

<b>1.01.28 Postsurgical Home Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis</b>			
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<b>Section:</b>	1.0 Durable Medical Equipment	<b>Page:</b>	Page 1 of 20

## Policy Statement

- I. Postsurgical home use of limb compression devices for venous thromboembolism (VTE) prophylaxis may be considered **medically necessary** in individuals with a contraindication to pharmacologic agents (see Policy Guidelines), in **either** of the following situations:
  - A. After major orthopedic surgery (total hip arthroplasty, total knee arthroplasty, hip fracture surgery)
  - B. After major nonorthopedic surgery or other orthopedic procedures in individuals who are at moderate or high risk of VTE (see Policy Guidelines)
- II. Postsurgical home use of limb compression devices for VTE prophylaxis for periods longer than 30 days postsurgery is considered **investigational**.
- III. Postsurgical home use of limb compression devices for venous thromboembolism (VTE) prophylaxis is considered **investigational** in all other situations, including but not limited to:
  - A. After major orthopedic surgery (total hip arthroplasty, total knee arthroplasty, hip fracture surgery) in individuals without a contraindication for anticoagulation
  - B. After major nonorthopedic surgery or other orthopedic procedures in individuals without a contraindication for anticoagulation who are at moderate or high risk of VTE (see Policy Guidelines)

**NOTE:** Refer to [Appendix A](#) to see the policy statement changes (if any) from the previous version.

## Policy Guidelines

This section reviews guidance on contraindications to using anticoagulants, determining risk for bleeding, determining risk for venous thromboembolism (VTE), and duration of treatment postoperatively.

### 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 greater than 65 y
- Age greater than 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		
	<i>Low Risk (0 Risk Factors)</i>	<i>Moderate Risk (1 Risk Factor)</i>	<i>High Risk (≥2 Risk Factors)</i>
<b>Anticoagulation 0-3 mo, %</b>			
Baseline risk	0.6	1.2	4.8
Increased risk	1.0	2.0	8.0
<b>Total risk</b>	<b>1.6</b>	<b>3.2</b>	<b>12.8</b>
<b>Anticoagulation after first 3 mo, %/y</b>			
Baseline risk	0.3	0.6	≥2.5
Increased risk	0.5	1.0	≥4.0
<b>Total risk</b>	<b>0.8</b>	<b>1.6</b>	<b>≥6.5</b>

Adapted from Kearon et al (2016).<sup>1</sup>

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 and 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 patients 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  $\geq$  60 years, prior VTE, anesthesia  $\geq$  2 h, and bed rest  $\geq$  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 <sup>2</sup> 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

Points	Risk factors
	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
5	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.

## Description

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.

## Related Policies

- Pneumatic Compression Pumps for Treatment of Lymphedema and Venous Ulcers

## Benefit Application

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

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

## Regulatory Status

A large number of pneumatic and peristaltic limb compression devices have been cleared for marketing by the FDA through the 510(k) process for indications including prevention of DVT. A sample of portable devices cleared by the FDA include (FDA product code: JOW):

- AIROS 6 Sequential Compression Device (AIROS Medical, Inc.): This device is safe for both home and hospital use.
- Plexus RPI00 Disposable Portable Deep Vein Thrombosis Prevention Device (Alleva Medical [D.G.] Ltd): This device is for home or clinical settings and is powered by an internal rechargeable battery.
- AeroDVx™ System (Sun Scientific Inc): This device is for hospital or outpatient use.
- VenaPro™ Vascular Therapy System (InnovaMed Health): This device is battery-powered.
- Venowave™ VW5 (Venowave): This device is battery-powered and strapped to the leg below the knee.
- ActiveCare® +S.F.T. System (Medical Compression Systems): The device applies sequential pneumatic compression to the lower limb; it has the option of being battery-operated. Foot compression is achieved with the use of a single-celled foot sleeve. Calf and thigh compression requires the use of a 3-celled cuff sleeve.
- Restep® DVT System (Stortford Medical): This lightweight device uses single-chamber pressure cuffs attached to the individual's lower legs.
- Kendall SCD™ 700 Sequential Compression System (Covidien): This pneumatic compression device can be used in the clinic or at home; it has a battery-powered option.
- PlasmaFlow™ (ManaMed): This system is portable, to be used at home or in a clinical setting.

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

## Rationale

### Background

#### Risk of Venous Thromboembolism

##### 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 individuals 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 individuals, 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 individuals 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.<sup>2,3</sup>

### **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 individuals 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 individuals 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, individuals 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,<sup>4</sup> 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%.<sup>5</sup> 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%.<sup>6</sup>

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.<sup>2</sup> 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.<sup>7</sup>

## **Nonorthopedic Surgery**

### **Pharmacologic and Limb Compression Prophylaxis**

The ACCP (2012) also issued guidelines on VTE prophylaxis in nonorthopedic surgery individuals.<sup>3</sup> 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 individuals 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.

### **Literature Review**

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 individuals 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.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

### **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 individuals 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 moderate-to-high postsurgical risk of VTE and no contraindication to pharmacologic prophylaxis.

### ***Interventions***

The therapy being considered is 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 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:

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

### **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.<sup>8,9,10,11,12,13</sup> 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:

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

### 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.<sup>14,15,16</sup> Populations include surgical and nonsurgical individuals, including critically ill individuals 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 individuals and some studies involving higher-risk individuals 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 individuals, 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 individuals undergoing cranial or spinal neurosurgery.<sup>17</sup> All individuals were also prescribed graduated compression stockings and 20% to 25% used anticoagulants. Individuals were evaluated at 9 days postsurgery, and those discharged earlier were permitted to use an IPC device at home (median duration of hospitalization, 4 days). Individuals who used the IPC device post-discharge received home visits at least daily to optimize compliance. Three (4%) of 75 individuals in the IPC group and 14 (19%) of 75 individuals 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.

### **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**

In 2011, the American Academy of Orthopaedic Surgeons (AAOS) updated its guidelines on the prevention of venous thromboembolism (VTE) in individuals undergoing elective hip and knee arthroplasty.<sup>18</sup> The guidelines included the following recommendations relevant to this evidence review:

5. "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)
6. 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)
7. 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

In 2016, the American College of Chest Physicians (ACCP) updated its 2012 evidence-based guideline<sup>19</sup> on antithrombotic therapy and prevention of thrombosis.<sup>1</sup> 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.<sup>20</sup> The 2016 update, which addressed antithrombotic therapy for VTE, outlined risk factors for bleeding with anticoagulant therapy and estimated the risks of major bleeding for individuals in various risk categories (see Table 1).

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 drug."

**Table 1. Guidelines for Risk of Bleeding**

Risk Factors	Estimated Absolute Risk of Major Bleeding		
	<i>Low Risk (0 Risk Factors)</i>	<i>Moderate Risk (1 Risk Factor)</i>	<i>High Risk (≥2 Risk Factors)</i>
<b>Anticoagulation 0-3 mo, %</b>			
Baseline risk	0.6	1.2	4.8
Increased risk	1.0	2.0	8.0
<b>Total risk</b>	<b>1.6</b>	<b>3.2</b>	<b>12.8</b>
<b>Anticoagulation after first 3 mo, %/y</b>			
Baseline risk	0.3	0.6	≥2.5
Increased risk	0.5	1.0	≥4.0
<b>Total risk</b>	<b>0.8</b>	<b>1.6</b>	<b>≥6.5</b>

Adapted from Kearon et al (2016).<sup>1</sup>

In the 2012 guidelines for the prevention of VTE in orthopaedic surgery individuals, the ACCP recommended the use of limb compression devices in orthopedic surgical individuals<sup>2</sup>:

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 Table 2.<sup>3</sup>

**Table 2. Recommendations on Limb Compression Device Use in Nonorthopedic General and Abdominal-Pelvic Surgical Individuals**

Patient Risk Group	Recommendation	GOR
Very low risk (<0.5%)	"[W]e recommend that no specific pharmacologic or mechanical prophylaxis be used other than early ambulation."	1B 2C
Low risk for VTE (~1.5%)	"[W]e suggest mechanical prophylaxis, preferably with intermittent pneumatic compression (IPC), over no prophylaxis."	2C
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."	2B 2B 2C
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."	2C
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."	1B 1B 2C
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."	2C
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."	2C
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."	1B

Adapted from Gould et al (2012)<sup>3</sup>.

GOR: grade of recommendation; 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

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.<sup>21</sup> As with ACCP recommendations discussed above, prophylaxis recommendations varied by individual risk level based on the Caprini Risk Assessment Model. For individuals 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**

In 2020, the American Orthopaedic Foot and Ankle Society re-approved a position statement on VTE prophylaxis after foot and ankle surgery. It stated that: "There is currently insufficient data for the American Orthopaedic Foot & Ankle Society (AOFAS) to recommend for or against routine VTE prophylaxis for individuals undergoing foot and ankle surgery. Further research in this field is necessary and is encouraged."<sup>22</sup> 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**

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.<sup>23</sup> 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.<sup>24</sup>The following are 2 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.

### U.S. Preventive Services Task Force Recommendations

Not applicable.

### Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

### Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 3.

**Table 3. Summary of Key Trials**

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT03259204	Swedish Multicenter Trial of Outpatient Prevention of Leg Clots (StopLegClots)	1400	December 2025

NCT: national clinical trial.

## References

1. Kearon C, Akl EA, Ornelas J, et al. Antithrombotic Therapy for VTE Disease: CHEST Guideline and Expert Panel Report. *Chest*. Feb 2016; 149(2): 315-352. PMID 26867832
2. Falck-Ytter Y, Francis CW, Johanson NA, et al. Prevention of VTE in orthopedic surgery patients: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. *Chest*. Feb 2012; 141(2 Suppl): e278S-e325S. PMID 22315265
3. Gould MK, Garcia DA, Wren SM, et al. Prevention of VTE in nonorthopedic surgical patients: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. *Chest*. Feb 2012; 141(2 Suppl): e227S-e277S. PMID 22315263
4. MD+CALC. HAS-BLED Score for Major Bleeding Risk. <http://www.mdcalc.com/has-bleed-score-for-major-bleeding-risk/>. Accessed February 15, 2024.

5. Fisher WD. Impact of venous thromboembolism on clinical management and therapy after hip and knee arthroplasty. *Can J Surg*. Oct 2011; 54(5): 344-51. PMID 21774881
6. Committee on Practice Bulletins--Gynecology, American College of Obstetricians and Gynecologists. ACOG Practice Bulletin No. 84: Prevention of deep vein thrombosis and pulmonary embolism. *Obstet Gynecol*. Aug 2007; 110(2 Pt 1): 429-40. PMID 17666620
7. Froimson MI, Murray TG, Fazekas AF. Venous thromboembolic disease reduction with a portable pneumatic compression device. *J Arthroplasty*. Feb 2009; 24(2): 310-6. PMID 18534456
8. Kakkos SK, Caprini JA, Geroulakos G, et al. Combined intermittent pneumatic leg compression and pharmacological prophylaxis for prevention of venous thromboembolism. *Cochrane Database Syst Rev*. Sep 07 2016; 9(9): CD005258. PMID 27600864
9. Kakkos S, Kirkilesis G, Caprini JA, et al. Combined intermittent pneumatic leg compression and pharmacological prophylaxis for prevention of venous thromboembolism. *Cochrane Database Syst Rev*. Jan 28 2022; 1(1): CD005258. PMID 35089599
10. O'Connell S, Bashar K, Broderick BJ, et al. The Use of Intermittent Pneumatic Compression in Orthopedic and Neurosurgical Postoperative Patients: A Systematic Review and Meta-analysis. *Ann Surg*. May 2016; 263(5): 888-9. PMID 26720432
11. Zareba P, Wu C, Agzarian J, et al. Meta-analysis of randomized trials comparing combined compression and anticoagulation with either modality alone for prevention of venous thromboembolism after surgery. *Br J Surg*. Aug 2014; 101(9): 1053-62. PMID 24916118
12. Sobieraj DM, Coleman CI, Tongbram V, et al. Comparative effectiveness of combined pharmacologic and mechanical thromboprophylaxis versus either method alone in major orthopedic surgery: a systematic review and meta-analysis. *Pharmacotherapy*. Mar 2013; 33(3): 275-83. PMID 23401017
13. Fan C, Jia L, Fang F, et al. Adjunctive Intermittent Pneumatic Compression in Hospitalized Patients Receiving Pharmacologic Prophylaxis for Venous Thromboprophylaxis: A Systematic Review and Meta-Analysis. *J Nurs Scholarsh*. 2020;52(4):397-405. doi:10.1111/jnu.12566
14. Ho KM, Tan JA. Stratified meta-analysis of intermittent pneumatic compression of the lower limbs to prevent venous thromboembolism in hospitalized patients. *Circulation*. Aug 27 2013; 128(9): 1003-20. PMID 23852609
15. Wang X, Zhang Y, Fang F, et al. Comparative efficacy and safety of pharmacological prophylaxis and intermittent pneumatic compression for prevention of venous thromboembolism in adult undergoing neurosurgery: a systematic review and network meta-analysis [published online ahead of print, 2020 Apr 16]. *Neurosurg Rev*. 2020;10.1007/s10143-020-01297-0. doi:10.1007/s10143-020-01297-0
16. Haykal T, Zayed Y, Dhillon H, et al. Meta-Analysis of the Role of Intermittent Pneumatic Compression of the Lower Limbs to Prevent Venous Thromboembolism in Critically Ill Patients. *Int J Low Extrem Wounds*. Mar 2022; 21(1): 31-40. PMID 32527203
17. Sobieraj-Teague M, Hirsh J, Yip G, et al. Randomized controlled trial of a new portable calf compression device (Venowave) for prevention of venous thrombosis in high-risk neurosurgical patients. *J Thromb Haemost*. Feb 2012; 10(2): 229-35. PMID 22188037
18. Mont MA, Jacobs JJ, Boggio LN, et al. Preventing venous thromboembolic disease in patients undergoing elective hip and knee arthroplasty. *J Am Acad Orthop Surg*. Dec 2011; 19(12): 768-76. PMID 22134209
19. Guyatt GH, Akl EA, Crowther M, et al. Introduction to the ninth edition: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. *Chest*. Feb 2012; 141(2 Suppl): 48S-52S. PMID 22315255
20. Stevens SM, Woller SC, Kreuziger LB, et al. Antithrombotic Therapy for VTE Disease: Second Update of the CHEST Guideline and Expert Panel Report. *Chest*. Dec 2021; 160(6): e545-e608. PMID 34352278
21. Clarke-Pearson DL, Barber EL, Landrum LM. Prevention of Venous Thromboembolism in Gynecologic Surgery: ACOG Practice Bulletin, Number 232. *Obstet Gynecol*. Jul 01 2021; 138(1): e1-e15. PMID 34259490



22. American Orthopaedic Foot & Ankle Society (AOFAS). Position Statement: The Use of VTED Prophylaxis in Foot and Ankle Surgery. 2020; [https://www.aofas.org/docs/default-source/research-and-policy/vted-prophylaxis-in-foot-and-ankle-surgery-position-statement.pdf?sfvrsn=21490028\\_2](https://www.aofas.org/docs/default-source/research-and-policy/vted-prophylaxis-in-foot-and-ankle-surgery-position-statement.pdf?sfvrsn=21490028_2). Accessed February 16, 2024.
23. Key NS, Khorana AA, Kuderer NM, et al. Venous Thromboembolism Prophylaxis and Treatment in Patients With Cancer: ASCO Guideline Update. *J Clin Oncol*. Jun 01 2023; 41(16): 3063-3071. PMID 37075273
24. Anderson DR, Morgano GP, Bennett C, et al. American Society of Hematology 2019 guidelines for management of venous thromboembolism: prevention of venous thromboembolism in surgical hospitalized patients. *Blood Adv*. Dec 10 2019; 3(23): 3898-3944. PMID 31794602

## Documentation for Clinical Review

### Please provide the following documentation:

- History and physical and/or consultation notes including:
  - Patient's risk for bleeding
  - Reason for contraindication to anticoagulation (if applicable)
  - Reason for pneumatic compression device
  - Type of surgery performed
- Operative report
- Prescription for pump and/or appliance

## Coding

*This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.*

*The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.*

Type	Code	Description
CPT®	None	
HCPCS	A4560	Neuromuscular electrical stimulator (NMES), disposable, replacement only
	E0650	Pneumatic compressor, nonsegmental home model
	E0651	Pneumatic compressor, segmental home model without calibrated gradient pressure
	E0652	Pneumatic compressor, segmental home model with calibrated gradient pressure
	E0655	Nonsegmental pneumatic appliance for use with pneumatic compressor, half arm
	E0656	Segmental pneumatic appliance for use with pneumatic compressor, trunk
	E0657	Segmental pneumatic appliance for use with pneumatic compressor, chest
	E0660	Nonsegmental pneumatic appliance for use with pneumatic compressor, full leg

Type	Code	Description
	E0665	Nonsegmental pneumatic appliance for use with pneumatic compressor, full arm
	E0666	Nonsegmental pneumatic appliance for use with pneumatic compressor, half leg
	E0667	Segmental pneumatic appliance for use with pneumatic compressor, full leg
	E0668	Segmental pneumatic appliance for use with pneumatic compressor, full arm
	E0669	Segmental pneumatic appliance for use with pneumatic compressor, half leg
	E0670	Segmental pneumatic appliance for use with pneumatic compressor, integrated, 2 full legs and trunk
	E0671	Segmental gradient pressure pneumatic appliance, full leg
	E0672	Segmental gradient pressure pneumatic appliance, full arm
	E0673	Segmental gradient pressure pneumatic appliance, half leg
	E0676	Intermittent limb compression device (includes all accessories), not otherwise specified
	E0683	Nonpneumatic, nonsequential, peristaltic wave compression pump <i>(Code effective 10/1/2024)</i>

## Policy History

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

Effective Date	Action
09/27/2013	BCBSA Medical Policy adoption
07/14/2014	Policy title change from Outpatient Use of Limb Pneumatic Compression Devices for Venous Thromboembolism Prophylaxis Policy revision with position change
05/29/2015	Coding update
06/01/2016	Policy title change from Postsurgical Outpatient Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis Policy revision without position change
05/01/2017	Policy revision without position change
05/01/2018	Policy revision without position change
06/01/2019	Policy revision without position change
04/01/2022	Policy reactivated. Previously archived from 05/01/2020 to 03/31/2022. Annual review. No change to policy statement. Policy guidelines and literature updated.
05/01/2023	Annual review. Policy statement, guidelines and literature updated. Coding Update.
05/01/2024	Annual review. No change to policy statement. Policy guidelines and literature review updated.
11/01/2024	Coding update

## Definitions of Decision Determinations

**Medically Necessary:** Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished

primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

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

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

### Prior Authorization Requirements and Feedback (as applicable to your plan)

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

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

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: [MedPolicy@blueshieldca.com](mailto:MedPolicy@blueshieldca.com)

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

**Appendix A**

POLICY STATEMENT (No changes)	
BEFORE	AFTER
<p><b>Postsurgical Home Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis 1.01.28</b></p> <p><b>Policy Statement:</b></p> <ul style="list-style-type: none"> <li>I. Postsurgical home use of limb compression devices for venous thromboembolism (VTE) prophylaxis may be considered <b>medically necessary</b> in individuals with a contraindication to pharmacologic agents (see Policy Guidelines), in <b>either</b> of the following situations:                             <ul style="list-style-type: none"> <li>A. After major orthopedic surgery (total hip arthroplasty, total knee arthroplasty, hip fracture surgery)</li> <li>B. After major nonorthopedic surgery or other orthopedic procedures in individuals who are at moderate or high risk of VTE (see Policy Guidelines).</li> </ul> </li>   <li>II. Postsurgical home use of limb compression devices for VTE prophylaxis for periods longer than 30 days postsurgery is considered <b>investigational</b>.</li>   <li>III. Postsurgical home use of limb compression devices for venous thromboembolism (VTE) prophylaxis is considered <b>investigational</b> in all other situations, including but not limited to:                             <ul style="list-style-type: none"> <li>A. After major orthopedic surgery (total hip arthroplasty, total knee arthroplasty, hip fracture surgery) in individuals without a contraindication for anticoagulation</li> <li>B. After major nonorthopedic surgery or other orthopedic procedures in individuals without a contraindication for anticoagulation who are at moderate or high risk of VTE (see Policy Guidelines).</li> </ul> </li> </ul>	<p><b>Postsurgical Home Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis 1.01.28</b></p> <p><b>Policy Statement:</b></p> <ul style="list-style-type: none"> <li>I. Postsurgical home use of limb compression devices for venous thromboembolism (VTE) prophylaxis may be considered <b>medically necessary</b> in individuals with a contraindication to pharmacologic agents (see Policy Guidelines), in <b>either</b> of the following situations:                             <ul style="list-style-type: none"> <li>A. After major orthopedic surgery (total hip arthroplasty, total knee arthroplasty, hip fracture surgery)</li> <li>B. After major nonorthopedic surgery or other orthopedic procedures in individuals who are at moderate or high risk of VTE (see Policy Guidelines)</li> </ul> </li>   <li>II. Postsurgical home use of limb compression devices for VTE prophylaxis for periods longer than 30 days postsurgery is considered <b>investigational</b>.</li>   <li>III. Postsurgical home use of limb compression devices for venous thromboembolism (VTE) prophylaxis is considered <b>investigational</b> in all other situations, including but not limited to:                             <ul style="list-style-type: none"> <li>A. After major orthopedic surgery (total hip arthroplasty, total knee arthroplasty, hip fracture surgery) in individuals without a contraindication for anticoagulation</li> <li>B. After major nonorthopedic surgery or other orthopedic procedures in individuals without a contraindication for anticoagulation who are at moderate or high risk of VTE (see Policy Guidelines)</li> </ul> </li> </ul>