTs have compared VTE prophylaxis with an IPC device to no prophylaxis in surgical patients in the hospital setting, and 1 RCT evaluated the feasibility of post discharge home use of an IPC device. Relevant outcomes are overall survival, symptoms, morbid events, and treatment-related morbidity. Results from meta-analyses suggest that in-hospital use of an IPC device improves VTE prophylaxis over no prophylaxis. Limitations include heterogeneity of participants and interventions; studies using a no prophylaxis control group might have included lower risk patients and some studies involving higher risk patients also included pharmacologic prophylaxis across groups. Nonetheless, the inference is supported that in patients with a contraindication to pharmacologic prophylaxis, post-discharge use of an IPC device is superior for VTE prophylaxis compared with no prophylaxis. A study of the post discharge use of an IPC device combined with home visits showed that home use is feasible. With post discharge planning and support, home use of an IPC device in moderate-to-high risk patients who have a contraindication to pharmacologic prophylaxis is likely to improve VTE prevention. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Other Indications:

Arterial Insufficiency: (2005) Current evidence supporting the use of pneumatic compression devices in peripheral arterial disease is limited to small pilot studies with short-term follow up. In a pilot study (n = 30), Ramaswami et al examined the usefulness of rapid, high-pressure, intermittent pneumatic calf and foot compression (IPCFC) in patients with stable intermittent claudication. These investigators concluded that “IPCFC improves walking distance in patients with stable intermittent claudication. The combination of IPCFC with other treatment such as risk-factor modification and daily

exercise may prove useful in patients with peripheral arterial occlusive disease. It may be a useful first line of therapy in patients with disabling claudication who are unfit for major reconstructive surgery. Improved walking on long-term follow-up and experience from different centers may establish a role for this treatment modality in the future".

(2005) Kakkos et al compared the effect of unsupervised exercise, supervised exercise and IPCFC on the claudication distance, lower limb arterial hemodynamics and quality of life of patients with intermittent claudication (n = 34). These researchers concluded that IPCFC achieved improvement in walking distance comparable with supervised exercise. Long-term results in a larger number of patients will provide valuable information on the optimal treatment modality of intermittent claudication.

Diabetic Ulcers: (2014) Evidence from two RCTs, examined by two SRs and one set of guidelines included in this report, suggest that IPC and compressed air massage improve clinical outcomes for DFU patients. One RCT, examining compressed air massage, found a significant reduction in the time to healing, but not in numbers receiving skin grafts or amputation rates. The average time to DFU healing was 58.1 days in those patients receiving compressed air massage, while those patients receiving only standard wound care averaged 82.7 days until ulcer healing. Time to healing was also significantly faster in treated patients who underwent skin grafting or amputation compared to untreated patients in these subgroups. The other RCT found a significant increase in healing efficacy and that this efficacy also had a statistically significant dependence on patient compliance with IPC therapy. After 12 weeks of therapy, 75% of patients receiving IPC had healed DFUs whereas only 51% of patients receiving the sham treatment were healed. In patients defined as compliant, (patients undergoing 50+ hours of compression therapy weekly), 100% of patients had healed DFUs at 12 weeks. There was no statistically significant difference in compliance, as defined previously, between treatment and placebo groups and averaged 20%.7 This RCT also found that significant edema reduction was achieved in the study arm receiving IPC therapy.

No relevant cost-effectiveness evidence was identified.

While the identified guidelines included an SR to examine the clinical effectiveness of compression therapy of DFU no relevant evidence-based guidelines were formulated. Although not an evidence-based recommendation, an evidence of Grade C was given to the statement, "The evidence suggests that foot compression in addition to standard wound care is more effective for healing of infected diabetic foot ulcers than standard care alone." These guidelines identified the same evidence, from two RCTs, as identified in the two SRs. In these guidelines, the RCT also included in the most recent SR was noted as not observing any benefits of compression massage in the rate of amputation, only the time to healing without considering those patients lost to follow-up. This study was not used to support the evidence statement due to insufficient quality. The other RCT was of higher quality and used to support the evidence statement. The guidelines states that this trial demonstrated good external validity and that IPC is shown to have a significant and clinically important advantage over the non-functioning placebo device.

No convincing consensus on the clinical effectiveness of compression therapy for the treatment of DFUs was identified because only data from one good quality trial was identified. This trial did not quantify or mention any adverse event outcomes.6 Identified evidence was limited to IPC therapy and compressed air massage, no evidence was available on other compression therapy interventions for DFU treatment. No cost-effectiveness data or evidence-based recommendations were identified for compression therapy of DFUs.

Femoro-Popliteal Bypass Surgery: (2011) te Slaa et al utilized a prospective, randomized trial, examined the effects of Intermittent pneumatic compression (IPC) for the treatment and prevention of post-reconstructive edema following femoro-popliteal bypass surgery. Patients were assigned to one of two groups. All patients suffered from peripheral arterial disease, and all were subjected to autologous femoro-popliteal bypass reconstruction. Patients in group one used a compression stocking (CS) above the knee exerting 18 mm Hg (class I) on the leg post-operatively for one week (day and night). Patients in group 2 used IPC on the foot post-operatively at night for one week. The lower leg circumference was measured pre-operatively and at 5 post-operative time points. A multi-variate analysis was done using a mixed model analysis of variance. A total of 57 patients were analyzed (n = 28 for CS; n = 29 for IPC). Indications for operation were severe claudication (CS 13; IPC 13), rest pain (10/5), or tissue loss (7/11). Re-vascularization was performed with either a supra-genicular (CS 13; IPC 10) or an infra-genicular (CS 15; IPC 19) autologous bypass. Leg circumference increased on day 1 (CS/IPC): 0.4 %/2.7 %, day 4 (2.1 %/6.1 %), day 7 (2.5 %/7.9 %), day 14 (4.7 %/7.3 %), and day 90 (1.0 %/3.3 %) from baseline (pre-operative situation). On days 1, 4, and 7 there was a significant difference in leg circumference between the 2 treatment groups. The authors concluded that edema following femoro-popliteal bypass surgery occurs in all patients. For the prevention and treatment of edema following femoro-popliteal bypass surgery, the use of a class I CS proved superior to treatment with IPC. The authors concluded that the use of CS remains the recommended practice following femoro-popliteal bypass surgery.

Fracture: (2008) Khanna et al stated that current methods of fracture care use various adjuncts to try and decrease time to fracture union, improve fracture union rates and enhance functional recovery; and one such modality is IPC. These researchers performed a literature review on this approach. A total of 16 studies on the use of IPC in fracture and soft-tissue healing were identified. These studies demonstrated that IPC facilitates both fracture and soft tissue healing with rapid functional recovery. The authors concluded that IPC appears to be an effective modality to enhance fracture and soft-tissue healing. Moreover, they noted that the number of subjects in human studies is small, and adequately powered RCTs are needed to produce stronger clinically relevant evidence.

(2006) Handoll et al examined the effects of rehabilitation interventions in adults with conservatively or surgically treated distal radial fractures. These investigators searched the Cochrane Bone, Joint and Muscle Trauma Group Specialised Register (December 2005), the Cochrane Central Register of Controlled Trials (The Cochrane Library Issue 4,

2005), MEDLINE, EMBASE, CINAHL, AMED, PEDro, OTseeker and other databases, conference proceedings and reference lists of articles. No language restrictions were applied. Randomized or quasi-RCTs evaluating rehabilitation as part of the management of fractures of the distal radius sustained by adults. Rehabilitation interventions such as active and passive mobilization exercises, and training for activities of daily living, could be used on their own or in combination, and be applied in various ways by various clinicians. The authors independently selected and reviewed trials. Study authors were contacted for additional information. No data pooling was done. A total of 15 trials, involving 746 mainly female and older patients, were included. Initial treatment was conservative, involving plaster cast immobilization, in all but 27 participants whose fractures were fixed surgically. Though some trials were well-conducted, others were methodologically compromised. For interventions started during immobilization, there was weak evidence of improved hand function for hand therapy in the days after plaster cast removal, with some beneficial effects continuing 1 month later (1 trial). There was weak evidence of improved hand function in the short-term, but not in the longer term (3 months), for early occupational therapy (1 trial), and of a lack of differences in outcome between supervised and unsupervised exercises (1 trial). For interventions started post-immobilization, there was weak evidence of a lack of clinically significant differences in outcome in patients receiving formal rehabilitation therapy (4 trials), passive mobilization (2 trials), ice or pulsed electromagnetic field (1 trial), or whirlpool immersion (1 trial) compared with no intervention. There was weak evidence of a short-term benefit of continuous passive motion (post-external fixation) (1 trial), IPC (1 trial) and ultrasound (1 trial). There was weak evidence of better short-term hand function in participants given physiotherapy than in those given instructions for home exercises by a surgeon (1 trial). The authors concluded that the available evidence from RCTs is insufficient to establish the relative effectiveness of the various interventions used in the rehabilitation of adults with fractures of the distal radius.

Restless Leg Syndrome: (2009) In a prospective, randomized, double-blinded, sham-controlled trial, Lettieri and Eliasson (evaluated the effectiveness of pneumatic compression devices (PCDs) as a non-pharmacologic treatment for restless legs syndrome (RLS). Subjects wore a therapeutic or sham device prior to the usual onset of symptoms for a minimum of 1 hour daily. Measures of severity of illness, quality of life, daytime sleepiness, and fatigue were compared at baseline and after 1 month of therapy. A total of 35 subjects were enrolled. Groups were similar at baseline. Therapeutic PCDs significantly improved all measured variables more than shams. Restless legs severity score improved from 14.1 +/- 3.9 to 8.4 +/- 3.4 ($p = 0.006$) and Johns Hopkins restless legs scale improved from 2.2 +/- 0.5 to 1.2 +/- 0.7 ($p = 0.01$). All quality-of-life domains improved more with therapeutic than sham devices (social function 14 % versus 1 %, respectively; $p = 0.03$; daytime function 21 % versus 6 %, respectively, $p = 0.02$; sleep quality 16 % versus 8 %, respectively, $p = 0.05$; emotional well-being 17 % versus 10 %, respectively, $p = 0.15$). Both Epworth sleepiness scale (6.5 +/- 4.0 versus 11.3 +/- 3.9, respectively, $p = 0.04$) and fatigue (4.1 +/- 2.1 versus 6.9 +/- 2.0, respectively, $p = 0.01$) improved more with therapeutic devices than sham devices. Complete relief occurred in 1/3 of subjects using therapeutic and in no subjects using sham devices. The authors

concluded that PCDs resulted in clinically significant improvements in symptoms of RLS in comparison to the use of sham devices and may be an effective adjunctive or alternative therapy for RLS. Moreover, the authors stated that before PCD therapy is ready for more wide-spread use, it will be important to see validating studies in various populations of RLS patients.

Stroke: (2010) Doyle et al examined the effects of interventions that target upper limb sensory impairment after stroke. These investigators searched the Cochrane Stroke Group Trials Register (last searched October 8, 2009), the Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library 2009, Issue 1), MEDLINE (1966 to January 2009), EMBASE (1980 to January 2009), and 6 further electronic databases to January 2009. They also hand-searched relevant journals, contacted authors in the field, searched doctoral dissertation databases, checked reference lists, and completed citation tracking. Randomized controlled trials and controlled trials comparing interventions for sensory impairment after stroke with no treatment, conventional treatment, attention placebo or with other interventions for sensory impairment were included in this analysis. Two review authors selected studies, assessed quality and extracted data. They analyzed study data using mean differences and odds ratios as appropriate. The primary outcome was sensory function; and secondary outcomes included upper limb function, activities of daily living, impact of stroke and quality of life as well as adverse events. These researchers included 13 studies, with a total 467 participants, testing a range of different interventions. Outcome measures included 36 measures of sensory impairment and 13 measures of upper limb function. All but 2 studies had unclear or high-risk of bias. While there is insufficient evidence to reach conclusions about the effects of interventions included in this review, 3 studies provided preliminary evidence for the effects of some specific interventions, including mirror therapy for improving detection of light touch, pressure and temperature pain; a thermal stimulation intervention for improving rate of recovery of sensation; and IPC intervention for improving tactile and kinesthetic sensation. These researchers could not perform meta-analysis due to a high degree of clinical heterogeneity in both interventions and outcomes. The authors concluded that there is insufficient evidence to support or refute the effectiveness of the described interventions in improving sensory impairment, upper limb function, or participants' functional status and participation. Moreover, they stated that there is a need for more well-designed, better-reported studies of sensory rehabilitation.

(2003) In a preliminary study, Cambier et al evaluated the effectiveness of IPC in treating sensory impairments in the hemiplegic upper limb in stroke patients. A total of 23 stroke patients were enrolled in this RCT that compared the application of IPC with a passive treatment strategy. The experimental group (n = 11) received standard physiotherapy combined with IPC treatment (10 cycles of 3 mins with a peak of 40 mmHg) for their hemiplegic upper limb. The control group (n = 12) received supplementary to their conventional physiotherapy a placebo treatment, namely sham short-wave therapy on the hemiplegic shoulder for 30 mins. Sensory impairments were clinically assessed at 3 occasions over a period of 4 weeks using the Nottingham Sensory Assessment scale. Both groups improved in somato-sensation over time, but the experimental group

improved more than the control group (p = 0.036) or 81.1% improvement versus 30.9 %. The authors concluded that the use of IPC in the rehabilitation of stroke patients may be of clinical importance for the restoration of sensory function. Drawbacks of this study included small sample size and short follow-up period.

Upper Extremity Vascular Ulcers: (2005) Pfizenmaier et al. noted that ischemic vascular ulcerations of the upper extremities are an uncommon and frequently painful condition most often associated with scleroderma and small vessel inflammatory diseases. Digital amputation has been advocated as primary therapy because of the poor outcome with medical care. Intermittent pneumatic compression pump therapy can improve ulcer healing in lower extremity ischemic ulcerations; however, the value of this treatment in upper extremity ischemic ulcerations is not known. This observational pilot study consisted of a consecutive series of 26 patients with 27 upper extremity ischemic vascular ulcers seen at the Mayo Gonda Vascular Center from 1996 to 2003. Inclusion criteria were documented index of ulcer size and follow-up ulcer size and use of the IPC pump as adjunctive wound treatment. Twenty-six of 27 ulcers (96 %) healed with the use of the IPC pump. Mean baseline ulcer size was 1.0 cm2 (SD = 0.3 cm2) and scleroderma was the underlying disease in 65 % (17/26) of cases. Laser Doppler blood flow in the affected digit was 7 flux units (normal greater than 100). The mean ulcer duration before IPC treatment was 31 weeks. The average pump use was 5 hours per day. The mean time to wound healing was 25 weeks. Twenty-five of 26 patients reported an improvement in wound pain with pump use. The authors concluded that intensive IPC pump use is feasible and associated with a high rate of healing in upper extremity ischemic ulcers. Furthermore, they stated that prospective, RCTs of IPC is needed to determine whether IPC treatment improves wound healing compared to standard medical care.

Summary of Evidence: Other Indications:
There is insufficient evidence in the published, scientific literature to support the safety and/or effectiveness of pneumatic compression devices in the treatment of other conditions (e.g., peripheral artery disease/arterial insufficiency, diabetic neuropathic ulcers of the lower extremities, fracture and soft-tissue healing, restless leg syndrome, rehabilitation for distal radial fracture, management of edema following femero-popliteal, treatment of sensory impairment in upper limb following a stroke and treatment of upper extremity vascular ulcers) and therefore, considered investigational.

Practice Guidelines and Position Statements
American Academy of Orthopaedic Surgeons (AAOS)
(2011) The AAOS updated its guidelines on the prevention of VTE in patients undergoing elective hip and knee arthroplasty. The guidelines included the following recommendations relevant to this evidence review:

- "The work group suggests the use of pharmacologic agents and/or mechanical compressive devices for the prevention of venous thromboembolism in patients undergoing elective hip or knee arthroplasty, and who are not at

elevated risk beyond that of the surgery itself for venous thromboembolism or bleeding. (Grade of Recommendation: Moderate) Current evidence is unclear about which prophylactic strategy (or strategies) is/are optimal or suboptimal. Therefore, the work group is unable to recommend for or against specific prophylactics in these patients. (Grade of Recommendation: Inconclusive) In the absence of reliable evidence about how long to employ these prophylactic strategies, it is the opinion of this work group that patients and physicians discuss the duration of prophylaxis. (Grade of Recommendation: Consensus)

- In the absence of reliable evidence, it is the opinion of this work group that patients undergoing elective hip or knee arthroplasty, and who have also had a previous venous thromboembolism, receive pharmacologic prophylaxis and mechanical compressive devices. (Grade of Recommendation: Consensus)
- In the absence of reliable evidence, it is the opinion of this work group that patients undergoing elective hip or knee arthroplasty, and who also have a known bleeding disorder (e.g., hemophilia) and/or active liver disease, use mechanical compressive devices for preventing venous thromboembolism. (Grade of Recommendation: Consensus)" (*Accessed September 2022*)

AHRQ (Agency for Healthcare Research and Quality)
(2010) A technology assessment requested by Centers for Medicare and Medicaid Services (CMS) conducted by McMaster University Evidence-based Practice Center for the Agency for Healthcare Research and Quality (AHRQ) diagnosis and treatment of secondary lymphedema. The review included randomized controlled trials or observation studies with comparison groups (e.g., cohort, case control). The assessment included the following:

Regarding the question of whether one type of pneumatic compression device and sleeve (e.g., non-segmented compression device, sequential segmented compression , or segmented compression with calibrated gradient pressure) is more effective in reducing lymphedema than another for any type of lymphedema along the continuum, or patient characteristics—the review found that there was a lack of evidence from which to determine whether one type of intermittent pneumatic compression device and sleeve were more effective in reducing lymphedema based on specific sets of patient characteristics:

- There was no evidence concerning the optimal criteria to initiate or stop treatment for secondary lymphedema.
- There was significant heterogeneity in terms of treatments, inclusion and exclusion criteria, and treatment protocols to suggest the optimality of one type of treatment over another.
- There is no evidence to suggest an optimal frequency or duration of treatment, the most efficacious treatment combinations, the length of time for which persons should be tested or treatment for lymphedema and whether certain tests or treatments may benefit some types of patients more than others. (*Accessed September 2022*)

American College of Chest Physicians (CHEST)
In 2016, the American College of Chest Physicians (ACCP) updated its 2012 evidence-based guideline, on antithrombotic therapy and prevention of thrombosis. There was a second update to these guidelines in 2021, however, there was no new information for the prevention of thrombosis or mention of the use of limb compression devices. The 2016 update, which addressed antithrombotic therapy for venous thromboembolism (VTE), outlined risk factors for bleeding with anticoagulant therapy and estimated the risks of major bleeding for patients in various risk categories (see Table 1) (*Accessed September 2022*)

Risk factors include (1 point per factor):

- Age >65 y
- Age >75 y
- Previous bleeding
- Cancer
- Metastatic cancer
- Renal failure
- Liver failure
- Thrombocytopenia
- Previous stroke
- Diabetes
- Anemia
- Antiplatelet therapy
- Poor anticoagulant control
- Comorbidity and reduced functional capacity
- Recent surgery
- Frequent falls
- Alcohol abuse
- Nonsteroidal anti-inflammatory drugs.

Table 1. Guidelines for Risk of Bleeding

Risk Factors	**Estimated Absolute Risk of Major Bleeding**		
	Low Risk (0 Risk Factors)	*Moderate Risk (1 Risk Factor)*	*High Risk (≥2 Risk Factors)*
Anticoagulation 0-3 mo, %			
Baseline risk	0.6	1.2	4.8
Increased risk	1.0	2.0	8.0
Total risk	1.6	3.2	12.8

Risk Factors	Estimated Absolute Risk of Major Bleeding		
	Low Risk (0 Risk Factors)	*Moderate Risk (1 Risk Factor)*	*High Risk (≥2 Risk Factors)*
Anticoagulation after first 3 mo, %/y			
Baseline risk	0.3	0.6	≥2.5
Increased risk	0.5	1.0	≥4.0
Total risk	0.8	1.6	≥6.5

Adapted from Kearon et al (2016).

In 2012, the CHEST recommendations on the use of limb compression devices in nonorthopedic general and abdominal-pelvic surgical patients, stratified by patient risk of VTE and risk of bleeding are listed in Table 2.

Table 2. Recommendations on Limb Compression Device Use in Nonorthopedic General and Abdominal-Pelvic Surgical Patients (Accessed September 2021)

Patient Risk Group	Recommendation
Very low risk (<0.5%)	"[W]e recommend that no specific pharmacologic or mechanical prophylaxis be used other than early ambulation."
Low risk for VTE (~1.5%)	"[W]e suggest mechanical prophylaxis, preferably with intermittent pneumatic compression (IPC), over no prophylaxis."
Moderate risk for VTE (~3%) and not at high risk of bleeding	"[W]e suggest low-molecular-weight heparin (LMWH), low-dose unfractionated heparin, or mechanical prophylaxis with IPC over no prophylaxis."
Moderate risk for VTE (~3%) and high risk for major bleeding complications or in whom bleeding consequences would be particularly severe	"We suggest mechanical prophylaxis, preferably with IPC, over no prophylaxis."
High risk for VTE (~6.0%) and not at high risk of bleeding	"[W]e recommend pharmacologic prophylaxis with LMWH or low-dose unfractionated heparin over no prophylaxis. In these patients, we suggest adding mechanical prophylaxis with elastic stockings or IPC to pharmacologic prophylaxis."
High risk for VTE (~6.0%) and high risk for major bleeding complications	"[W]e suggest use of mechanical prophylaxis, preferably with IPC, over no prophylaxis until the

Patient Risk Group	Recommendation
or in whom bleeding consequences would be particularly severe	risk of bleeding diminishes and pharmacologic prophylaxis may be initiated."
High risk for VTE, both LMWH and unfractionated heparin contraindicated or unavailable and not at high risk for major bleeding complications:	"[W]e suggest low-dose aspirin, fondaparinux, or mechanical prophylaxis, preferably with IPC, over no prophylaxis."
High risk for VTE, undergoing abdominal or pelvic surgery for cancer and not otherwise at high risk for major bleeding complications	"[W]e recommend extended-duration, postoperative, pharmacologic prophylaxis (4 weeks) with LMWH over limited-duration prophylaxis."

Adapted from Gould et al (2012) IPC: intermittent pneumatic compression; LMWH: low molecular weight heparin; VTE: venous thromboembolism.

Note: The recommendation for patients with contraindications to pharmacologic prophylaxis who are undergoing major orthopedic surgery (total hip arthroplasty, total knee arthroplasty, hip fracture surgery), the guidelines are consistent with use of intermittent limb compression devices for 10 to 14 days after surgery.

The suggestion on extended prophylaxis (up to 35 days) was a weak recommendation that did not mention limb compression devices as an option. that a standard duration of prophylaxis was not defined. Limited duration prophylaxis was defined as lasting 1 week. An "extended-duration" prophylaxis was defined as lasting 4 weeks.

American College of Obstetricians and Gynecologists (ACOG)
(2007; reaffirmed 2021) ACOG updated its practice bulletin on Prevention of Venous Thromboembolism in Gynecologic Surgery. Prophylaxis recommendations varied by patient risk level.

- Level B (based on limited or inconsistent scientific evidence) For gynecologic surgery patients at high risk of VTE and major bleeding complications, and for whom both LMWH and low dose unfractionated heparin are contraindicated, or not available, mechanical prophylaxis alone (preferably with intermittent pneumatic compression) is recommended until the risk of bleeding diminishes and pharmacologic prophylaxis with fondaparinux can be added. (*Accessed September 2022*)

For patients at moderate and high-risk of DVT, intermittent pneumatic compression (IPC) was one of the recommended options for DVT prophylaxis. For patients at highest risk (i.e., > 60 years plus prior VTE, cancer, or molecular hyper coagulable state), IPC or graduated compression stockings plus low-dose unfractionated heparin or low-molecular-weight heparin were recommended as prophylactic options. For all but the highest risk patients, the practice bulletin stated that, when IPC devices were used, "the devices

should be used continuously until ambulation and discontinued only at the time of hospital discharge." For the highest risk patients, the bulletin stated that continuing prophylaxis for 2 to 4 weeks after discharge should be considered.

American Orthopaedic Foot and Ankle Society (AOFAS)
(2020) The AOFAS re-approved a position statement on VTE prophylaxis after foot and ankle surgery. It stated: "There is currently insufficient data for the AOFAS to recommend for or against routine VTED prophylaxis for patients undergoing foot and ankle surgery. Further research in this field is necessary and is encouraged." The position statement further notes the following with regards to the use of mechanical prophylaxis: "Mechanical prophylaxis such as elastic compression stockings and sequential compression calf pumps or foot pumps on the contralateral extremity can be utilized intraoperatively and continued postoperatively through the duration of the hospital stay. While the true efficacy of this modality in foot and ankle surgery is unknown, complications are negligible and compression pumps may be considered in both the outpatient and inpatient setting. Whether there is a threshold duration of the surgical procedure for which these are beneficial is unknown, as is the optimal duration of their use post-operatively." (*Accessed September 2022*)

American Society of Clinical Oncology (ASCO)
In 2019, the American Society of Clinical Oncology (ASCO) released updates to the clinical practice guideline on VTE prophylaxis and treatment in patients with cancer. The guideline makes the following recommendation for mechanical prophylaxis in this patient population:

- Recommendation 3.3.
    - "Mechanical methods may be added to pharmacologic thromboprophylaxis but should not be used as monotherapy for VTE prevention unless pharmacologic methods are contraindicated because of active bleeding or high bleeding risk (Type: evidence based; Evidence quality: intermediate; Strength of recommendation: strong) "

- Recommendation 3.4.
    - "A combined regimen of pharmacologic and mechanical prophylaxis may improve efficacy, especially in the highest-risk patients (Type: evidence-based; Evidence quality: intermediate; Strength of recommendation: moderate)"

(*Accessed September 2022*)

Canadian Agency for Drugs and Technologies in Health (CADTH)
(2020) Rapid response on recommendations regarding the use of compression therapy for those with or at risk of lower body extremity wounds

- Patients undergoing major surgery are recommended to undergo mechanical prophylaxis, with pneumatic compression prophylaxis preferred over graduated compression stockings.
- Pneumatic compression devices or graduated compression stockings are suggested for VTE prophylaxis in acutely or critically ill medical patients (*Accessed September 2022*)

(2017) Rapid response: The evidence suggested that intermittent pneumatic compression (IPC) may not provide additional benefits when used in combination with routine management of lymphedema. No literature for the comparative clinical effectiveness between single chamber and multi-chamber IPC devices was identified. A 2014 evidence-based guideline recommended the short-term use of IPC in combination with a lymphedema treatment program for reducing breast cancer-related lymphedema. The evidence from the included systematic reviews and randomized controlled trials suggested that IPC may not provide additional benefits when used in combination with the routine management of lymphedema. (*Accessed September 2022)*

International Union of Phlebology (UIP)
(2013) A consensus statement from UIP 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-message, skin care, exercises, and, if desired, pneumatic compression therapy applied in the home. (*Accessed September 2022*)

National Comprehensive Cancer Network (NCCN)
(Version 1.2022) Guidelines on Survivorship: Lymphedema noted the following:
- Education, including self-care management, skin care and self-bandage.
- Refer to a certified lymphedema therapist (if available) for consideration of the following:
    - Fit for compression garments
    - Review the use of garments
    - Pneumatic compression for ongoing home management
- Progressive resistance training under supervision
- Manual lymphatic drainage
- Refer to a qualified therapist for range of motion exercises

(*Accessed September 2022*)

Society for Vascular Surgery (SVS)
(2014) A clinical practice guideline for the management of venous leg ulcers that states:
1. In a patient with a venous leg ulcer, the Committee recommends compression therapy over no compression therapy to increase venous leg ulcer healing rate. [Grade - 1; Level of Evidence - A]
2. In a patient with a healed venous leg ulcer, the Committee suggests compression therapy to decrease the risk of ulcer recurrence. [Grade - 2; Level of Evidence - B]

3. The Committee suggests the use of multicomponent compression bandage over single-component bandages for the treatment of venous leg ulcers. [Grade - 2; Level of Evidence - B]
4. In a patient with a venous leg ulcer and underlying arterial disease, the Committee does not suggest compression bandages or stockings if the ankle-brachial index is 0.5 or less or if absolute ankle pressure is less than 60 mm Hg. [Grade - 2; Level of Evidence - C]
5. The Committee suggests 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] (*Accessed September 2022*)

Wound Healing Society
(2015) A guideline from the Wound Healing Society states that for patients with venous ulcers, intermittent pneumatic pressure can be used with or without compression dressings and can provide another option in patients who cannot or will not use an adequate compression dressing system. (*Accessed September 2022*)

Regulatory Status
Devices and systems to perform pneumatic compression are regulated by the Food and Drug Administration (FDA) as Class II devices. A large number of numbers of pneumatic limb compression devices have been cleared by the FDA through the 510(k) process for the *home care setting*. See the following website for more information (product code JOW): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm *(Accessed September 16, 2022*)

Although the US Food and Drug Administration (FDA) has approved pneumatic compression therapy devices for **arterial insufficiency** (e.g., peripheral arterial occlusive disease, unreconstructable peripheral vascular disease), Wellmark Blue Cross & Blue Shield has determined that the safety and/or effectiveness of these devices cannot be established by review of the available published peer-reviewed literature.

PRIOR APPROVAL

Not applicable.

POLICY

Medically Necessary: Lymphedema Non-Programmable Pumps in the Home Setting
The use non-programmable/non-self-calibrated pneumatic compression devices in the *home setting* for the treatment of lymphedema applied to the **limb**, may be considered **medically necessary** when all of the following are met:

- The requested device meets the specific FDA approved indication; **and**
    - *Note: Search with product code JOW*

- The individual has been diagnosed with lymphedema. **and**
- The individual has documented *compliance* of a **four-week** trial of conservative therapy which includes:
    - Use of an appropriate compression bandage or compression garment providing 30 mmHg; **and**
    - Exercise; **and**
    - Elevation of the affected limb; **and**
    - The treating physician documents there has been no significant improvement, based on circumference measures, and significant symptoms remain after the trial of conservative therapy.

Medically Necessary: Lymphedema Programmable Pumps in the Home Setting
The use of programmable/self-calibrated pneumatic compression devices in the *home setting* for the treatment of lymphedema applied to the **limb** may be considered **medically necessary,** when **all of the following** criteria is met:

- The requested device meets the specific FDA approved indication; **and**
    - *Note: Search with product code JOW*
- The individual has been diagnosed with lymphedema*; **and***
- The individual's medical condition has failed to respond to therapy using non-programmable pneumatic compression devices; **or**
- The individual has clear documentation of unique characteristics that *prevent satisfactory pneumatic compression treatment* using non-programmable pneumatic compression devices.
    - *Note: This would only be considered for a small subset of patients with the following where nonprogrammable pumps cannot be utilized. (e.g., scarring, fibrosis, and contractures).*

Investigational: Lymphedema Pumps in the Home Setting
All other uses of pneumatic compression devices in the *home setting* are considered **investigational** including but not limited to the following because the evidence is insufficient to determine the improved effects of this technology on net health outcomes:

- Diabetic neuropathic ulcers
- Edema following femoro-popliteal bypass surgery
- Enhancing fracture and soft tissue healing
- Head/Neck edema involvement
- Indications not meeting the above criteria
- Peripheral artery disease/arterial insufficiency
- Rehabilitation for distal radial fracture
- Restless leg syndrome
- Treatment of sensory impairment in the upper limb following a stroke
- Treatment of upper extremity vascular ulcers
- Treatment of venous ulcers
- Truncal/Chest edema involvement
- Where edema is anticipated but not currently present

Medically Necessary: Postsurgical use in the Home Setting
The use of postsurgical *intermittent* or *non-programmable* compression devices for venous thromboembolism (VTE) prophylaxis of the **limb** in the *home setting* may be considered **medically necessary** in **one of the following** indications:

- After major orthopedic surgery (total hip arthroplasty, total knee arthroplasty, hip fracture surgery) with a *contraindication* to pharmacologic agent: **or**
- After major non-orthopedic surgery or other orthopedic procedures with a *contraindication* to pharmacologic agents in individuals who are at moderate or high risk of venous thromboembolism (VTE) as defined by **one or more of the following**:
    - Age > 65 years old
    - Previous bleeding
    - Cancer
    - Metastatic cancer
    - Renal failure
    - Liver failure
    - Thrombocytopenia
    - Previous stroke
    - Diabetes
    - Anemia
    - Antiplatelet therapy
    - Poor anticoagulant control
    - Comorbidity and reduced functional capacity
    - Recent surgery
    - Frequent falls
    - Alcohol abuse
    - Nonsteroidal anti-inflammatory drugs; **and**
- The requested device meets the specific FDA approved indication
    - *Note: Search with product code JOW*

Investigational: Postsurgical use in the Home Setting
Postsurgical use of compression devices on the **limb** for venous thromboembolism (VTE) prophylaxis in the *home setting* is considered **investigational** for all other indications, including but not limited to the following:

- After major orthopedic surgery (e.g., total hip arthroplasty, total knee arthroplasty, hip fracture surgery) in patients *without* a contraindication to pharmacologic agents; **or**
- After major non-orthopedic surgery or other orthopedic procedures in patients without a contraindication to pharmacologic agents, who are at moderate or high risk of venous thromboembolism (VTE).

Postsurgical use of intermittent or non-programmable compression devices for the management of surgical swelling/edema is considered **investigational** because the

evidence is insufficient to determine the technology results in an improvement in net health outcomes.

Policy Guidelines

Contraindications to Anticoagulants
The main contraindication to anticoagulants is a high risk of bleeding. However, there is no absolute threshold at which anticoagulants cannot be used. Rather, there is a risk-benefit continuum that takes into account the benefits of treatment and risks of bleeding. There may also be intolerance to specific agents, although uncommon. Intolerance may result from allergic reactions or adverse events. Finally, when heparin preparations are used, serum antibodies and heparin-induced thrombocytosis can develop, precluding further use of heparin products.

Claims for Pneumatic Compression Devices
Claims for pneumatic compression devices are coded with two HCPCS codes:

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

Some examples are included but not limited to the following:

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:
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

PROCEDURE CODES AND BILLING GUIDELINES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnosis codes.

- 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
- E0670 Segmental pneumatic appliance for use with pneumatic compressor, integrated, 2 full legs and trunk
- E0671 Segmental gradient pressure pneumatic appliance, full leg
- E0672 Segmental gradient pressure pneumatic appliance, full arm
- E0673 Segmental gradient pressure pneumatic appliance, half leg
- E0675 Pneumatic compression device, high pressure, rapid inflation/deflation cycle, for arterial insufficiency (unilateral or bilateral system)
- E0676 Intermittent limb compression device (includes all accessories), not otherwise specified

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POLICY HISTORY

Date	Reason	Action
September 2022	Annual Review	Policy Revised
September 2021	Annual Review	Policy Revised
September 2020	Annual Review	Policy Revised
September 2019	Annual Review	Policy Revised
September 2018	Annual Review	Policy Revised
September 2017	Annual Review	Policy Revised
September 2016	Annual Review	Policy Revised
October 2015	Annual Review	Policy Revised
November 2014	Annual Review	Policy Revised
January 2014	Annual Review	Policy Revised
January 2013	Annual Review	Policy Renewed
February 2012	Annual Review	Policy Renewed
March 2011	Interim Review	Policy Revised

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

Wellmark Blue Cross and Blue Shield
Medical Policy Analyst
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