



FEP Medical Policy Manual

FEP 1.01.28 Postsurgical Home Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis

Effective Policy Date: July 1, 2021

Original Policy Date: December 2013

Related Policies:

1.01.18 - Pneumatic Compression Pumps for Treatment of Lymphedema and Venous Ulcers

Postsurgical Home Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis

Description

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Antithrombotic prophylaxis is recommended for surgical patients at moderate-to-high risk of postoperative venous thromboembolism (VTE), including deep vein thrombosis and pulmonary embolism, 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 events and allergic reactions. Limb compression devices have been used as an adjunct or alternative to anticoagulation in the home setting for patients in the postoperative period as a method to reduce VTEs.

OBJECTIVE

The objective of this evidence review is to determine whether the use of limb compression devices in the home setting improves the net health outcome for patients at the risk of VTE in the postsurgical period.

POLICY STATEMENT

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

- After major orthopedic surgery (total hip arthroplasty, total knee arthroplasty, hip fracture surgery) in patients without a contraindication for anticoagulation; OR
- 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).

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

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

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

POLICY GUIDELINES

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

Contraindications to Anticoagulants

The main contraindication to anticoagulants is a high risk of bleeding. However, there is no absolute threshold at which anticoagulants cannot be used. Rather, there is a risk-benefit continuum that takes into account the benefits of treatment and risks of bleeding. There may also be intolerance to specific agents, although uncommon. Intolerance may result from allergic reactions or adverse events. Finally, when heparin preparations are used, serum antibodies and heparin-induced thrombocytosis can develop, precluding further use of heparin products.

Guidance on Determining High Risk for Bleeding

American College of Chest Physicians (ACCP) guidelines on prevention of VTE in orthopedic surgery patients listed the following general risk factors for bleeding [1](#).

- "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) [2](#).

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		
	<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).²

Clinical guidelines from the American Academy of Orthopaedic Surgeons have indicated that:³

"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.¹ 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.⁴ 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 :⁴

"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 2018), the American College of Obstetricians and Gynecologists revised its risk classification for VTE in patients undergoing major gynecologic surgery :⁵

"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."

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA REGULATORY STATUS

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

- AIROS 6 Sequential Compression Device (AIROS Medical, Inc.): This device is safe for both home and hospital use.
- Plexus 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): This device is battery-powered.
- Venowave™ VW5 (Venowave): This device is battery-powered and strapped to the leg below the knee.
- ActiveCare+S.F.T. System (Medical Compression Systems): The device applies sequential pneumatic compression to the lower limb; it has the option of being battery-operated. Foot compression is achieved with the use of a single-celled foot sleeve. Calf and thigh compression requires the use of a 3-celled cuff sleeve.
- Restep DVT System (Stortford Medical): This lightweight device uses single-chamber pressure cuffs attached to the patient's lower legs.
- Kendall SCD™ 700 Sequential Compression System (Covidien): This pneumatic compression device can be used in the clinic or at home; it has a battery-powered option.
- PlasmaFlow™ (ManaMed): This system is portable, to be used at home or in a clinical setting.

A full listing of products cleared by the FDA can be found at the following link: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?start_search=1&Center=&Panel=&ProductCode=JOW&KNumber=&Applicant=&DeviceName=&Type=&ThirdPartyReviewed=&ClinicalTrials=&Decision=&DecisionDateFrom=&DecisionDateTo=01%2F23%2F2021&IVDProducts=&Redact510K=&CombinationProducts=&ZNumber=&PAGENUM=500

RATIONALE

Summary of Evidence

For individuals who have a moderate-to-high postsurgical risk of venous thromboembolism (VTE) and no contraindication to pharmacologic prophylaxis who receive home use of an intermittent pneumatic compression (IPC) device as an adjunct to anticoagulation, there are no randomized controlled trials (RCTs) assessing the incremental benefit of home use of an IPC device. Multiple meta-analyses of RCTs have compared medication plus an IPC device with medication alone in surgical 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 are no RCTs assessing the incremental benefit 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, and 1 RCT evaluated the feasibility of post discharge home use of an IPC device. 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

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

American College of Chest Physicians

In 2016, the American College of Chest Physicians (ACCP) (updated its 2012 evidence-based guideline¹⁸ on antithrombotic therapy and prevention of thrombosis.² 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 >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
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Adapted from Kearon et al (2016).²

In a 2017 review of ACCP 2012 and American Academy of Orthopaedic Surgeons 2011 guidelines on antithrombotic therapy and prevention of VTE in patients undergoing orthopedic and nonorthopedic surgery, the ACCP recommended the use of limb compression devices in orthopedic surgical patients^{19.1}:

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 2.⁴

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 mechanical prophylaxis with elastic stockings or IPC to pharmacologic prophylaxis."	1B 1B 2C
High risk for VTE (~6.0%) and high risk for major bleeding complications or in whom bleeding consequences would be particularly severe	"[W]e suggest use of mechanical prophylaxis, preferably with IPC, over no prophylaxis until the risk of bleeding diminishes and pharmacologic prophylaxis may be initiated."	2C
High risk for VTE, both LMWH and unfractionated heparin contraindicated or unavailable and not at high risk for major bleeding complications:	"[W]e suggest low-dose aspirin, fondaparinux, or mechanical prophylaxis, preferably with IPC, over no prophylaxis."	2C
High risk for VTE, undergoing abdominal or pelvic surgery for cancer and not otherwise at high risk for major bleeding complications	"[W]e recommend extended-duration, postoperative, pharmacologic prophylaxis (4 weeks) with LMWH over limited-duration prophylaxis."	1B

Adapted from Gould et al (2012)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 Academy of Orthopaedic Surgeons

In 2011, the American Academy of Orthopaedic Surgeons (2011) updated its guidelines on the prevention of VTE in patients undergoing elective hip and knee arthroplasty.³ The guidelines included the following recommendations relevant to this evidence review:

5. "The work group suggests the use of pharmacologic agents and/or mechanical compressive devices for the prevention of venous thromboembolism in patients undergoing elective hip or knee arthroplasty, and who are not at elevated risk beyond that of the surgery itself for venous thromboembolism or bleeding. (Grade of Recommendation: Moderate) Current evidence is unclear about which prophylactic strategy (or strategies) is/are optimal or suboptimal. Therefore, the work group is unable to recommend for or against specific prophylactics in these patients. (Grade of Recommendation: Inconclusive) In the absence of reliable evidence about how long to employ these prophylactic strategies, it is the opinion of this work group that patients and physicians discuss the duration of prophylaxis. (Grade of Recommendation: Consensus)

6. In the absence of reliable evidence, it is the opinion of this work group that patients undergoing elective hip or knee arthroplasty, and who have also had a previous venous thromboembolism, receive pharmacologic prophylaxis and mechanical compressive devices. (Grade of Recommendation: Consensus)

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

American College of Obstetricians and Gynecologists

The 2007 (reaffirmed 2018) American College of Obstetricians and Gynecologists updated its practice bulletin on prevention of deep vein thrombosis (DVT) and pulmonary embolism after gynecologic surgery.⁵ As with ACCP recommendations discussed above, prophylaxis recommendations varied by patient risk level. For patients at moderate and high-risk of DVT, intermittent pneumatic compression (IPC) was one of the recommended options for DVT prophylaxis. For patients at highest risk (ie, >60 years plus prior VTE, cancer, or molecular hyper coagulable state), IPC or graduated compression stockings plus low-dose unfractionated heparin or low-molecular-weight heparin were recommended as prophylactic options. For all but the highest risk patients, the practice bulletin stated that, when 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 2020, the American Orthopaedic Foot and Ankle Society re-approved a position statement on VTE prophylaxis after foot and ankle surgery. It stated that: "There is currently insufficient data for the American Orthopaedic Foot & Ankle Society (AOFAS) to recommend for or against routine VTE prophylaxis for patients undergoing foot and ankle surgery. Further research in this field is necessary and is encouraged."²⁰ 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 Hematology

In 2019, the American Society of Hematology issued guidelines for the prevention and management and of venous thromboembolism in surgical hospitalized patients.²¹ 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."²¹

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

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

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
December 2013	New policy	
March 2014	Replace policy	Policy updated with literature review. "Pneumatic" removed from policy statements and policy title. Major non-orthopedic surgery changed to "major non-orthopedic surgery or non-major orthopedic surgery" in 3rd and 4th policy statements. "Post-surgical" added to policy. Reference 8 added.
March 2015	Replace policy	Policy updated with literature review. References 7 and 10 added. No change to policy statements.
June 2018	Replace policy	Policy updated with literature review through January 8, 2018; references 3, 7, 11, 13-14, 16-17, and 20-24 added. Policy statements and Policy Guidelines rewritten for clarity; intent of statements is unchanged. In title, "Outpatient" deleted and "Home" added.
June 2019	Replace policy	Policy updated with literature review through January 6, 2019; reference updated. Policy statements unchanged.
June 2020	Replace policy	Policy updated with literature review through January 13, 2020; no references added. Policy statements unchanged.
June 2021	Replace policy	Policy updated with literature review through January 25, 2021; references added. Policy statements unchanged. In title, "Outpatient" deleted and "Home" added per 2016 policy history.