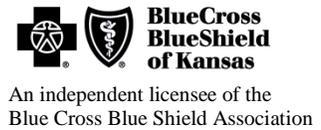


Medical Policy



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

See Also: *Pneumatic Compression Pumps for Treatment of Lymphedema and Venous Ulcers (for Home Use)*

Professional

Original Effective Date: April 9, 2013
Revision Date(s): April 9, 2013;
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Populations	Interventions	Comparators	Outcomes
Individuals: • With moderate-to-high postsurgical risk of venous thromboembolism and no contraindication to pharmacologic prophylaxis	Interventions of interest are: • Home use of a limb compression device as an adjunct to anticoagulation	Comparators of interest are: • Anticoagulation only	Relevant outcomes include: • Overall survival • Symptoms • Morbid events • Treatment-related morbidity
Individuals: • With moderate-to-high postsurgical risk of venous thromboembolism and a contraindication to pharmacologic prophylaxis	Interventions of interest are: • Home use of a limb compression device	Comparators of interest are: • No outpatient venous prophylaxis or other methods of mechanical prophylaxis	Relevant outcomes include: • Overall survival • Symptoms • Morbid events • Treatment-related morbidity

DESCRIPTION

Antithrombotic prophylaxis is recommended for surgical patients who are 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 (eg, 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 effects 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.

OBJECTIVE

The objective of this policy is to determine whether the use of limb compression devices in the home setting reduces the risk of venous thromboembolism in the postsurgical period.

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). 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 that have 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, will subsequently 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 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. In addition, 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 an acute DVT is PE, which can be fatal; this occurs when a DVT blood clot detaches and migrates to the lungs. In addition, 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 also be at increased risk of VTE during and after hospitalization. For example, it is estimated that rates of VTE without prophylaxis after gynecologic surgery is about 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 the ACCP recommend 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 postdischarge 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, 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

ACCP 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, ACCP has recommended prophylaxis with pharmacologic agents or intermittent pneumatic compression rather than no prophylaxis. For patients at low risk for VTE ($\approx 1.5\%$), the guidelines have suggested mechanical prophylaxis. Unlike the guidelines on major orthopedic surgery, which recommend a minimum of 10 to 14 days of VTE prophylaxis, the guidelines on nonorthopedic surgery patients do not include a general timeframe for prophylaxis. They have, however, defined “extended duration” pharmacologic prophylaxis as lasting 4 weeks; the latter is recommended only for 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 postdischarge home setting. However, given the availability of portable, battery-operated devices, there is interest in home use of 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 510(k) process for indications including prevention of deep vein thrombosis. Portable devices cleared by FDA include (product code: JOW):

- VenaPro™ Vascular Therapy System (InnovaMed Health, San Antonio, TX): This device is battery-powered.
- Venowave™ VW5 (Venowave; Stouffville, ON): The device is battery-powered and strapped to the leg below the knee.
- ActiveCare® + S.F.T. System (Medical Compression Systems, Or Akiva, Israel): 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 use of a 3-celled cuff sleeve.

- Restep® DVT System (Stortford Medical, West Windsor, NJ): This lightweight device uses single-chamber pressure cuffs attached to the patient's lower legs.
- Kendall SCD™ 700 Sequential Compression System (Covidien, Mansfield, MA): This pneumatic compression device can be used in the clinic or at home. It has a battery-operated option.
- PlasmaFlow™ (ManaMed): This system is portable, to be used at home or in a clinical setting.

POLICY

- A. 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), in the following situations:
1. After major orthopedic surgery (total hip arthroplasty, total knee arthroplasty, hip fracture surgery); **OR**
 2. After major nonorthopedic surgery or other orthopedic procedures in patients who are at moderate or high risk of VTE (see Policy Guidelines)
- B. Postsurgical home use of limb compression devices for VTE prophylaxis is considered **experimental / investigational** in all other situations, including, but not limited to:
1. After major orthopedic surgery (total hip arthroplasty, total knee arthroplasty, hip fracture surgery) in patients without a contraindication for anticoagulation; **OR**
 2. 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)
- C. Postsurgical home use of limb compression devices for VTE prophylaxis for periods longer than 30 days postsurgery is **not medically necessary**.
- D. Home use of limb compression devices for venous thromboembolism (VTE) prophylaxis after all other surgeries is considered **experimental / investigational**.

Policy Guidelines

This section reviews guidance on contraindications to use of 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 >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 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 (ACOG) revised its risk classification for VTE in patients undergoing major gynecological 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.”

RATIONALE

The evidence review has been updated with searches of the MEDLINE database. The most recent literature review is through January 8, 2018. The key published literature is summarized below.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of

life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to 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 a technology, 2 domains are examined: the relevance and the 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

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 venous thromboembolism (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	Pooled	95% CI	I ²
			Pharmacologic	Pharmacologic			
			Tx ^a	Tx ^a	OR		
Pulmonary embolus	10	3544	1.20% (22/1833)	2.92% (50/1711)	0.39	0.23 to 0.64	0%

Outcome	Trials	N	IPC +		Pooled OR	95% CI	I ²
			Pharmacologic Tx ^a	Pharmacologic Tx ^a			
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; $I^2=60\%$). 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; $I^2=2\%$).

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 (total N=4866 patients) compared pharmacologic prophylaxis plus compression with pharmacologic prophylaxis alone. IPC was used in 5 studies and graduated compression stockings in the other 6. A pooled analysis of 10 studies found that 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; $I^2=11\%$). 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; $I^2=0\%$). Reviewers noted that 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; $I^2=0\%$).

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.¹⁰ Six trials (total N=961 patients) were identified, five 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 (2 studies), proximal DVT (3 studies), or distal DVT (2 studies).

A meta-analysis by Kakkos et al (2012) focused on patients undergoing hip and knee replacement.¹¹ Six RCTs (total N=1399 patients) were included; four of 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 Venous Thromboembolism 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 (eg, orthopedic surgery, nonorthopedic surgery, medical patients), compression devices (IPCs, foot pumps, sequential compression devices), cointerventions (eg, 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 (eg, 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

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).¹² 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 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.¹³ All patients were also prescribed graduated compression stockings and 20% to 25% used anticoagulants. Patients were evaluated at 9 days postsurgery, and those discharged earlier were permitted to use an IPC at home (median duration of hospitalization, 4 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 (ie, 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.^{14,15} 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 a 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. Relevant outcomes are overall survival, 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 pulmonary embolism; 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 a 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. Relevant outcomes are overall survival, symptoms, morbid events, and treatment-related morbidity. The meta-analysis showed significantly fewer incidence of DVT (40 RCTs) and pulmonary embolism (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.

PRACTICE GUIDELINES AND POSITION STATEMENTS

American College of Chest Physicians

In 2016, the American College of Chest Physicians (ACCP) published an update to its 2012 evidence-based guideline¹⁶ on antithrombotic therapy and prevention of thrombosis.¹⁷ The 2016 update addressing antithrombotic therapy for venous thromboembolism (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 2).

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 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).¹⁷

In its updated 2012 guidelines on antithrombotic therapy and prevention of VTE in patients undergoing orthopedic and nonorthopedic surgery, ACCP recommended use of limb compression devices in orthopedic surgical patients¹:

- 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)."
- 2.1.2 "In patients undergoing hip fracture surgery (HFS), we recommend use of one of the following rather than no antithrombotic prophylaxis for a minimum of 10 to 14 days: LMWH, fondaparinux, LDUH, adjusted-dose VKA, aspirin (all Grade 1B), or an 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)."

For all above recommendations related to pneumatic compression pumps, ACCP recommended only portable, battery-powered devices be used and stated that efforts should be made to ensure devices are worn for 18 hours a day. Guidelines noted that compliance is the biggest challenge with use of pneumatic compression devices.

ACCP recommendations on 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 4 weeks.

American Academy of Orthopaedic Surgeons

In 2011, the American Academy of Orthopaedic Surgeons updated its guidelines on 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

In 2007 (reaffirmed in 2012), the American College of Obstetricians and Gynecologists updated its practice bulletin on prevention of deep vein thrombosis (DVT) and pulmonary embolism (PE) after gynecologic surgery.⁵ As with ACCP recommendations described above, prophylaxis recommendations varied by patient risk level. For patients at moderate and high risk of DVT, intermittent pneumatic compression was one of the recommended options for DVT prophylaxis. For patients at highest risk (ie, >60 years plus prior VTE, cancer, or molecular hypocoagulable state), IPC or graduated compression stockings plus LDUH or LMWH were recommended as prophylactic options. For all but the highest risk patients, the practice bulletin stated that, when IPC devices were used, "the devices should be used continuously until ambulation and discontinued only at the time of hospital discharge." For the highest risk patients, the bulletin stated that continuing prophylaxis for 2 to 4 weeks after discharge should be considered.

American Orthopaedic Foot and Ankle Society

In 2013, the American Orthopaedic Foot and Ankle Society 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

In 2018, the European Society of Anesthesiology 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 undergoing thoracic surgery, IPC is recommended. For high-risk patients undergoing thoracic surgery, pharmacologic prophylaxis plus IPC are recommended.	2C 2C 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

Patient Risk Group	Recommendation	GOR
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.

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	Compression Treatment Effects on Complications and Healing of Achilles Tendon Rupture	150	Sep 2017 (ongoing)
NCT02987946 ^a	Leiden Trial in Prevention of Post-Operative Thromboembolic Events (TIPOTEE)	280	May 2018
NCT03044574 ^a	Intermittent Pneumatic Compression in Surgical Patients at Extremely High Risk for Venous Thromboembolism (IPCSUPER)	400	Jul 2018

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. 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.

CPT/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
- E0660 Nonsegmental pneumatic appliance for use with pneumatic compressor, full leg
- E0666 Nonsegmental pneumatic appliance for use with pneumatic compressor, half leg
- E0667 Segmental pneumatic appliance for use with pneumatic compressor, full leg
- 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
- E0673 Segmental gradient pressure pneumatic appliance, half leg
- E0676 Intermittent limb compression device (includes all accessories), not otherwise specified

ICD-10 Diagnoses

The appropriate ICD-10 diagnoses consistent with the medical criteria and intent of the policy should be used.

REVISIONS

04-09-2013	Policy added to the bcbsks.com web site. Effective for Institutional providers 30 days after the Revision Date.
12-07-2015	<p>Policy published 11-6-2015. Effective 12-7-2015.</p> <p>Revised title to "Postsurgical Outpatient Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis" from "Outpatient Use of Limb Pneumatic Compression Devices for Venous Thromboembolism Prophylaxis"</p> <p>Description section updated</p> <p>In Policy section:</p> <ul style="list-style-type: none"> ▪ In Items C and D added "or non-major orthopedic surgery" to read, "after major non-orthopedic surgery or non-major orthopedic surgery" ▪ In Items A, B, C, D, E, F removed the word "pneumatic" to read, "...limb compression devices..." ▪ Policy Guidelines updated. <p>Rationale section updated</p> <p>In Coding section:</p> <ul style="list-style-type: none"> ▪ Removed HCPCS code: E0675 ▪ ICD-10 codes not added due to the high volume of ICD-10 codes (over 850) ▪ Removed specific ICD-9 codes. ▪ Added the phrase "The appropriate ICD-9 or ICD-10 diagnoses consistent with the medical criteria and intent of the policy should be used." <p>References updated</p>
12-01-2016	<p>Revised Title to "Postsurgical Home Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis" from "Postsurgical Home Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis"</p> <p>Description section updated</p> <p>In Policy section:</p> <ul style="list-style-type: none"> ▪ Revised to current language from the language below. This update represented primarily a format change combining medically necessary items together and E/I items together. No change of intent is noted. <p>"A. Outpatient use of limb compression devices for venous thromboembolism (VTE) prophylaxis after major orthopedic surgery may be considered medically necessary in patients with a contraindication to pharmacological agents ie, at high risk for bleeding.</p> <p>B. Outpatient use of limb compression devices for venous thromboembolism (VTE) prophylaxis after major orthopedic surgery is considered experimental / investigational in patients without a contraindication to pharmacological prophylaxis.</p> <p>C. Outpatient use of limb compression devices for venous thromboembolism (VTE) prophylaxis after major non-orthopedic surgery or non-major orthopedic surgery may be considered medically necessary in patients who are at moderate or high risk of venous thromboembolism (VTE) (see Policy Guidelines) with a contraindication to pharmacological agents ie, at high-risk for bleeding.</p> <p>D. Outpatient use of limb compression devices for venous thromboembolism prophylaxis (VTE) after major non-orthopedic surgery or non-major orthopedic surgery is considered experimental / investigational in patients who are at moderate or high risk of venous thromboembolism (VTE) without a contraindication to pharmacological prophylaxis and in patients who are at low risk of venous thromboembolism (VTE).</p>

	<p>E. Outpatient use of limb compression devices for venous thromboembolism (VTE) prophylaxis after all other surgeries is considered experimental / investigational.</p> <p>F. Outpatient use of limb compression devices for venous thromboembolism (VTE) prophylaxis for periods longer than 30 days post-surgery is not medically necessary.</p> <ul style="list-style-type: none"> ▪ In Item D revised "Outpatient" to "Home" to read "Home use of limb compression devices..." ▪ Updated Policy Guidelines updated
	Rationale section updated
	References updated
04-28-2017	<p>In Title section:</p> <ul style="list-style-type: none"> ▪ Added " See Also: Pneumatic Compression Pumps for Treatment of Lymphedema and Venous Ulcers"
	Description section updated
	<p>In Policy section:</p> <ul style="list-style-type: none"> ▪ Policy Guidelines updated
	Rationale section updated
	References updated
04-11-2018	Updated Description section.
	Updated Rationale section.
	<p>In Coding section:</p> <ul style="list-style-type: none"> ▪ Removed reference to ICD-9 coding.
	Updated References section.

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