
Medical Policy



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Title: Postsurgical Home Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis

Description/Background

RISK OF VENOUS THROMBOEMBOLISM

Orthopedic Surgery

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 (PE), 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 effects 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 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 neurosurgery procedures. Assessment and quantitation of bleeding risk can be performed using instruments such as the HAS-BLED scoring system,(3) although these tools were not developed specifically for the postoperative period.

Major orthopedic surgeries have 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%.(7) 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, 2012 clinical practice guidelines published by ACCP recommended that one of several pharmacologic agents or mechanical prophylaxis be provided rather than no thromboprophylaxis.(1) The guidelines further recommend 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 post-discharge home use.

Limb Compression Prophylaxis

The ACCP guidelines have also noted that compliance is a major issue with home use of limb compression devices for thromboprophylaxis and recommend that, if this prophylactic option is selected, use should be limited to portable, battery-operated devices. Moreover, AACP recommended that devices be used for 18 hours per day. A 2009 non-randomized study found that there was better compliance with a portable battery-operated limb compression device than with a non-mobile 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 non-orthopedic surgery patients.(4) 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 (IPC) rather than no prophylaxis. For patients at low risk for VTE (about 1.5%), the guidelines have suggested mechanical prophylaxis. Unlike the guidelines on major orthopedic surgery, which recommended a minimum of 10-14 days of VTE prophylaxis, the guidelines on nonorthopedic surgery patients do not include a general timeframe for prophylaxis. They have, however, defined “extended duration” pharmacologic prophylaxis as lasting 4 weeks; the latter is recommended only for 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 use of limb compression devices in the post-discharge home setting. However, given the availability of portable, battery-operated devices, there is interest in home use of outpatient limb compression devices for VTE prevention following discharge from the hospital for major orthopedic and nonorthopedic surgery.

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 (FDA) through the 501(k) process for indications including prevention of deep vein thrombosis. A sample of portable devices cleared by FDA include:

- AIROS 6 Sequential Compression Device (AIROS Medical, Inc.): This device is safe for both home and hospital use.
- Plexus RP100 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, San Antonio, TX): This device is battery-powered.
- Venowave™ VW5 (Venowave): This device is battery-powered and strapped to the leg below the knee.
- ActiveCare®+SFT 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 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.

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

Medical Policy Statement

The safety and effectiveness of postsurgical home limb compression devices for venous thromboembolism prophylaxis have been established. It may be considered a useful therapeutic option when clinical criteria are met.

Inclusionary and Exclusionary Guidelines

Inclusions:

Postsurgical home use of limb compression devices for venous thromboembolism (VTE) prophylaxis is indicated when **one** of the following criteria are met:

- After major orthopedic procedures^a in individuals with a contraindication^b to anticoagulant and antiplatelet agents (i.e., at high-risk for bleeding);
- After major non-orthopedic or other orthopedic procedures in individuals who are at moderate or high risk of venous thromboembolism (see Tables IE 1 & 2) with a contraindication^b to anticoagulant and antiplatelet agents (i.e., at high-risk for bleeding);
- After major orthopedic^a or major non-orthopedic procedures^c, as an adjunct to anticoagulant and/or antiplatelet therapy, in individuals who are at extremely high risk^d for venous thromboembolism

Exclusions:

- Individuals who are at low-risk of venous thromboembolism.
- Home use of limb compression devices for venous thromboembolism prophylaxis for periods longer than 30 days post-surgery.

^a Examples include: *Major orthopedic surgery includes total hip arthroplasty, total knee arthroplasty, or hip fracture surgery.*

^b *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 thrombocytopenia can develop, precluding further use of heparin products.*

^c *Examples of major non-orthopedic surgery may include: urological, abdominal, pelvic, neurological, and extensive trauma procedures.*

^{dc} *Individuals older than 60 years plus prior VTE, cancer or molecular hypercoagulable state.*

Table IE 1. Caprini Score to Assess Risk of Venous Thromboembolism

Points	Risk factors
1	Age 41–60 years Minor surgery BMI greater than 25 kg/m ²

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

BMI: body mass index; VTE: venous thromboembolism.

Table IE 2. Caprini Score Converted to Risk Level for Venous Thromboembolism

Risk of Symptomatic VTE	Caprini Score
Low (~ 1.5%)	1-2 points
Moderate (~ 3.0%)	3-4 points
High (~6.0%)	5 or greater points

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

E0650	E0651	E0652	E0655	E0656	E0657
E0660	E0665	E0666	E0667	E0668	E0669
E0670	E0671	E0672	E0673	E0676	

Other codes (investigational, not medically necessary, etc.):

N/A

Policy Guidelines

Guidance on Determining High Risk for Bleeding

The American College of Chest Physicians (ACCP) guidelines on prevention of VTE in orthopedic surgery patients 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 patients in various risk categories (see Table PG1)

Risk factors include (1 point per risk factor):

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

Table PG1. Guidelines for Risk of Bleeding

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

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 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. 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 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 patients 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 ≥ 60 years, prior VTE, anesthesia ≥ 2 h, and bed rest ≥ 4 days; older age, male sex, longer length of hospital stay, and higher Charlson comorbidity score; and sepsis, pregnancy or postpartum state, central venous access, malignancy, prior VTE, and inpatient hospital stay > 2 days. In another study, most of the moderate to strong independent risk factors for VTE were surgical complications, including urinary tract infection, acute renal insufficiency, postoperative transfusion, perioperative myocardial infarction, and pneumonia.”

The American College of Obstetricians and Gynecologists use the Caprini Risk Assessment Model to determine VTE risk level in patients 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 patients and general surgery patients, and the ACCP has defined each of these risk groups by the expected rate of VTE in a population of patients 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	<ul style="list-style-type: none"> Age 41–60 years Minor surgery BMI greater than 25 kg/m² Swollen legs Varicose veins Pregnancy or postpartum state History of unexplained or recurrent pregnancy losses (greater than 3) Oral contraceptive, hormone replacement, or selective estrogen receptor modulator use* Sepsis (less than 1 month) Serious lung disease, including pneumonia (less than 1 month) Abnormal pulmonary function Acute myocardial infarction Congestive heart failure (less than 1 month) History of inflammatory bowel disease Medical patient on bed rest
2	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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.

Rationale

MODERATE-TO-HIGH POSTSURGICAL RISK OF VENOUS THROMBOEMBOLISM AND NO CONTRAINDICATION TO PHARMACOLOGIC PROPHYLAXIS

Clinical Context and Therapy Purpose

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

The following PICOs were 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 (OS), symptoms, morbid events, and treatment-related morbidity.

The existing literature evaluating home use of a limb compression device as an adjunct to anticoagulation as a treatment for moderate-to-high postsurgical risk of VTE and no contraindication to pharmacologic prophylaxis has varying lengths of follow-up. While studies described below all reported at least one outcome of interest, longer follow-up was necessary to fully observe outcomes.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

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

Review of Evidence

This section focuses on evidence that post-discharge use of limb compression devices (commonly referred to in the literature as intermittent pneumatic compression [IPC] devices) in addition to pharmacologic agents provide an incremental benefit to the net health outcome compared with pharmacologic agents alone. The ideal study to address patients with moderate-to-high postsurgical risk of venous thromboembolism (VTE) and no contraindication to pharmacologic prophylaxis is a superiority-randomized controlled trial (RCT) comparing venous thromboembolism (VTE) prophylaxis consisting of pharmaceutical agents plus home use of limb compression devices with pharmacologic agents alone. No RCTs with this study design were identified for patients discharged after major orthopedic surgery or other types of major surgery. There are, however, RCTs and meta-analyses of RCTs comparing medication plus compression devices with medication alone in surgical patients in the hospital setting. These studies may not permit inference 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 patients in the hospital setting.(8-13) Surgical populations represented in these analyses include patients undergoing abdominal, cardiac, neurologic, and orthopedic surgery. Commonly reported outcomes include the occurrence of deep vein thrombosis (DVT), symptomatic DVT, and 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. 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).

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 patients in the hospital setting. Relevant outcomes are overall survival, symptoms, morbid events, and treatment-related morbidity. Results of these meta-analyses suggest that in-hospital addition of an IPC device to pharmacologic management improves VTE prophylaxis. Limitations of these meta-analyses include: not distinguishing between asymptomatic and symptomatic DVT, sparse data on PE, and results generally not being stratified by patient risk or specific intervention(s). Moreover, these trials do not permit inferences to the post-discharge home setting since the post discharge setting differs in important respects from the hospital setting. Discharged patients tend to be healthier than those in the hospital. Factors such as treatment consistency, duration, and application errors in use also differ in the home.

MODERATE-TO-HIGH POSTSURGICAL RISK OF VTE AND 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 following PICO's were 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 principles described in the first indication.

Review of Evidence

This section addresses whether post-discharge limb compression device (commonly referred to in the literature as an IPC device) use in moderate-to-high risk patients with a contraindication to pharmacologic prophylaxis improves the net health outcome compared with no post-discharge VTE prophylaxis. The ideal study design is an RCT comparing limb compression devices and no prophylaxis after hospital discharge. However, there may be ethical and practical barriers to conducting such as study, especially in higher risk patients. Alternatively, a network meta-analysis could indirectly compare outcomes of limb compression device use to no VTE prophylaxis. One RCT of post-discharge use in patients with contraindication to pharmacologic prophylaxis was identified. Briefly summarized below are data from inpatients comparing limb compression device use to no prophylaxis.

Systematic Reviews

A few meta-analyses of RCTs have compared IPC devices to no prophylaxis in the hospital setting.(14-16) Populations include surgical and nonsurgical patients, including critically ill patients in a medical or surgical intensive care unit (ICU). Commonly reported outcomes include the occurrence of DVT and PE. As with the meta-analyses reviewed above, there was heterogeneity of participants and interventions. Studies using a no prophylaxis control group might have included lower risk patients and some studies involving higher risk patients also included pharmacologic prophylaxis across groups. Overall, findings from meta-analyses suggest that the in-hospital addition of an IPC device improves VTE prophylaxis over no prophylaxis, especially for the prevention of DVT; 2 of the 3 meta-analyses also saw statistically significant reductions in the incidence of PE.

Randomized Controlled Trials

To draw inferences about the benefit of limb compression devices post-discharge in these patients, the feasibility of home use should be considered. An unblinded RCT by Sobieraj-Teague et al (2012) compared the use of a portable battery-operated IPC device to usual care alone in patients undergoing cranial or spinal neurosurgery.(17) All patients were also prescribed graduated compression stockings and 20% to 25% used anticoagulants. Patients were evaluated at 9 days post-surgery and those discharged earlier were permitted to use an IPC at home (median duration of hospitalization, 4 days). Patients who used the IPC device post-discharge received home visits at least daily to optimize compliance. Three (4%) of 75 patients in the IPC group and 14 (19%) of 75 patients in the usual care group developed VTE; the difference between groups was statistically significant (p=0.008). Among evaluable patients in the IPC group, 23.3% were continuous users, 53.4% were intermittent users, and 23.3% discontinued use (this includes both inpatient and outpatient use). The mean duration of IPC use was 6.6 days. Findings 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 VTE and 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 patients in the hospital setting, and 1 RCT evaluated the feasibility of post-discharge home use of an IPC. Relevant outcomes are overall survival, symptoms, morbid events, and treatment-related morbidity. Results from meta-analyses suggest that in-hospital use of an IPC device improves VTE prophylaxis over no prophylaxis. Limitations include heterogeneity of participants and interventions; studies using a no prophylaxis control group might have included lower risk patients and some studies involving higher risk patients also included pharmacologic prophylaxis across groups. Nonetheless, the inference is supported that in patients with a contraindication to pharmacologic prophylaxis, post-discharge use of an IPC device is superior for VTE prophylaxis compared with no prophylaxis. A study of the post discharge use of an IPC device combined with home visits showed that home use is feasible. With post discharge planning and support, home use of an IPC device in moderate-to-high risk patients who have a contraindication to pharmacologic prophylaxis is likely to improve VTE prevention.

SUMMARY OF EVIDENCE

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

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

Supplemental Information

PRACTICE GUIDELINES AND POSITION STATEMENTS

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 patients undergoing elective hip and knee arthroplasty.⁽¹⁸⁾ The guidelines included the following recommendations relevant to this evidence review:

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

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

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

American College of Chest Physicians

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

Risk factors include (1 point per factor):

- Age >65 y
- Age>75y
- 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>
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).

In the 2012 guidelines for the prevention of VTE in orthopaedic surgery patients, the ACCP recommended the use of limb compression devices in orthopedic surgical patients:(2)

- 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 patients, stratified by patient risk of VTE and risk of bleeding are listed in Table 2.(3)

Table 2. 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	1B 1B 2C

	mechanical prophylaxis with elastic stockings or IPC to pharmacologic prophylaxis.”	
High risk for VTE (>6.0%) and high risk for major bleeding complications or in whom bleeding consequences would be particularly severe	“[W]e suggest use of mechanical prophylaxis, preferably with IPC, over no prophylaxis until the risk of bleeding diminishes and pharmacologic prophylaxis may be initiated.”	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)⁴

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-Gynecologists practice bulletin on prevention of deep vein thrombosis (DVT) and pulmonary embolism after gynecologic surgery was replaced in 2021.⁽²¹⁾ As with the ACCP recommendations discussed above, prophylaxis recommendations varied by patient risk level based on the Caprini Risk Assessment Model. For patients at moderate and high risk of DVT, intermittent pneumatic compression 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

The American Orthopaedic Foot & Ankle Society (2020) 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 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.”(22) 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 2019, the American Society of Clinical Oncology (ASCO) released updates to the clinical practice guideline on VTE prophylaxis and treatment in patients with cancer.(23) The guideline makes the following recommendation for mechanical prophylaxis in this patient population:

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

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

American Society of Hematology

The American Society of Hematology (2019) issued guidelines for the prevention and management of venous thromboembolism in surgical hospitalized patients.(24) The following are 2 suggestions for patients 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 patients considered at high risk of VTE, combined prophylaxis is particularly favored over mechanical or pharmacological prophylaxis alone."

Ongoing and Unpublished Clinical Trials

There are currently no ongoing and unpublished trials that might influence this review.

Government Regulations

National:

No national coverage determination was found for postsurgical prophylactic home use for venous thromboembolism prevention.

Local:

Local Coverage Article: Pneumatic Compression Devices (A52488), Original Effective Date: 10/01/15; Revision Date: 1/1/23

PREVENTION OF VENOUS THROMBOEMBOLISM

A pneumatic compression device (PCD) that provides intermittent limb compression for the purpose of prevention of venous thromboembolism (E0676) is a preventive service. Items that are used for a preventative service or function are excluded from coverage under the Medicare DME benefit.

E0676	Intermittent limb compression device (includes all accessories), not otherwise specified
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Therefore, claims for E0676 will be statutorily denied as no Medicare benefit.

Local Coverage Determination: Pneumatic Compression Devices (L33829), Original Effective Date 10/1/15, Revision Effective Date 6/7/22 **(Note: for the purposes of this policy, references to the treatment of Deep Venous Thrombosis Prevention are the focus)**

Coverage Indications, Limitations, and/or Medical Necessity

Deep Venous Thrombosis Prevention

A PCD coded as E0676 is used only for prevention of venous thrombosis. Refer to the related Policy Article nonmedical necessity coverage and payment rules section for information about lack of a Medicare benefit for devices used for prophylaxis of venous thrombosis.

ACCESSORIES

PCD related accessories (E0655-E0673) are eligible for reimbursement only when the appropriate, related base PCDs (E0650-E0651, E0675) meets the applicable coverage criteria for that type of PCD. If the base PCD is not covered, related accessories are not eligible for reimbursement. Claims for related items will be denied as not reasonable and necessary.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

N/A

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 7/27/23, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
7/1/13	4/16/13	4/22/13	Joint policy established
1/1/15	10/24/14	11/3/14	Routine maintenance Removed procedure code; added codes E0650-E0673 and E0676 Policy title revised - added "Postsurgical" and removed the word "Pneumatic"
5/1/16	2/16/16	2/16/16	Routine maintenance
5/1/17	2/21/17	2/21/17	Routine maintenance Policy extensively rewritten References updated In title, "Outpatient" deleted and "Home" added.
5/1/18	2/20/18	2/20/18	Routine maintenance
5/1/19	2/19/19		Routine maintenance
1/1/20	10/15/19		Routine maintenance
1/1/21	10/20/20		Routine maintenance
1/1/22	10/19/21		Routine maintenance
1/1/23	10/18/22		Routine maintenance (slp)
1/1/24	10/25/23		<ul style="list-style-type: none"> • Routine maintenance (slp) • Vendor managed: Northwood • Pharmacological therapies clarified in inclusions as anticoagulants and antiplatelets

Next Review Date: 4th Qtr, 2024

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: POSTSURGICAL HOME USE OF LIMB COMPRESSION DEVICES FOR VENOUS
THROMBOEMBOLISM PROPHYLAXIS

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered, policy criteria apply
BCNA (Medicare Advantage)	Refer to the Medicare information under the Government Regulations section of this policy.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.