

1.01.28 Postsurgical Home Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis			
Original Policy Date:	September 27, 2013	Effective Date:	June 1, 2019
Section:	1.0 Durable Medical Equipment	Page:	Page 1 of 19

Policy Statement

Postsurgical home use of limb compression devices for venous thromboembolism (VTE) prophylaxis may be considered **medically necessary** in patients with a contraindication to pharmacologic agents (see Policy Guidelines section), in **either** of the following situations:

- After major orthopedic surgery (total hip arthroplasty, total knee arthroplasty, hip fracture surgery)
- After major nonorthopedic surgery or other orthopedic procedures in patients who are at moderate or high risk of VTE (see Policy Guidelines section)

Postsurgical home use of limb compression devices for venous thromboembolism (VTE) prophylaxis is considered **investigational** in all other situations, including but not limited to:

- After major orthopedic surgery (total hip arthroplasty, total knee arthroplasty, hip fracture surgery) in patients without a contraindication for anticoagulation
- After major nonorthopedic surgery or other orthopedic procedures in patients without a contraindication for anticoagulation who are at moderate or high risk of VTE (see Policy Guidelines section)

Postsurgical home use of limb compression devices for VTE prophylaxis for periods longer than 30 days postsurgery is considered **not medically necessary**.

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 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

American College of Chest Physicians (ACCP) guidelines on prevention of VTE in orthopedic surgery patients listed the following general risk factors for bleeding (Falck-Ytter et al, 2012):

- "Previous major bleeding (and previous bleeding risk similar to current risk)
- Severe renal failure
- Concomitant antiplatelet agent
- Surgical factors: 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 patients in various risk categories (see Table PG1) (Kearon et al, 2016).

Risk factors include (1 point per risk factor):

- "Age greater than 65 years
- Age greater than 75 years
- 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 (Mont et al, 2011) 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 patients 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 (Falck-Ytter et al, 2012). 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 patients 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 patients at high risk for 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 patients included the following discussion of risk levels (Gould et al, 2012):

“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 ≥ 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.”

In 2007 (reaffirmed in 2012), the American College of Obstetricians and Gynecologists revised its risk classification for VTE in patients undergoing major gynecologic surgery (American College of Obstetricians and Gynecologists, 2007):

“Low: Surgery lasting less than 30 minutes in patients younger than 40 years with no additional risk factors.

Moderate: Surgery lasting less than 30 minutes in patients with additional risk factors; surgery lasting less than 30 minutes in patients aged 40 to 60 years with no additional risk factors; major surgery in patients younger than 40 years with no additional risk factors.

High: Surgery lasting less than 30 minutes in patients older than 60 years or with additional risk factors; major surgery in patients older than 40 years or with additional risk factors.

Highest: Major surgery in patients older than 60 years plus prior venous thromboembolism, cancer, or hypercoagulable state.”

Description

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

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 U.S. Food and Drug Administration through the 510(k) process for indications including prevention of DVT. Portable devices cleared by the Food and Drug Administration include (Food and Drug Administration product code: JOW):

- 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 patient'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.

Rationale

Background

Risk of Venous Thromboembolism

Orthopedic Surgery

Antithrombotic prophylaxis is recommended for surgical patients at moderate-to-high risk of postoperative VTE, including deep vein thrombosis (DVT) and pulmonary embolism (PE). Patients may be classified as moderate-to-high risk of VTE based on the surgical procedure and/or patient 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 patients 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 patient-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 patients, 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 assessment of individual patient risk. Pharmacologic prophylaxis is indicated for patients at moderate-to-high risk for VTE. As described in the ACCP guidelines, there are preferred antithrombotic prophylaxis regimens according to procedure and patient risk characteristics.^{1,2}

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 patients undergoing major surgery will not have an increased risk of bleeding precluding the use of anticoagulants, because these patients 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 patients with a high bleeding risk will undergo major surgery, such as patients with severe renal failure who require an essential procedure. Other patients may develop contraindications during the episode of care. For example, patients who have excessive bleeding during or after surgery, or patients 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 HAS-BLED scoring system,³ 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. PE 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%.⁴ Other surgical patients 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%.⁵

Thus, antithrombotic prophylaxis is recommended for patients undergoing major orthopedic surgery and other surgical procedures who are at increased risk of VTE. For patients 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.¹ The guidelines further recommended the use of pharmacologic prophylaxis during hospitalization, whether or not patients are using a limb compression device. A minimum of 10 to 14 days of prophylaxis is recommended, a portion of which can be postdischarge 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 patients in the hospital following hip or knee replacement surgery.⁶

Nonorthopedic Surgery

Pharmacologic and Limb Compression Prophylaxis

The ACCP (2012) also issued guidelines on VTE prophylaxis in nonorthopedic surgery patients.² For patients 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 rather than no prophylaxis. For patients at low-risk for VTE ($\geq 1.5\%$), the guidelines have suggested mechanical prophylaxis. Unlike the guidelines on major orthopedic surgery, which recommends 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 four weeks; the latter is recommended only for patients 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 postdischarge 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 technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function-including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

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

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

Clinical Context and Test 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 VTE and no contraindication to pharmacologic prophylaxis.

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

The following PICOTS were used to select literature to inform this review.

Patients

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 (OS), symptoms, morbid events, and treatment-related morbidity.

Timing

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.

Setting

Patients with moderate-to-high postsurgical risk of VTE and no contraindication to pharmacologic prophylaxis are actively managed by cardiologists and primary care providers in an outpatient clinical setting.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

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

This section focuses on evidence that postdischarge use of limb compression devices in addition to pharmacologic agents provide an incremental benefit to the net health outcome compared with pharmacologic agents alone. The ideal study design to address patients with moderate-to-high postsurgical risk of VTE and no contraindication to pharmacologic prophylaxis is a superiority RCT comparing VTE prophylaxis plus pharmaceutical agents and limb compression devices with pharmacologic agents alone. No RCTs with this study design were identified for patients discharged after major orthopedic surgery or other types of major surgery. There are, however, RCTs and meta-analyses of RCTs comparing medication plus compression devices with medication alone in surgical patients in the hospital setting. These studies may not permit inferences to the postdischarge home setting. Meta-analyses of RCTs are described next.

Kakkos et al (2016) reported on a Cochrane review that compared the efficacy of combined intermittent pneumatic compression (IPC) plus pharmacologic prophylaxis with single therapies alone in preventing VTE, updating a review initially published in 2008.⁷ Overall, 22 trials (total n=9137 patients) were included, of which 15 were RCTs (n=7762). For the comparison of IPC plus pharmacologic therapy with pharmacologic therapy alone, 10 studies evaluated the effect of combined therapies on the incidence of symptomatic pulmonary embolism (PE), 11 studies evaluated the effect on the incidence of deep vein thrombosis (DVT), and 5 studies evaluated

the effect on the incidence of symptomatic DVT. The primary pooled study results are summarized in Table 1.

Table 1. IPC Plus Pharmacologic Therapy vs Pharmacologic Therapy

Outcome	Trials	N	IPC + Pharmacologic Tx ^a	Pharmacologic Tx ^a	Pooled OR	95% CI	I ²
Pulmonary embolus	10	3544	1.20% (22/1833)	2.92% (50/1711)	0.39	0.23 to 0.64	0%
DVT	11	2866	2.9% (41/1414)	6.2% (90/1452)	0.42	0.18 to 1.03	68%
Symptomatic DVT	5	2312	0.43% (5/1155)	0.43% (5/1157)	1.02	0.29 to 3.54	0%

Adapted from Kakkos et al (2016).⁷

CI: confidence interval; DVT: deep vein thrombosis; IPC: intermittent pneumatic compression; OR: odds ratio; Tx: treatment.

^a Values are % (n/N).

These findings were similar in subgroup analyses by surgical type, including orthopedic surgeries. The risk of bias in the selected studies was generally unclear or high. Overall, reviewers concluded that combined modalities for VTE prophylaxis were more effective than single modalities. Although the risks for bias were high, the findings of the meta-analysis were consistent with those of previous studies.

A meta-analysis by O'Connell et al (2016) included 9 RCTs (total n=3347 patients) comparing IPC, with or without pharmacologic therapy, to pharmacologic agent alone in orthopedic and neurologic surgical patients.⁸ Six studies included patients undergoing major orthopedic surgery. In a pooled analysis of all 9 trials, significantly fewer patients in the IPC group (38/1680 [2.3%]) were diagnosed with DVT than in the control group (89/1667 [5.3%]) (pooled relative risk [RR], 0.49; 95% confidence interval [CI], 0.25 to 0.96; I²=60%). A pooled analysis of 8 studies did not find a significant difference in the rate of PE in the IPC and control groups; however, the total number of events was low (5 [0.6%] in the IPC group vs 7 [0.9%] in the control group), and 5 studies had no PE (pooled RR=0.71; 95% CI, 0.22 to 2.24; I²=2%).

Zareba et al (2014) published a meta-analysis of RCTs comparing compression plus pharmacologic prophylaxis with either intervention alone for postsurgical VTE prevention.⁹ Twenty-five studies met inclusion criteria: 13 on orthopedic surgery, 7 on abdominal surgery, 3 on neurosurgery, and 1 on cardiac surgery (the population in the remaining study was not reported). Eleven RCTs (totaln=4866 patients) compared pharmacologic prophylaxis plus compression with pharmacologic prophylaxis alone. IPC was used in five studies and graduated compression stockings in the other six. A pooled analysis of ten studies found the risk of DVT with pharmacologic prophylaxis plus compression was significantly lower than with pharmacologic prophylaxis alone (5.1% vs 10.4%; RR=0.51; 95% CI, 0.36 to 0.73; I²=11%). In addition, there was a significant between-group difference in the risk of PE (9 studies; RR=0.43; 95% CI, 0.27 to 0.66; I²=0%). Reviewers noted the PE analysis was heavily weighted by a large (n=2786 patients) study of patients undergoing cardiac surgery, which provided 69 of 89 total PE events. Four studies reported on symptomatic DVT. A pooled analysis did not find a significant difference between groups in risk of symptomatic DVT (4 studies; pooled RR=0.39; 95% CI, 0.05 to 2.90; I²=0%).

A systematic review and meta-analysis by Sobieraj et al (2013) included RCTs comparing pharmacologic and mechanical prophylaxis with either treatment alone in patients undergoing major orthopedic surgery.⁹ Six trials (totaln=961 patients) were identified, 5 of which compared combination prophylaxis with pharmacologic prophylaxis alone. Mechanical prophylaxis included IPCs, venous foot pumps, and graduated compression stockings. A pooled analysis of 4 RCTs found a significantly lower risk of DVT with combination prophylaxis than with pharmacologic prophylaxis alone (RR=0.48; 95% CI, 0.32 to 0.72). In other pooled analyses, there were no significant differences between groups in risk of PE (two studies), proximal DVT (three studies), or distal DVT (two studies).

A meta-analysis by Kakkos et al (2012) focused on patients undergoing hip and knee replacement.¹⁰ Six RCTs (totaln=1399 patients) were included; 4of them compared pharmacologic plus mechanical prophylaxis with pharmacologic prophylaxis alone. Three studies included both hip and knee replacement patients and the fourth included only hip replacement patients. A pooled analysis of 3 trials on total knee replacement found a significantly lower rate of DVT in the combined prophylaxis group (3.7%) than in the pharmacologic prophylaxis only group (18.7%; RR=0.27; 95% CI, 0.08 to 0.89; $I^2=42\%$). Similarly, there was a significantly lower risk of DVT with combined prophylaxis when pooling findings of 4 studies on hip replacement (0.9% vs 9.7%; RR=0.17; 95% CI, 0.06 to 0.46; $I^2=0\%$).

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

Findings from meta-analyses have suggested that the in-hospital addition of limb compression devices to pharmacologic management improves VTE prophylaxis, especially for prevention of DVTs. Findings related to the risk of PE are more limited because analyses might have been underpowered due to the small number of PE events. RCTs varied regarding patient populations (e.g., orthopedic surgery, nonorthopedic surgery, medical patients), compression devices (IPCs, foot pumps, sequential compression devices), cointerventions (e.g., compression stockings), duration of follow-up, and outcomes reported. The meta-analyses reported on the risk of DVT but some did not distinguish between symptomatic DVT, which is more clinically relevant, and asymptomatic (imaging-detected) DVT.

The available evidence also does not address the question of interest to this review: Is there an incremental benefit in the postdischarge setting by adding limb compression devices to pharmacologic prophylaxis? The postdischarge setting has important characteristics that preclude making inferences from the inpatient setting. Patient characteristics vary because discharged patients tend to be healthier than those in the hospital. Characteristics of home use also vary (e.g., treatment consistency, duration, application errors in use). RCTs evaluating the addition of limb compression devices to pharmacologic management postdischarge in the home setting are needed to permit conclusions about the incremental benefit of this technology on VTE prophylaxis.

Moderate-to-High Postsurgical Risk of VTE and a Contraindication to Pharmacologic Prophylaxis Clinical Context and Therapy Purpose

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

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

The following PICOTS were used to select literature to inform this review.

Patients

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, and morbid events.

Timing

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 one outcome of interest, longer follow-up was necessary to fully observe outcomes.

Setting

Patients with moderate-to-high postsurgical risk of VTE and a contraindication to pharmacologic prophylaxis are actively managed by cardiologists and primary care providers in an outpatient clinical setting.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

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

This section addresses whether postdischarge limb compression device use in moderate-to-high risk patients with a contraindication to pharmacologic prophylaxis improves the net health outcome compared with no postdischarge VTE prophylaxis. The ideal study design is an RCT comparing limb compression devices with no prophylaxis after hospital discharge. However, there may be ethical and practical barriers to conducting such a study, especially in higher risk patients. Alternatively, a network meta-analysis could indirectly compare outcomes of limb compression device use with no VTE prophylaxis. No RCTs or network meta-analyses of postdischarge use in patients with contraindication to pharmacologic prophylaxis were identified.

There is, however, a meta-analysis of RCTs comparing IPC use with placebo in the hospital setting. The meta-analysis was published by Ho and Tan (2013).¹¹ It included RCTs comparing IPC with no prophylaxis or another type of prophylaxis in hospitalized surgical and nonsurgical patients. 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 in both groups. A pooled analysis of 40 RCTs found a significantly lower rate of DVT with IPCs (7.3%) than with placebo (16.7%; RR=0.43; 95% CI, 0.36 to 0.52). Similarly, a pooled analysis of 26 trials found a significantly lower rate of PE with IPC (1.2%) than with placebo (2.8%; RR=0.48; 95% CI, 0.33 to 0.69). Results of the Ho and Tan (2013) meta-analysis suggested that IPC devices can be beneficial for VTE prophylaxis in patients with a contraindication to medication.

To draw inferences about the benefit of limb compression devices postdischarge 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.¹² All patients were also prescribed graduated compression stockings and 20% to 25% used anticoagulants. Patients were evaluated at nine days postsurgery, and those discharged earlier were permitted to use an IPC at home (median duration of hospitalization, four days). Patients who used the IPC device postdischarge received home visits at least daily to optimize compliance. Three (4%) of 75 patients in the IPC group and 14 (19%) of 75 patients in the usual care group developed VTE; the difference between groups was statistically significant ($p=0.008$). Among evaluable patients

in the IPC group, 23.3% were continuous users, 53.4% were intermittent users, and 23.3% discontinued use (this includes both inpatient and outpatient use). The mean duration of IPC use was 6.6 days. Findings would suggest that in-home use of IPC devices is feasible with adequate postdischarge planning and support.

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

A meta-analysis has supported the conclusion that the use of limb compression devices is superior to placebo for VTE prevention in hospitalized patients. Notably, the incidences of both DVT and PE were significantly lower among patients receiving limb compression. A limitation of the meta-analysis is that it did not stratify patients by risk level, nor was pharmacologic prophylaxis absent in all cases. Nonetheless, the inference is supported that in patients with a contraindication to pharmacologic prophylaxis, postdischarge use of limb compression devices is superior for VTE prophylaxis compared with no prophylaxis.

Results of an unblinded RCT, which only enrolled 150 patients and evaluated a single approach to patient support in the home (i.e., daily visits by care provider), were consistent with the feasibility of postdischarge home use of limb compression devices. In the U.S. health care system, appropriate postdischarge planning and transition are recognized as critical to reducing readmissions.^{13,14} When appropriate postdischarge planning and support are in place, the use of limb compression devices in the home in moderate-to-high risk patients with a contraindication to pharmacologic prophylaxis is likely to improve VTE prevention.

Summary of Evidence

For individuals who have moderate-to-high postsurgical risk of VTE and no contraindication to pharmacologic prophylaxis who receive home use of a limb compression device as an adjunct to anticoagulation, the evidence includes no RCTs assessing any incremental benefit of home use of a limb compression device, plus pharmacologic agents. The relevant outcomes are OS, symptoms, morbid events, and treatment-related morbidity. Four meta-analyses of RCTs have compared medication plus intermittent pneumatic compression with medication alone in surgical patients in the hospital setting. These trials do not permit inferences to the postdischarge home setting. Results of the meta-analyses have suggested that in-hospital addition of limb compression devices to pharmacologic management improves DVT prophylaxis. Limitations are: not distinguishing between asymptomatic and symptomatic DVT; sparse data on PE; and results generally not stratified by patient risk or specific intervention. Moreover, the postdischarge setting differs in important respects from the hospital setting. Discharged patients tend to be healthier than those in the hospital. Factors such as treatment consistency, duration, and application errors in use differ in the home. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have moderate-to-high postsurgical risk of VTE and a contraindication to pharmacologic prophylaxis who receive home use of a limb compression device, the evidence includes a meta-analysis of inpatients and a study comparing the use of postdischarge limb compression in the home setting to no prophylaxis. The relevant outcomes are OS, symptoms, morbid events, and treatment-related morbidity. The meta-analysis showed significantly fewer incidence of DVT (40 RCTs) and PE (26 RCTs) with limb compression. Despite limitations related to stratification of patient risk and pharmacologic prophylaxis, the meta-analysis showed that limb compression is superior to no prophylaxis. A study of the postdischarge use of a limb compression device combined with home visits showed that home use is feasible. With postdischarge planning and support, home use of limb compression devices in moderate-to-high risk patients who have a contraindication to pharmacologic prophylaxis is likely to improve VTE prevention. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Supplemental Information Practice Guidelines and Position Statements

American College of Chest Physicians

The ACCP(2016) updated its 2012 evidence-based guideline¹⁵ on antithrombotic therapy and prevention of thrombosis.¹⁶ The 2016 update, which addressed antithrombotic therapy for venous thromboembolism (VTE), outlined risk factors for bleeding with anticoagulant therapy and estimated the risks of major bleeding for patients in various risk categories (see Table 2).

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 2. 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).¹⁶

In its updated 2017 guidelines on antithrombotic therapy and prevention of VTE in patients undergoing orthopedic and nonorthopedic surgery, the ACCP recommended use of limb compression devices in orthopedic surgical patients^{17,18}:

- 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."

The ACCP recommendations on the use of limb compression devices in nonorthopedic general and abdominal-pelvic surgical patients, stratified by patient risk of VTE and risk of bleeding are listed in Table 3.²

Table 3. Recommendations on Limb Compression Device Use in Nonorthopedic General and Abdominal-Pelvic Surgical Patients

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

GOR: grade of recommendation VTE: venous thromboembolism.

Note that a standard duration of prophylaxis was not defined. An "extended-duration" prophylaxis was defined as lasting four weeks.

American Academy of Orthopaedic Surgeons

The American Academy of Orthopaedic Surgeons (2011) updated its guidelines on the prevention of VTE in patients undergoing elective hip and knee arthroplasty.¹⁸ 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 Obstetricians and Gynecologists

The American College of Obstetricians and Gynecologists (2007; reaffirmed 2012) updated its practice bulletin on prevention of deep vein thrombosis and pulmonary embolism after gynecologic surgery.⁵ As with ACCP recommendations discussed above, prophylaxis recommendations varied by patient risk level. For patients at moderate and high-risk of deep vein thrombosis, intermittent pneumatic compression was one of the recommended options for deep vein thrombosis prophylaxis. For patients at highest risk (i.e., >60 years plus prior VTE, cancer, or molecular hypocoagulable state), intermittent pneumatic compression or graduated compression stockings plus low-dose unfractionated heparin or low-molecular-weight heparin were recommended as prophylactic options. For all but the highest risk patients, the practice bulletin stated that, when intermittent pneumatic compression devices were used, "the devices should be used continuously until ambulation and discontinued only at the time of hospital discharge." For the highest risk patients, the bulletin stated that continuing prophylaxis for two to four weeks after discharge should be considered.

American Orthopaedic Foot and Ankle Society

The American Orthopaedic Foot and Ankle Society (2013) published 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 patients undergoing foot and ankle surgery. Further research in this field is necessary and is encouraged."¹⁹

European Society of Anesthesiology

The European Society of Anesthesiology (2018) published a series of guidelines on the prevention of VTE, with specific recommendations as listed in Table 4.

Table 4. Recommendations on Prevention of VTE

Patient Risk Group	Recommendation	GOR
Mechanical prophylaxis ²⁰ .	In patients with contraindications to pharmacologic thromboprophylaxis, IPC is recommended. In patients not at high risk for VTE, IPC is not recommended.	1B
Elderly patients ²¹ .	Multifaceted interventions (pneumatic compression devices and oral anticoagulants) are recommended after knee and hip replacement	1C
Cardiovascular and thoracic surgery ²² .	For patients undergoing coronary artery bypass graft and bioprosthetic aortic valve implantation, IPC is recommended. For low-risk patients	2C
	undergoing thoracic surgery, IPC is recommended. For high-risk patients undergoing thoracic surgery, pharmacologic prophylaxis plus IPC are recommended.	2B
Neurosurgery ²³ .	Patients undergoing craniotomy or with nontraumatic intracranial hemorrhage, IPC is recommended on admission. In patients with spinal cord injury or significant motor impairment, thromboprophylaxis extended into rehabilitation is suggested.	1C
		2C
Obese patients ²⁴ .	For patients undergoing bariatric surgery, IPC or anticoagulants recommended for low-risk patients, and IPC plus anticoagulants recommended for high-risk patients.	2C
		1C

GOR: grade of recommendation; IPC: intermittent pneumatic compression; VTE: venous thromboembolism.

None of the guidelines specified use of compression devices in the home setting.

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 5.

Table 5. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT01317160	Intermittent Pneumatic Compression Effects on Venous Thromboembolism Incidence and Healing of Achilles Tendon Rupture	150	Sep2018 (completed)
NCT02987946 ^a	Optimizing Anti Coagulant Therapy in Neurosurgical Interventions in Patients with an Increased Risk for Thrombo-embolic Complications	280	Dec 2019
NCT03044574 ^a	Trial to Assess the Effectiveness of Intermittent Pneumatic Compression in the Prevention of Postoperative Venous Thromboembolism in Surgical Patients at Extremely High Risk	407	Dec 2018 (ongoing)

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

References

1. 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-325S. PMID 22315265.
2. 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-277S. PMID 22315263.
3. MD+CALC. HAS-BLED Score for Major Bleeding Risk. n.d.; <http://www.mdcalc.com/has-bleed-score-for-major-bleeding-risk/>. Accessed January 22, 2018.
4. Fisher WD. Impact of venous thromboembolism on clinical management and therapy after hip and knee arthroplasty. Can J Surg. Oct 2011;54(5):344-351. PMID 21774881.
5. Committee on Practice Bulletins--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):429-440. PMID 17666620.
6. Froimson MI, Murray TG, Fazekas AF. Venous thromboembolic disease reduction with a portable pneumatic compression device. J Arthroplasty. Feb 2009;24(2):310-316. PMID 18534456.
7. 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: CD005258. PMID 27600864.
8. 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- 889. PMID 26720432.

9. 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):275-283. PMID 23401017.
10. Kakkos SK, Warwick D, Nicolaides AN, et al. Combined (mechanical and pharmacological) modalities for the prevention of venous thromboembolism in joint replacement surgery. *J Bone Joint Surg Br*. Jun 2012;94(6):729- 734. PMID 22628585.
11. 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):1003-1020. PMID 23852609.
12. 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):229-235. PMID 22188037.
13. Family Caregiver Alliance. Hospital Discharge Planning: A Guide for Families and Caregivers. 2009; <https://www.caregiver.org/hospital-discharge-planning-guide-families-and-caregivers>. Accessed January 22, 2018.
14. Boutwell A, Hwu S. Effective Interventions to Reduce Rehospitalizations: A Survey of the Published Evidence. Cambridge, MA: Institute for Healthcare Improvement; 2009.
15. 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.
16. 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.
17. Lieberman JR, Heckmann N. Venous Thromboembolism Prophylaxis in Total Hip Arthroplasty and Total Knee Arthroplasty Patients: From Guidelines to Practice. *J Am Acad Orthop Surg*. 2017 Dec;25(12):789-798. PMID: 29176502.
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):768-776. PMID 22134209.
19. American Orthopaedic Foot & Ankle Society (AOFAS). Position Statement: The Use of VTED Prophylaxis in Foot and Ankle Surgery. 2013; <http://www.aofas.org/medical-community/health-policy/Documents/VTED-Position-Statement-approv-7-9-13-FINAL.pdf>. Accessed January 22, 2018.
20. Afshari A, Fenger-Eriksen C, Monreal M, et al. European guidelines on perioperative venous thromboembolism prophylaxis: Mechanical prophylaxis. *Eur J Anaesthesiol*. Feb 2018;35(2):112-115. PMID 29112550.
21. Kozek-Langenecker S, Fenger-Eriksen C, Thienpont E, et al. European guidelines on perioperative venous thromboembolism prophylaxis: Surgery in the elderly. *Eur J Anaesthesiol*. Feb 2018;35(2):116-122. PMID 28901992.
22. Ahmed AB, Koster A, Lance M, et al. European guidelines on perioperative venous thromboembolism prophylaxis: Cardiovascular and thoracic surgery. *Eur J Anaesthesiol*. Feb 2018;35(2):84-89. PMID 29112541.
23. Faraoni D, Comes RF, Geerts W, et al. European guidelines on perioperative venous thromboembolism prophylaxis: Neurosurgery. *Eur J Anaesthesiol*. Feb 2018;35(2):90-95. PMID 29112542.
24. Venclauskas L, Maleckas A, Arcelus JI, et al. European guidelines on perioperative venous thromboembolism prophylaxis: Surgery in the obese patient. *Eur J Anaesthesiol*. Feb 2018;35(2):147-153. PMID 29112546.
25. Blue Cross Blue Shield Association. Medical Policy Reference Manual, No. 1.01.28 (March 2019).

Documentation for Clinical Review

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

- 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. Inclusion or exclusion of codes does not constitute or imply member coverage or provider reimbursement.

MN/IE

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

Type	Code	Description
CPT®	None	
HCPCS	E0650	Pneumatic compressor, nonsegmental home model
	E0651	Pneumatic compressor, segmental home model without calibrated gradient pressure
	E0652	Pneumatic compressor, segmental home model with calibrated gradient pressure
	E0655	Nonsegmental pneumatic appliance for use with pneumatic compressor, half arm
	E0656	Segmental pneumatic appliance for use with pneumatic compressor, trunk
	E0657	Segmental pneumatic appliance for use with pneumatic compressor, chest
	E0660	Nonsegmental pneumatic appliance for use with pneumatic compressor, full leg
	E0665	Nonsegmental pneumatic appliance for use with pneumatic compressor, full arm
	E0666	Nonsegmental pneumatic appliance for use with pneumatic compressor, half leg
	E0667	Segmental pneumatic appliance for use with pneumatic compressor, full leg
	E0668	Segmental pneumatic appliance for use with pneumatic compressor, full arm
	E0669	Segmental pneumatic appliance for use with pneumatic compressor, half leg
	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

Type	Code	Description
ICD-10 Procedure	None	

Policy History

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

Effective Date	Action	Reason
09/27/2013	BCBSA Medical Policy adoption	Medical Policy Committee
07/14/2014	Policy title change from Outpatient Use of Limb Pneumatic Compression Devices for Venous Thromboembolism Prophylaxis Policy revision with position change	Medical Policy Committee
05/29/2015	Coding update	Administrative Review
06/01/2016	Policy title change from Postsurgical Outpatient Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis Policy revision without position change	Medical Policy Committee
05/01/2017	Policy revision without position change	Medical Policy Committee
05/01/2018	Policy revision without position change	Medical Policy Committee
06/01/2019	Policy revision without position change	Medical Policy Committee

Definitions of Decision Determinations

Medically Necessary: A treatment, procedure, or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

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

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

Prior Authorization Requirements (as applicable to your plan)

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

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department. Please call (800) 541-6652 or visit the provider portal at www.blueshieldca.com/provider.

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