01.01.17 Pneumatic Compression Devices in the Home Setting

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- Related Policies
- 02.01.57 Bioimpedance Devices for Detection and Management of Lymphedema
- 01.01.25 Noncontact Ultrasound Treatment for Wounds

Summary

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 pumps are proposed as a treatment for individuals with lymphedema who have failed conservative measures. They are also proposed to supplement standard care for individuals with venous ulcers. A variety of pumps are available; they can be single chamber (nonsegmented) or multichamber (segmented) and have varying designs and complexity.

Antithrombotic prophylaxis is recommended for surgical individuals at moderate-to-high risk of postoperative venous thromboembolism (VTE), including deep vein thrombosis (DVT) and pulmonary embolism (PE), based on the surgical procedure and/or individual 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 individual 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 individuals in the postoperative period as a method to reduce VTEs.

Summary of Evidence

Lymphedema of the Limb Only

For individuals who have lymphedema who failed to respond to conservative therapy who receive pneumatic compression pumps applied to limb only, the evidence includes randomized controlled trials (RCTs) and systematic reviews primarily focusing on upper-limb lymphedema secondary to breast cancer. Relevant outcomes are symptoms, change in disease status, functional outcomes, and quality of life. Most of these RCTs were deemed moderate-to-high quality by the Agency for Healthcare Research and Quality, and about half reported significant improvements with the use of pumps compared to conservative care. Recent meta-analyses indicate that incorporating intermittent pneumatic compression (IPC) with complete decongestive therapy can further enhance lymphedema management within four weeks post-treatment. Similar findings are observed when IPC is combined with decongestive lymphatic therapy compared to decongestive lymphatic therapy alone in managing upper limb lymphedema after breast cancer surgery, with the former combined regimen showing improved external rotation joint mobility. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Lymphedema of the Trunk and/or Chest as well as Limb

For individuals who have lymphedema who failed to respond to conservative therapy who receive pneumatic compression pumps applied to limb and chest and/or trunk, the evidence includes two RCTs of the Flexitouch system (Tactile Medical), published in 2012, comparing treatment with and without truncal involvement. Relevant outcomes are symptoms, change in disease status, functional outcomes, and quality of life. In one RCT, two (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 (eg, amount of fluid removed) rather than health outcomes (eg, functional status, quality of life). The second RCT did not find statistically significant differences between groups for any of the efficacy outcomes. The available evidence does not demonstrate that pumps treating the trunk or chest provide incremental improvement beyond that provided by pumps treating the affected limb only. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Lymphedema of the Head and Neck

For individuals who have lymphedema who failed to respond to conservative therapy who receive pneumatic compression pumps applied to the head and neck, the evidence includes one RCT and a systematic review to assess the use of pneumatic compression treatment for head and neck lymphedema. Relevant outcomes are symptoms, change in disease status, functional outcomes, and quality of life. The RCT, comparing treatment with a pneumatic compression pump along with lymphedema self-management compared to self-management alone, examined the feasibility, adherence, and safety of the Flexitouch advanced pneumatic compression device (APCD) by Tactile Medical. The findings showed some improvements in patient-reported outcomes and swelling, although adherence was

low, with only one patient using the device twice daily as prescribed. The systematic review also suggested benefits from using the APCD, and it was considered safe and feasible according to the observational studies that reported adverse events. Most studies included participants who had completed or were concurrently undergoing complete decongestive therapy. Out of the 5 observational studies included in the systematic review, four (80%) had potential conflicts of interest related to the funding source. The only study not sponsored by the industry highlighted difficulties in obtaining the APCD, with fewer than half of the patients receiving the device as prescribed. Further research with larger sample sizes and comparisons against the criterion standard of complete decongestive therapy is necessary to establish the efficacy of this treatment approach. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Venous Ulcers

For individuals who have venous ulcers who receive pneumatic compression pumps, the evidence includes RCTs and one systematic review. 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. A 2020 RCT compared lymphedema pumps with continuous compression did not find significant between-group differences in healing rates or durability of pain relief. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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

For individuals who have a moderate-to-high postsurgical risk of venous thromboembolism (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 randomized controlled trials (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 individuals 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 (DVT); sparse data on pulmonary embolism (PE); and results generally not being stratified by individual 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 individuals tend to be healthier than those in the hospital. Factors such as treatment consistency, duration, and application errors in use also differ in the home. The evidence is insufficient to determine that the technology results in an improvement in the net health outcomes.

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 one RCT assessing the benefit and feasibility of home use of an IPC device. Meta-analyses of RCTs have compared VTE prophylaxis with an IPC device to no prophylaxis in surgical individuals in the hospital setting. 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 individuals and some studies involving higher-risk individuals also included pharmacologic prophylaxis across groups. Nonetheless, the inference is supported that in individuals 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 individuals 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 outcomes.

Other Conditions

***Note**: Cooling devices may be considered a non-covered benefit, please refer to the member's benefit document.*

For individuals who receive 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 femoral popliteal, post-surgical pain and swelling, treatment of sensory impairment in upper limb following a stroke and treatment of upper extremity vascular ulcers) the evidence includes systematic reviews, randomized controlled trials and observational studies. Relevant outcomes are symptoms, change in disease status, morbid events, and quality of life. The RCTs found no significant reduction in pain or medication use compared with standard of care. Trial limitations included small sample size, lack of blinding and individual non-compliance. Further RCTs are warranted to include larger sample sizes, blinding and individual compliance. The role pneumatic compression therapy in the treatment of other conditions in the home setting is unclear. The clinical effectiveness of these devices cannot be determined, and further research is indicated. The evidence is insufficient to determine the technology results in an improvement in the net health outcomes.

Additional Information

None

OBJECTIVE

The objective of this evidence review is to:

- determine whether the use of limb compression devices in the home setting improves the net health outcome for individuals at risk of venous thromboembolism (VTE) in the postsurgical period **and/or;**
- evaluate whether the use of pneumatic compression pumps improves net health outcomes in individuals with lymphedema or venous ulcers.

PRIOR APPROVAL

Not applicable.

POLICY

Medically Necessary: Lymphedema Non-Programmable Pumps in the Home Setting

Nonprogrammable/non-self-calibrated pneumatic compression devices *home use* applied to the **limb** may be considered **medically necessary for** the treatment of lymphedema that has failed to respond to a **four-week** trial of conservative therapy with documented *compliance* to **all of the following**:

- 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

Programmable/self-calibrated pneumatic compression devices *home use* applied to the **limb** may be considered **medically necessary** for the treatment of lymphedema when **all of the following** criteria are met:

- The individual's medical condition has failed to respond to therapy using non-programmable pneumatic compression devices; **or**
- There is 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 individuals with the following where nonprogrammable pumps cannot be utilized. (e.g., significant 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:

- Diabetic neuropathic ulcers
- Edema following femoral popliteal bypass surgery
- Enhancing fracture and soft tissue healing
- Head/Neck
- 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

because the evidence is insufficient to determine the improved effects of this technology on net health outcomes.

Medically Necessary: Postsurgical use in the Home Setting

Postsurgical **home** use of *(intermittent* or *non-programmable)* **limb** compression devices for venous thromboembolism (VTE) prophylaxis of the may be considered **medically necessary** in individuals with a **contraindication** to pharmacologic agent(s) in **one of the following** situations:

- After major orthopedic surgery (total hip arthroplasty, total knee arthroplasty, hip fracture surgery): **or**
- After major non-orthopedic surgery or other orthopedic procedures 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

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 individuals *without* a contraindication to pharmacologic agents; **or**
- After major non-orthopedic surgery or other orthopedic procedures in individuals without a contraindication to pharmacologic agents, who are at moderate or high risk of venous thromboembolism (VTE).
- When the above criteria has not been met
- Postsurgical use of pneumatic compression devices for the management of surgical pain and/or swelling/edema

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.

Guidance on Determining High Risk for Bleeding

The American College of Chest Physicians (ACCP) guidelines on prevention of VTE in orthopedic surgery individuals listed the following general risk factors for bleeding.

- "Previous major bleeding (and previous bleeding risk similar to current risk)
- Severe renal failure
- Concomitant antiplatelet agent
- Surgical factors: a history of or difficult-to-control surgical bleeding during the current operative procedure, extensive surgical dissection, and revision surgery."

The guidelines indicated, however, that "…specific thresholds for using mechanical compression devices or no prophylaxis instead of anticoagulant thromboprophylaxis have not been established."

The 2016 ACCP guidelines addressing antithrombotic therapy for VTE disease outlined risk factors for bleeding with anticoagulant therapy and estimated the risks of major bleeding for individuals in various risk categories (see Table PG1).

Risk factors include (1 point per risk 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
- Alcohol abuse
- Nonsteroidal anti-inflammatory drug.”

Table PG1. 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
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).

Clinical guidelines from the American Academy of Orthopaedic Surgeons (AAOS) have indicated that: “Patients undergoing elective hip or knee arthroplasty are at risk for bleeding and bleeding-associated complications. In the absence of reliable evidence, it is the opinion of this work group that patients be assessed for known bleeding disorders like hemophilia for the presence of active liver disease which further increase the risk for bleeding and bleeding-associated complications. (Grade of Recommendation: Consensus) Current evidence is not clear about whether factors other than the presence of a known

bleeding disorder or active liver disease increase the chance of bleeding in these patients and, therefore, the work group is unable to recommend for or against using them to assess a patient's risk of bleeding. (Grade of Recommendation: Inconclusive)"

Guidance on Duration of Use

In individuals with contraindications to pharmacologic prophylaxis who are undergoing major orthopedic surgery (total hip arthroplasty, total knee arthroplasty, hip fracture surgery), ACCP guidelines are consistent with use of intermittent limb compression devices for 10 to 14 days after surgery. The ACCP suggestion on extended prophylaxis (up to 35 days) was a weak recommendation that did not mention limb compression devices as an option.

In the ACCP guidelines on VTE prophylaxis in individuals undergoing nonorthopedic surgery, the standard duration or "limited duration" of prophylaxis was not defined. However, "extended duration" pharmacologic prophylaxis was defined as 4 weeks, which was recommended only for individuals at high risk of VTE undergoing abdominal or pelvic surgery for cancer and not otherwise at high risk for major bleeding complications.

Guidance on Determining Risk Level for Nonorthopedic Surgery

The ACCP guidelines on prevention of VTE in nonorthopedic surgery individuals included the following discussion of risk levels:

"In patients undergoing general and abdominal-pelvic surgery, the risk of VTE varies depending on both patient-specific and procedure-specific factors. Examples of relatively low-risk procedures include laparoscopic cholecystectomy, appendectomy, transurethral prostatectomy, inguinal herniorrhaphy, and unilateral or bilateral mastectomy. Open-abdominal and open-pelvic procedures are associated with a higher risk of VTE. VTE risk appears to be highest for individuals undergoing abdominal or pelvic surgery for cancer….

Patient-specific factors also determine the risk of VTE, as demonstrated in several relatively large studies of VTE in mixed surgical populations. Independent risk factors in these studies include age > 60 years, prior VTE, and cancer; age ≥ 60 years, prior VTE, anesthesia ≥ 2 h, and bed rest ≥ 4 days; older age, male sex, longer length of hospital stay, and higher Charlson comorbidity score; and sepsis, pregnancy or postpartum state, central venous access, malignancy, prior VTE, and inpatient hospital stay > 2 days. In another study, most of the moderate to strong independent risk factors for VTE were surgical complications, including urinary tract infection, acute renal insufficiency, postoperative transfusion, perioperative myocardial infarction, and pneumonia."

The American College of Obstetricians and Gynecologists use the Caprini Risk Assessment Model to determine VTE risk level in individuals undergoing major gynecology surgery (see Table PG2); this tool was used in developing the ACCP guidelines on VTE prevention. Caprini scores of 1 to 2, 3 to 4, and 5 or higher indicate a low (1.5%), moderate (~3%), and high (~6%) risk of symptomatic VTE, respectively. The Caprini score is extensively used and has been validated in plastic surgery individuals and general surgery individuals, and the ACCP has defined each of these risk groups by the expected rate of VTE in a population of individuals undergoing general, abdominal-pelvic, bariatric, vascular, and plastic surgery without thromboprophylaxis.

Table PG2. Caprini Score to Assess Risk of Venous Thromboembolism

Points	Risk factors

1	Age 41–60 years Minor surgery BMI greater than 25 kg/m^2 Swollen legs Varicose veins Pregnancy or postpartum state History of unexplained or recurrent pregnancy losses (greater than 3) Oral contraceptive, hormone replacement, or selective estrogen receptor modulator use* Sepsis (less than 1 month) Serious lung disease, including pneumonia (less than 1 month) Abnormal pulmonary function Acute myocardial infarction Congestive heart failure (less than 1 month) History of inflammatory bowel disease Medical patient on bed rest
2	Age 61–74 years Major open surgery (greater than 45 minutes) Laparoscopic surgery (greater than 45 minutes) Malignancy Confined to bed (greater than 72 hours) Central venous access
3	Age 75 years or older History of VTE Family history of VTE Factor V Leiden Prothrombin 20210A Lupus anticoagulant Anticardiolipin antibodies Elevated serum homocysteine Heparin-induced thrombocytopenia Other congenital or acquired thrombophilia
4	Stroke (less than 1 month) Elective arthroplasty Hip, pelvis, or leg fracture Acute spinal cord injury (less than 1 month)

Adapted from Gould et al (2012).
BMI: body mass index; VTE: venous thromboembolism.

Coding

See the Codes table for details.

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

BACKGROUND

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 individuals with lymphedema who have failed conservative measures, to supplement the standard of care for individuals 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.

Lymphedema

Lymphedema is an accumulation of fluid due to disruption of lymphatic drainage. It is characterized by nonpitting swelling of an extremity or trunk, and is associated with wound healing impairment, recurrent skin infections, pain, and decreased quality of life. Lymphedema can be caused by congenital or inherited abnormalities in the lymphatic system (primary lymphedema) but is most often caused by acquired damage to the lymphatic system (secondary lymphedema). Breast cancer treatment (surgical removal of lymph nodes and radiotherapy) is one of the most common causes of secondary lymphedema. In a systematic review of 72 studies (N=29,612 women), DiSipio et al (2013) reported that nearly 20% of breast cancer survivors will develop arm lymphedema.1, The risk factors with robust evidence for the development of lymphedema included extensive surgical procedures (such as axillary lymph node dissection, a higher number of lymph nodes removed, and mastectomy) as well as being overweight or obese.

Diagnosis and Staging

A diagnosis of secondary lymphedema is based on history (e.g., cancer treatment, trauma) and physical examination (localized, progressive edema and asymmetric limb measurements) when other causes of edema can be excluded. Imaging, such as MRI, computed tomography, ultrasound, or lymphoscintigraphy, may be used to differentiate lymphedema from other causes of edema in diagnostically challenging cases.

Table 1 lists International Society of Lymphology guidance for staging lymphedema (2023) based on "softness" or "firmness" of the limb and the changes with an elevation of the limb.

Table 1. Recommendations for Staging Lymphedema

Stage	Description
Stage 0 (latent or subclinical)	Swelling is not yet evident despite impaired lymph transport, subtle alterations in tissue fluid/composition, and changes in subjective symptoms. It can be transitory and may exist months or years before overt edema occurs (Stages 1-lll).
Stage I (mild)	Early accumulation of fluid relatively high in protein content (e.g., in comparison with "venous" edema) which subsides with limb elevation. Pitting may occur. An increase in various types of proliferating cells may also be seen
Stage II (moderate)	Involves the permanent accumulation of pathologic solids such as fat and proteins and limb elevation alone rarely reduces tissue swelling, and pitting is manifest. Later in this stage, the limb may not pit as excess subcutaneous fat and fibrosis develop.
Stage III (severe)	Encompasses lymphostatic elephantiasis where pitting can be absent and trophic skin changes such as acanthosis, alterations in skin character and thickness, further deposition of fat and fibrosis, and warty overgrowths have developed. It should be noted that a limb may exhibit more than one stage, which may reflect alterations in different lymphatic territories.

Management and Treatment

Lymphedema is treated using elevation, compression, and exercise. Conservative therapy may consist of several features depending on the severity of the lymphedema. Individuals are educated on the

importance of self-care including hygiene practices to prevent infection, maintaining ideal body weight through diet and exercise, and limb elevation. Compression therapy consists of repeatedly applying padding and bandages or compression garments. Manual lymphatic drainage is a light pressure massage performed by trained physical therapists or by affected individuals designed to move fluid from obstructed areas into functioning lymph vessels and lymph nodes. Complete decongestive therapy is a multiphase treatment program involving all of the previously mentioned conservative treatment components at different intensities. Pneumatic compression pumps may also be considered as an adjunct to conservative therapy or as an alternative to self-manual lymphatic drainage in individuals who have difficulty performing self-manual lymphatic drainage. In individuals with more advanced lymphedema after fat deposition and tissue fibrosis has occurred, palliative surgery using reductive techniques such as liposuction may be performed.

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

Pneumatic compression pumps (PCPs) may be used in lymphedema or wound care clinics, purchased, or rented for home use; home use is addressed herein. PCPs 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 PCPs 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. PCPs are also proposed to supplement standard care for patients with venous ulcers.

Postsurgical

Orthopedic Surgery

Antithrombotic prophylaxis is recommended for surgical individuals at moderate-to-high risk of postoperative venous thromboembolism (VTE), including deep vein thrombosis (DVT) and pulmonary embolism (PE). Individuals may be classified as moderate-to-high risk of VTE based on the surgical procedure and/or individual characteristics. For some types of surgery, such as 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. The specific orthopedic procedures of concern are total knee arthroplasty, total hip arthroplasty, and hip fracture surgery. For these surgeries, all individuals undergoing the procedure are considered at high-risk for VTE.

Other surgeries with an increased risk of VTE include abdominal surgery, pelvic surgery, cancer surgery, and surgery for major trauma. For these types of surgeries, the risk varies. There are numerous individual-related risk factors such as increasing age, prior VTE, malignancy, pregnancy, and significant

comorbidities that can be used in conjunction with the type of surgery to determine risk. There are tools for assessing VTE risk in surgical individual, such as the modified Caprini Risk Assessment Model used in developing the 2012 American College of Chest Physicians (ACCP) guidelines on VTE prevention. However, in clinical practice, this and similar instruments are not regarded as definitive for the assessment of individual risk. Pharmacologic prophylaxis is indicated for individual at moderate-to-high risk for VTE. As described in the ACCP guidelines, there are preferred antithrombotic prophylaxis regimens according to procedure and individual risk characteristics.

Pharmacologic Prophylaxis

Pharmacologic prophylaxis is effective at reducing postoperative VTE but also has risks. The main risk is bleeding, although other adverse events such as allergic reactions and development of heparin antibodies can occur. Contraindications to pharmacologic prophylaxis include previous intolerance to these agents and increased risk of bleeding. Most individual undergoing major surgery will not have an increased risk of bleeding precluding the use of anticoagulants, because these individuals would also likely have had a contraindication to the surgery itself and, thus, are likely to avoid the procedure. However, there are some cases in which individual with a high bleeding risk will undergo major surgery, such as individuals with severe renal failure who require an essential procedure. Other individuals may develop contraindications during the episode of care. For example, individual who have excessive bleeding during or after surgery, or individuals who develop bleeding complications such as a gastrointestinal bleed, are considered to have a contraindication to anticoagulants. There are a few surgeries for which anticoagulants are contraindicated or avoided, most notably some neurosurgical procedures. Assessment and quantitation of bleeding risk can be performed using instruments such as the HAS-BLED scoring system, although these tools were not developed specifically for the postoperative period.

Major orthopedic surgeries have a high risk of DVT due to venous stasis of the lower limbs as a consequence of immobility during and after surgery. Also, direct venous wall damage associated with the surgical procedure itself may occur; DVTs are frequently asymptomatic and generally resolve when mobility is restored. However, some episodes of acute DVT can be associated with substantial morbidity and mortality. The most serious adverse consequence of acute DVT is PE, which can be fatal. Pulmonary embolism occurs when a DVT blood clot detaches and migrates to the lungs. Also, DVT may produce long-term vascular damage that leads to chronic venous insufficiency. Without thromboprophylaxis, the incidence of venographically detected DVT is approximately 42% to 57% after total hip replacement, and the risk of PE is approximately 1% to 28%.5, Other surgical individuals may be at increased risk of VTE during and after hospitalization. For example, it is estimated that rates of VTE without prophylaxis after gynecologic surgery are 15% to 40%.

Thus, antithrombotic prophylaxis is recommended for individuals undergoing major orthopedic surgery and other surgical procedures who are at increased risk of VTE. For individuals undergoing major orthopedic surgery, clinical practice guidelines published by the ACCP (2012) recommended that one of several pharmacologic agents or mechanical prophylaxis be provided rather than no thromboprophylaxis. The guidelines further recommended the use of pharmacologic prophylaxis during hospitalization, whether or not individuals are using a limb compression device. A minimum of 10 to 14 days of prophylaxis is recommended, a portion of which can be post-discharge home use.

Limb Compression Prophylaxis

The ACCP guidelines have also noted that compliance is a major issue with the home use of limb compression devices for thromboprophylaxis and recommended that, if this prophylactic option is selected, use should be limited to portable, battery-operated devices. Moreover, ACCP recommended that devices be used for 18 hours a day. A 2009 nonrandomized study found that there was better

compliance with a portable battery-operated limb compression device than with a nonmobile device when used by individuals in the *hospital* following hip or knee replacement surgery.

Nonorthopedic Surgery: Pharmacologic and Limb Compression Prophylaxis

The ACCP (2012) also issued guidelines on VTE prophylaxis in nonorthopedic surgery individuals. For individuals undergoing general or abdominal-pelvic surgery who have a risk of VTE of 3% or higher, the ACCP has recommended prophylaxis with pharmacologic agents or intermittent pneumatic compression (IPC) rather than no prophylaxis. For individuals at low risk for VTE (~1.5%), the guidelines have suggested mechanical prophylaxis. Unlike the guidelines on major orthopedic surgery, which recommend a minimum of 10 to 14 days of VTE prophylaxis, the guidelines on nonorthopedic surgery patients do not include a general timeframe for prophylaxis. They have, however, defined “extended duration” pharmacologic prophylaxis as lasting 4 weeks; the latter is recommended only for individuals at high risk for VTE, undergoing abdominal or pelvic surgery for cancer, and who are not otherwise at high risk for major bleeding complications.

National clinical guidelines have not specifically recommended the use of limb compression devices in the post-discharge home setting. However, given the availability of portable, battery-operated devices, there is interest in the home use of limb compression devices for VTE prevention following discharge from the hospital for major orthopedic and nonorthopedic surgery.

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).

A full listing of products cleared by the FDA can be found at the following link: 510(k) Premarket Notification (fda.gov)

RATIONALE

The evidence review was created in September 2009 and has been updated regularly with searches of the PubMed database. The most recent literature update was performed through May 2025.

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

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse

events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Pneumatic Compression Pumps Applied to Venous Ulcers

Clinical Context and Therapy Purpose

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

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

Populations

The relevant population of interest is individuals 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

RCTs and a systematic review have assessed the use of pneumatic compression treatment for venous ulcers. 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. A more recent small RCT comparing lymphedema pumps with continuous compression did not find significant between-group differences in healing rates.

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

Populations

The relevant population of interest is individuals 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

Systematic Reviews
Cheng et al. (2023) performed a systematic review and meta-analysis of 23 studies published through January 2023 (N=2147 participants) to evaluate rehabilitation interventions for lymphedema of the head and neck. The studies were categorized by type of intervention, encompassing standard lymphedema therapy (standard or modified CDT, early manual lymphatic drainage, focused exercise) and adjunct therapies (advanced pneumatic compression devices (APCDs), kinesio taping, photobiomodulation, acupuncture/moxibustion, sodium selenite supplement use\). Six studies (n=399 participants), including one RCT and five observational studies, assessed the Flexitouch APCD (Tactile Medical). The RCT by Ridner et al. (2021) detailed below (n=49) revealed that most participants, who had either finished CDT or lacked access to it, used the device for a single 32-minute session per day during the 8-week industry-sponsored trial, as opposed to the recommended two sessions per day. In the observational studies, the majority of participants also adhered to one 32-minute session daily. The duration of the intervention in these studies varied from a single session to six months. Most studies featured participants who had completed CDT or were concurrently undergoing CDT, while one study specifically noted that none of its participants used CDT. Four studies (80%) were funded by or had authors affiliated with Flexitouch. The single non-industry-sponsored study reported difficulties in obtaining the APCD, with only 35 (of 84) participants (42%) receiving the device as prescribed. Although the included studies showed benefits of using APCD, they had a high risk of bias and were therefore considered low-quality evidence. The Ridner RCT involved a 2-month intervention compared to a waitlist control group. This trial showed improvements in clinician-rated external lymphedema and subjective swallowing in the

APCD group, although no improvement was found in endoscopic assessments of internal lymphedema. The largest observational study, conducted by Gutierrez et al (2020) with 205 participants who had used the APCD for over 5 years following a diagnosis of head and neck cancer-associated lymphedema, reported subjective improvements in symptoms and function after APCD use. Overall, the current evidence does not provide sufficient information to determine the optimal timing, duration, and intensity of APCD use in the management of lymphedema associated with head and neck.

Randomized Controlled Trials

Ridner et al. (2021) (included in the above systematic review) evaluated the Flexitouch system for head and neck lymphedema in an open-label, randomized, wait-list controlled study. Patients were randomized to lymphedema self-management or lymphedema self-management plus the use of the Flexitouch system twice daily for 8 weeks. Patients were trained on use of the Flexitouch system and were instructed on time of use, which varied based upon size of garment and ranged from 23 to 45 minutes. Patients who were initially randomized to lymphedema self-management only could opt to continue on after the initial 8-week period to receive the Flexitouch system for a subsequent 8-week treatment period. A summary of the design and key results are included in Tables 1 and 2. Adherence to the device was low; at week 8, only 4 of the 19 patients still enrolled in the intervention group used the Flexitouch system as prescribed for at least 5 days (only 1 patient used it twice a day, every day).

Table 1: Summary of Key RCT Characteristics

Study	Countries	Sites	Dates	Participants	Interventions[a]	
					Active	Comparator
Ridner (2021)	US	2	NR	N=49 patients who had completed treatment for head and neck cancer with no active disease, had a clinical diagnosis of head and neck lymphedema, and had either already received lymphedema therapy or were unable to access therapy due to barriers (e.g., lack of insurance)	Lymphedema self-management plus the use of the Flexitouch system twice daily for 8 weeks (n=24)	Lymphedema self-management (n=25)

NR: not reported; RCT: randomized controlled trial.
[a]All patients were provided with a self-care kit that included a diary, self-care checklist, and calendar of future study appointments.

Table 2: Summary of Key RCT Results

Study	LSIDS-HN, change from baseline (median [IQR])	Swelling, median change from baseline in percentage grids with observable swelling	Adverse events

Ridner (2021)	Soft tissue	Neurological	Activity	Function	Front view	Right view	Left view	
Lymphedema self-management plus Flexitouch system (n=19)	-2.0 [-2, 0]	0.0 [-2, 0]	0.0 [-3, 0]	0.0 [-1, +1]	-24%	-22%	-17%	4 serious adverse events reported (considered unrelated to device use)
Lymphedema self-management only (n=24)	0.0 [0, +2]	0.0 [0, +2]	0.0 [-3, +1]	0.0 [-1, +2]	+5%	-7%	-4%	-
p-value	.004	.047	.08	.479	<.001	.004	.005	

IQR: interquartile range; LSIDS-HN: Lymphedema Symptom Intensity and Distress Survey-Head and Neck; RCT: randomized controlled trial.

The tables below are notable limitations identified in the study.

Table 3: Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-up[e]
Ridner (2021)		1. Unclear what therapies were included as part of the self-care kit; 3. Low rates of adherence	1. Unclear what therapies were included as part of the self-care kit		1. Longer-term outcomes not evaluated

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 4: Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]

Ridner (2021)		1. Blinding not feasible; most measures were patient-reported 3. Assessment of swelling by physician was not blinded		6. Intention to treat analysis not used (5 of 24 patients in intervention group did not complete the trial)	2. Feasibility trial, so no power calculations were performed	2. No adjustment for multiplicity

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Section Summary: Lymphedema–Pneumatic Compression Pumps Applied to Head and Neck

One RCT and a systematic review have assessed the use of pneumatic compression treatment for head and neck lymphedema. The RCT, comparing treatment with a pneumatic compression pump along with lymphedema self-management compared to self-management alone, examined the feasibility, adherence, and safety of the Flexitouch advanced pneumatic compression device (APCD) by Tactile Medical. The findings showed some improvements in patient-reported outcomes and swelling, although adherence was low, with only one patient using the device twice daily as prescribed. The systematic review also suggested benefits from using the APCD, and it was considered safe and feasible according to the observational studies that reported adverse events. Most studies included participants who had completed or were concurrently undergoing CDT. Out of the 5 observational studies included in the systematic review, four (80%) were funded by or had authors affiliated with Flexitouch. The only study not sponsored by the industry highlighted difficulties in obtaining the APCD, with fewer than half of the patients receiving the device as prescribed. Further research with larger sample sizes and comparisons against the gold standard of CDT is necessary to establish the efficacy of this treatment approach.

Lymphedema–Pneumatic Compression Pumps Applied to the Limb Only

Clinical Context and Therapy Purpose

The purpose of pneumatic compression pumps (PCPs) applied to the limb only is to provide a treatment option that is an alternative to or an improvement on existing therapies for individuals 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 individuals 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

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

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

A systematic review by Shao et al. (2014) 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).

Hou et al (2024) conducted a systematic review and meta-analysis of 12 studies (identified through March 2024) comparing the efficacy of IPC as an addition to complete decongestive therapy (CDT) for treatment of breast cancer-related upper limb lymphedema.[6] Results showed that additional application of IPC to CDT could further improve lymphedema within 4 weeks after the treatment period (standardized mean difference (SMD), -0.2 mL; 95% CI, -0.33 to -0.07 mL). However, this additional benefit was weakened within about 9.4±2.6 weeks' follow-up duration after ceasing physical therapy (SMD, -0.15 mL; 95% CI, -0.33 to 0.04 mL). To sustain the synergistic benefits of CDT and IPC in fostering lymphatic drainage and alleviating lymphedema, the authors recommend periodic, continuous treatment. The duration of treatment examined in the studies spanned from 4 to 12 weeks, which may introduce potential bias.

Yao et al (2024) conducted a systematic review and meta-analysis of 9 RCTs to compare the efficacy of decongestive lymphatic therapy (DLT) with IPC versus DLT alone in the management of upper limb lymphedema following breast cancer surgery.[7] The pooled SMD for percentage volume reduction was 0.63 (95% CI, -0.24 to 1.50; I^2 = 91%), showing no significant difference between the DLT alone and DLT combined with IPC (p=.15). Pain and heaviness scores were also comparable between the groups. There was a significant difference in external rotation joint mobility (SMD = 0.62; 95% CI, 0.08 to 1.16; I^2 = 23.8%), favoring DLT with IPC. Overall, the study indicates that DLT with IPC is as effective as DLT alone in managing upper limb lymphedema following breast cancer surgery. DLT with IPC has a more pronounced effect on enhancing external rotation joint mobility.

Section Summary: Lymphedema–Pneumatic Compression Pumps Applied to the Limb Only

Multiple RCTs and systematic reviews have been conducted primarily focusing on upper-limb lymphedema secondary to breast cancer. Most of these RCTs were deemed moderate-to-high quality by the Agency for Healthcare Research and Quality, and about half reported significant improvements with the use of pumps compared to conservative care. Recent meta-analyses indicate that incorporating intermittent pneumatic compression (IPC) with complete decongestive therapy can further enhance lymphedema management within four weeks post-treatment. Similar findings are observed when IPC is combined with decongestive lymphatic therapy compared to decongestive lymphatic therapy alone in managing upper limb lymphedema after breast cancer surgery, with the former combined regimen showing improved external rotation joint mobility.

Lymphedema–Pneumatic Compression Pumps Applied to the Limb and Chest and/or Trunk

Clinical Context and Therapy Purpose

The purpose of pneumatic compression pumps applied to the limb and chest and/or trunk 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 following PICO was used to select literature to inform this review.

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

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

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 XX individuals 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 Limb and Chest and/or Trunk

Two industry-sponsored RCTs of the Flexitouch system (Tactile Medical), published in 2012, have compared treatment with and without truncal involvement. In one RCT, two (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 (eg, amount of fluid removed) rather than health outcomes (eg, functional status, quality of life). The second 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.

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

Clinical Context and Therapy Purpose

The purpose of home use of a limb compression device as an adjunct to anticoagulation is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as anticoagulation only, in patients with moderate-to-high postsurgical risk of venous thromboembolism (VTE) and no contraindication to pharmacologic prophylaxis.

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 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 anticoagulation only. Treatments include an anticoagulation regimen and 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 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 one 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 individuals 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 individuals 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 individuals 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.

Systematic Reviews
Multiple meta-analyses of RCTs have compared pharmacological VTE prophylaxis plus an IPC device with medication alone in surgical individuals in the hospital setting. Surgical populations represented in these analyses include individuals undergoing abdominal, cardiac, neurologic, and orthopedic surgery. Commonly reported outcomes include the occurrence of deep vein thrombosis (DVT), symptomatic DVT, and pulmonary embolism (PE). In addition to an IPC device, cointerventions with other mechanical prophylaxis strategies (graduated compression stockings, etc.) have also been reported in some analyses. Overall, findings from meta-analyses suggest that the in-hospital addition of an IPC device to pharmacologic management improves VTE prophylaxis, especially for the prevention of DVT. Findings

related to the risk of PE are more limited because analyses might have been underpowered due to the small number of PE events.

The post-discharge setting has important characteristics that preclude making inferences from the inpatient setting. Individual characteristics vary because discharged individuals tend to be healthier than those in the hospital. Characteristics of home use also vary (e.g., treatment consistency, duration, application errors in use).

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

For individuals who have a moderate-to-high postsurgical risk of VTE and no contraindication to pharmacologic prophylaxis who receive home use of an IPC device as an adjunct to anticoagulation, there are no RCTs assessing the incremental benefit of home use of an IPC device. Meta-analyses of RCTs have compared medication plus an IPC device with medication alone in surgical individuals 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 DVT, sparse data on PE, and results generally not being stratified by individual 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 individuals tend to be healthier than those in the hospital. Factors such as treatment consistency, duration, and application errors in use also differ in the home.

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 individuals with a moderate-to-high postsurgical risk of VTE and a contraindication to pharmacologic prophylaxis.

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 individuals 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 individuals . 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 individuals 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 individuals were also prescribed graduated compression stockings and 20% to 25% used anticoagulants. Individuals 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). Individuals 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 individuals 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 feasibility and incremental benefit of post-discharge 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 individuals 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 individuals and some studies involving higher risk individuals also included pharmacologic prophylaxis across groups. Nonetheless, the inference is supported that in individuals 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 individuals who have a contraindication to pharmacologic prophylaxis is likely to improve VTE prevention.

Other Conditions

Clinical Context and Therapy Purpose

The purpose of home use of a compression device is to provide a treatment option that is an alternative to or an improvement on existing therapies.

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

Populations

The relevant population of interest are individuals with one of the following:

- Arterial insufficiency
- Diabetic Ulcers
- Femoral Popliteal Bypass Surgery
- Fracture
- Restless Leg Syndrome
- Stroke
- Upper Extremity Vascular Ulcer
- Who had surgery (post-surgical) with pain and swelling who failed to respond to conservative therapy.

Interventions

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

Comparators

Comparators of interest include no home venous prophylaxis or other methods of mechanical prophylaxis. Treatment includes conservative therapy (e.g., exercise, compression therapy, elevation), manual lymphatic drainage, complete decongestive therapy, medication therapy, and heat/cold therapy.

Outcomes

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

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.

Evidence on the use of PCD's for other conditions includes studies in both the inpatient and home settings. Although inpatient studies may not permit inferences to the post-discharge home setting, however, they are briefly summarized for informational purposes.

Arterial Insufficiency

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 (2005) 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. he 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 individuals 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".

Kakkos et al (2005) 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 individuals will provide valuable information on the optimal treatment modality of intermittent claudication.

Diabetic Ulcers

Systematic Review

The Canadian Agency for Drugs and Technologies in Health published a Review of Clinical Effectiveness, Cost-Effectiveness and Guidelines in 2014. Evidence from two RCTs, examined by two SRs and one set of guidelines included in the 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, 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."

Femoral Popliteal Bypass Surgery

Randomized Controlled Trial

te Slaa et al (2011) 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

Khanna et al (2008) 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. 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.

Handoll et al (2006) examined the effects of rehabilitation interventions in adults with conservatively or surgically treated distal radial fractures. 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. 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

In a prospective, randomized, double-blinded, sham-controlled trial, Lettieri and Eliasson (2009) (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

Systematic Review

Zhang et al (2018) completed a systematic review and meta-analysis on the effect of intermittent pneumatic compression on preventing deep vein thrombosis among stroke patients. They identified seven

randomized controlled trials that included 3,551 stroke patients. The average calculated κ for the various parameters was κ = 0.96 (0.70-1). Overall, IPC significantly reduced the incidence of DVT in stroke patients (risk ratio [RR] = 0.50; 95% confidence interval [CI 0.27, 0.94]). At the same time, IPC increased IPC-related adverse events (RR = 5.71; 95% CI [3.40, 9.58]). Though IPC was associated with a significant increase in survival by 4.5 days during 6 months of follow-up (148-152 days; 95% CI [-0.2, 9.1]), there was a mean gain of only 0.9 days (26.7-27.6 days; 95% CI [2.1, 3.9]) in quality-adjusted survival during the 6-month follow-up. Overall, sensitivity analyses did not alter these findings. This review provides an important basis for preventing DVT in stroke patients, especially in hemorrhagic stroke patients. IPC significantly reduces the risk of DVT and significantly improves survival in a wide variety of patients who are immobile after stroke. However, IPC does not significantly improve quality-adjusted survival. Clinicians should take functional status and quality of life into consideration when making decisions for stroke patients.

Doyle et al (2010) examined the effects of interventions that target upper limb sensory impairment after stroke. 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.

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

Randomized Controlled Trials

In a multicenter RCT, Su et al (2012) 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.

Waterman et al (2012) 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%).

Noyes et al (2018) 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. Visual 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.

Observational Studies

Murgier et al (2017) 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 post-surgery. 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.

Kraeutler et al (2015) 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.

Upper Extremity Vascular Ulcers

Pfizenmaier et al (2005) conducted an 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.

Section Summary: Other Conditions

For individuals who utilize pneumatic compression devices for 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 femoral popliteal, post-surgical pain and swelling, treatment of sensory impairment in upper limb following a stroke and treatment of upper extremity vascular ulcers), the evidence includes systematic reviews, randomized controlled trials and observational studies. The RCTs found no significant reduction in pain or medication use compared with standard of care. Trial limitations included small sample size, lack of blinding and individual non-compliance. The role of pneumatic of compression therapy in the treatment of other conditions in the home setting is unclear. Further multi-center RCTs with larger sample sizes and relevant treatment comparison groups in the home are needed to assess the safety and long-term effectiveness.

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in ‘Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Academy of Orthopaedic Surgeons (AAOS)

In 2011, the American Academy of Orthopaedic Surgeons (AAOS) updated its guidelines on the prevention of VTE in individuals 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)"

American College of Chest Physicians (ACCP)

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 the Table 5 below).

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
- Alcohol abuse
- Nonsteroidal anti-inflammatory drugs.

Table 5: 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

Risk Factors	Estimated Absolute Risk of Major Bleeding		
	Low Risk (0 Risk Factors)	*Moderate Risk (1 Risk Factor)*	*High Risk (≥2 Risk Factors)*
Increased risk	1.0	2.0	8.0
Total risk	1.6	3.2	12.8
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 the 2012 guidelines for the prevention of VTE in orthopedic surgery individuals, the ACCP recommended the use of limb compression devices in orthopedic surgical individuals]:

2.1.1 “In patients undergoing total hip arthroplasty (THA) or total knee arthroplasty (TKA), we recommend use of one of the following for a minimum of 10 to 14 days rather than no antithrombotic prophylaxis: low-molecular-weight heparin (LMWH), fondaparinux, apixaban, dabigatran, rivaroxaban, low-dose unfractionated heparin (LDUH), adjusted-dose vitamin K antagonist (VKA), aspirin (all Grade 1B), or an intermittent pneumatic compression device (IPCD) (Grade 1C).”

2.5 “In patients undergoing major orthopedic surgery, we suggest using dual prophylaxis with an antithrombotic agent and an IPCD during the hospital stay (Grade 2C).”

2.6 “In patients undergoing major orthopedic surgery and increased risk of bleeding, we suggest using an IPCD or no prophylaxis rather than pharmacologic treatment (Grade 2C).”

“The efficacy of mobile mechanical compression devices alone has not been compared with any chemoprophylaxis agent in an appropriately powered randomized trial. In addition, concerns have arisen with regard to patient compliance after hospital discharge and the high cost of these devices.”

In 2012, the ACCP recommendations on the use of limb compression devices in nonorthopedic general and abdominal-pelvic surgical individuals, stratified by individual risk of VTE and risk of bleeding are listed in the table below.

Table 6; Recommendations on Limb Compression Device Use in Nonorthopedic General and Abdominal-Pelvic Surgical Patients

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.”

Patient Risk Group	Recommendation
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 or in whom bleeding consequences would be particularly severe	"[W]e suggest use of mechanical prophylaxis, preferably with IPC, over no prophylaxis until the 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 that a standard duration of prophylaxis was not defined. An "extended duration" prophylaxis was defined as lasting 4 weeks.

American College of Obstetricians and Gynecologists (ACOG)

A 2007 American College of Obstetricians and Gynecologists (ACOG) practice bulletin on prevention of deep vein thrombosis (DVT) and pulmonary embolism (PE) after gynecologic surgery was replaced in 2021. As with ACCP recommendations discussed above, prophylaxis recommendations varied by individual risk level based on the Caprini Risk Assessment Model. For patients at moderate and high-risk of DVT, intermittent pneumatic compression (IPC) was one of the recommended options for DVT prophylaxis.

Relevant recommendations based on Level A evidence were as follows:

- “For gynecologic surgery patients who are at high risk of VTE and average risk of bleeding complications, dual thromboprophylaxis with a combination of mechanical prophylaxis (preferably with intermittent pneumatic compression) and pharmacologic prophylaxis (low-dose unfractionated heparin or LMWH) is recommended.”
- “For patients at high risk of VTE who are undergoing cancer surgery, in-hospital dual thromboprophylaxis and extended-duration pharmacologic prophylaxis with LMWH after hospital discharge are recommended.”

Relevant recommendations based on Level B evidence were as follows:

- “For gynecologic surgery patients who are at moderate risk of VTE and not at increased risk of bleeding complications, mechanical thromboprophylaxis (preferably with intermittent pneumatic compression) or pharmacologic thromboprophylaxis (with low-dose unfractionated heparin or LMWH) is recommended.”
- “For gynecologic surgery patients who are at moderate risk of VTE and high risk of major bleeding complications, mechanical prophylaxis (preferably with intermittent pneumatic compression) is recommended.”
- “For gynecologic surgery patients who are at high risk of both VTE and bleeding complications, mechanical prophylaxis (preferably with intermittent pneumatic compression) is recommended until the risk of bleeding decreases and pharmacologic prophylaxis can be added.”
- “For gynecologic surgery patients at high risk of VTE for whom both LMWH and low-dose unfractionated heparin are contraindicated or not available and who are not at high risk of major bleeding complications, fondaparinux, mechanical prophylaxis (preferably with intermittent pneumatic compression), or both is recommended.”
- “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.”

American Orthopaedic Foot and Ankle Society (AOFAS)

In 2020, 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 individuals 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."

American Society of Clinical Oncology (ASCO)

In 2023, 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 was unchanged from the previous 2019 guideline and makes the following recommendation for mechanical prophylaxis in this 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)"

American Society of Hematology

In 2019, the American Society of Hematology (ASH) issued guidelines for the prevention and management of VTE in surgical hospitalized individuals. The following are two suggestions for individuals undergoing major surgery:

- Recommendation 3: For those "who receive mechanical prophylaxis,...[use] intermittent compression devices over graduated compression stockings (conditional recommendation based on very low certainty in the evidence of effects)."
- Recommendation 4: For those "who receive pharmacologic prophylaxis,...[use] combined prophylaxis with mechanical and pharmacological methods over prophylaxis with pharmacological agents alone (conditional recommendation based on very low certainty in the evidence of effects). Remark: For individuals considered at high risk of VTE, combined prophylaxis is particularly favored over mechanical or pharmacological prophylaxis alone.

American Academy of Family Physicians

In 2019, the American Academy of Family Physicians published recommendations for diagnosis and treatment of venous ulcers. The following statements were issued regarding use of intermittent pneumatic compression.

- "Intermittent pneumatic compression may be considered when there is generalized, refractory edema from venous insufficiency; lymphatic obstruction; and significant ulceration of the lower extremity. Although intermittent pneumatic compression is more effective than no compression, its effectiveness compared with other forms of compression is unclear. Intermittent pneumatic compression may improve ulcer healing when added to layered compression."

American Venous Forum et al

In 2022, the American Venous Forum, American Vein and Lymphatic Society, and the Society for Vascular Medicine published an expert opinion consensus statement on lymphedema diagnosis and treatment. The following statements were issued regarding use of pneumatic compression:

- "Sequential pneumatic compression should be recommended for lymphedema patients." (92% panel agreement; 32% strongly agree)
- "Sequential pneumatic compression should be used for treatment of early stages of lymphedema." (62% panel agreement - consensus not reached; 38% panel disagreement; 2% strongly disagreed)

International Union of Phlebology (UIP)

A 2013 consensus statement from International Union of Phlebology stated that primary lymphedema can be managed effectively by a sequenced and targeted management program based on a combination of decongestive lymphatic therapy and compression therapy. Treatment should include compression garments, self-message, skin care, exercises, and, if desired, pneumatic compression therapy applied in the home.

National Comprehensive Cancer Network (NCCN)

NCCN updated their guidelines (Version 1.2025) on Survivorship: Lymphedema noting the following:

- Early detection/diagnosis and early referral are key for optimal lymphedema management because stages 0 and 1 are reversible, whereas stages 2 and 3 are less responsive to treatment. Therefore, survivors at risk for lymphedema should be regularly screened for lymphedema by symptom assessment, clinical exam, and validated volumetric tools and/or tools that measure extracellular fluid. Patients should be educated about early symptoms and signs of lymphedema including fullness, tightness, heaviness, and pain.
- Treatment of Lymphedema High-level evidence supporting treatments for lymphedema are lacking, and most studies have been performed in breast cancer survivors. Most of the recommendations made by the Panel are thus based on lower-level evidence, clinical experience, and expert consensus.
- Treatment:
    - Survivor lymphedema education, including selfcare management, skin care, and self-bandage (SLYMPH-A)
    - Refer to certified lymphedema therapist (if available) for consideration of the following:
        - Compression:
            - Fit for compression garments
            - Review use of garments
            - Pneumatic compression for ongoing home management
            - Review use of multilayered bandage wrapping
        - Progressive resistance training under supervision
        - Manual lymphatic drainage
    - Refer to qualified therapist for range-of-motion exercises
    - For select patients, consider referral to a lymphedema surgeon, in consultation with a certified lymphedema therapist and/or physiatrist specializing in lymphedema

NCCN updated their guideline (Version 2.2025) on Head and Neck Cancer noting the following:

- Evaluation and management of lymphedema and trismus should be conducted as clinically indicated with appropriate referrals to occupational and physical therapy.
- Lymphedema of the head and neck commonly occurs in patients and is associated with increased symptom burden (eg, negative cosmetic impact, trouble breathing, swallow dysfunction, and pain).
- As lymphedema and fibrosis negatively impact function and QOL, evaluation and management is warranted. Patient referrals to occupational therapy to learn massage techniques (eg, lymphatic decompression therapy) or to be fitted for custom-made compression devices may be warranted.

Society for Vascular Surgery (SVS) and American Venous Forum

The 2014 joint guidelines from the Society for Vascular Surgery and the American Venous Forum for the management of venous leg ulcers included the following statement on pneumatic compression:

- "We suggest use of intermittent pneumatic compression when other compression options are not available, cannot be used, or have failed to aid in venous leg ulcer healing after prolonged compression therapy. [Grade - 2; Level of Evidence - C]"

Wound Healing Society

A 2015 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.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review can be located at clinicaltrials.gov.

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CODES

To report provider services, use appropriate CPT codes, HCPCS codes, Revenue codes, and/or ICD diagnosis codes.

Codes	Number	Description
CPT		
	No code(s)	
HCPCS		
	E0650	Pneumatic compressor, nonsegmental home model
	E0651	Pneumatic compressor, segmental home model without calibrated gradient pressure
	E0652	Pneumatic compressor, segmental home model with calibrated gradient pressure
	E0655	Nonsegmental pneumatic appliance for use with pneumatic compressor, half arm
	E0656	Segmental pneumatic appliance for use with pneumatic compressor, trunk
	E0657	Segmental pneumatic appliance for use with pneumatic compressor, chest
	E0658	Segmental pneumatic appliance for use with pneumatic compressor, integrated, 2 full arms and chest
	E0659	Segmental pneumatic appliance for use with pneumatic compressor, integrated, head, neck and 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

Codes	Number	Description
	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
Type of Service	DME	
Place of Service	Home	

POLICY HISTORY

Date	Reason	Action
May 2025	Annual Review	Policy Renewed
May 2024	Annual Review	Policy Revised
May 2023	Annual Review	Policy Revised
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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