

## MEDICAL POLICY – 1.01.525

# Postsurgical Home Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis

BCBSA Ref. Policy: 1.01.28

Effective Date: Dec. 1, 2024

Last Revised: Nov. 12, 2024


RELATED MEDICAL POLICIES:

1.01.18 Pneumatic Compression Pumps for Treatment of Lymphedema and Venous Ulcers

1.01.538 Cooling Devices Used in the Outpatient Setting

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## Introduction

One known risk after surgery is the development of blood clots. Clots can occur in your legs due to decreased blood flow when you are not up and about after surgery. These clots may move to your lungs and cause a pulmonary embolus (blood clot), which can be life threatening. Doctors now have treatments to decrease the risk of forming clots after a surgery. The usual way to prevent blood clots is with medication. Another way to prevent blood clots is with a device that gently squeezes the legs. This is known as a limb compression device. Limb compression devices are commonly used in the hospital setting, especially before people are able to be walking around. Most people are able to ambulate once they are sent home from the hospital. For some people who have a very high risk of getting clots or who are unable to walk after hospital discharge, using a limb compression device at home is considered medically necessary to prevent blood clots after surgery. This policy describes when home compression devices are considered medically necessary and paid for by the health plan.

**Note:** The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a

service may be covered.

## Policy Coverage Criteria

Procedure	Medical Necessity
<b>Major orthopedic procedure</b>	<p><b>Postsurgical home use of limb compression devices for venous thromboembolism (VTE) prophylaxis may be considered medically necessary in individuals with a documented contraindication to using standard anticoagulant medications (i.e., at high-risk for bleeding*) for the following surgeries:</b></p> <ul style="list-style-type: none"><li>• After major orthopedic surgery, including any of the following:<ul style="list-style-type: none"><li>○ A total hip arthroplasty (THA/THR)</li><li>○ A total knee arthroplasty (TKA/TKR)</li><li>○ A hip fracture surgery (HFS)</li></ul></li></ul> <p><b>Postsurgical home use of limb compression devices for venous thromboembolism prophylaxis after major orthopedic surgery (total hip arthroplasty, total knee arthroplasty, or hip fracturesurgery) is considered not medically necessary in individuals without a contraindication to using standard anticoagulant medications</b></p> <p><b>*Note:</b> General risk factors for bleeding from the American College of Chest Physicians (ACCP) guidelines on prevention of VTE in orthopedic surgery individuals: previous major bleeding, severe renal failure, concomitant antiplatelet agent, surgical factors such as a history of or difficult-to-control surgical bleeding during the current operative procedure or an extensive surgical dissection, or a revision surgery. And from the American Academy of Orthopedic Surgeons (AAOS) guidelines: individuals with hemophilia or active liver disease</p>

Procedure	Medical Necessity
<b>Major non-orthopedic surgery</b>	<p><b>Postsurgical home use of limb compression devices for venous thromboembolism (VTE) prophylaxis may be considered medically necessary in individuals who are at moderate or high-risk of venous thromboembolism** with a documented</b></p>



Procedure	Medical Necessity
	<p><b>contraindication to using standard anticoagulant medications (i.e., at high risk for bleeding*) for the following surgeries:</b></p> <ul style="list-style-type: none"> <li>• After a major non-orthopedic surgery including the following surgeries: <ul style="list-style-type: none"> <li>○ Individual had open abdominal or open pelvic surgery</li> <li>○ Surgery for a cancer diagnosis</li> </ul> </li> </ul> <p><b>Postsurgical home use of limb compression devices for venous thromboembolism prophylaxis after major non-orthopedic surgery (open abdominal and open pelvic procedures, surgery for a cancer diagnosis) is considered not medically necessary in individuals who are at moderate or high-risk of venous thromboembolism** without a contraindication to using standard anticoagulant medications (i.e. at high risk for bleeding*)</b></p> <p><b>**Note::</b> Risk factors for VTE considered moderate to high risk from the ACCP guidelines on prevention of VTE in non-orthopedic surgery individuals include: prior VTE, age ≥ 60, diagnosis of cancer, bed rest ≥ 4 days, anesthesia ≥ 2 hours. From the American College of Obstetricians and Gynecologists (ACOG): age ≥ 60, prior VTE, cancer diagnosis, molecular hypercoagulable state,</p>

Procedure	Medical Necessity
<b>All other situations</b>	<b>Postsurgical home use of limb compression devices for venous thromboembolism (VTE) prophylaxis in all other situations than those indicated above is considered not medically necessary</b>

Initial authorization	Medical Necessity
	<b>Posturgical home use of limb compression devices for venous thromboembolism prophylaxis for periods longer than 30 days postsurgery is considered not medically necessary</b>



## Documentation Requirements

The individual's medical records submitted for review should document that medical necessity criteria are met. The record should include the following:

- Clinical documentation of the surgery member has undergone plus the following:
  - The device will only be used for 30 days
  - Member has a condition that prevents member from taking standard blood clot medication

## Coding

Code	Description
HCPCS	
E0676	Intermittent limb compression device (includes all accessories), not otherwise specified

**Note:** CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

## Related Information

### 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 individuals listed the following general risk factors for bleeding:



- "Previous major bleeding (and previous bleeding risk similar to current risk)
- Severe renal failure
- Concomitant antiplatelet agent
- Surgical factors: history of or difficult-to-control surgical bleeding during the current operative procedure, extensive surgical dissection, and revision surgery."

The guidelines indicated, however, that "...specific thresholds for using mechanical compression devices or no prophylaxis instead of anticoagulant thromboprophylaxis have not been established."

The 2016 ACCP guidelines addressing antithrombotic therapy for VTE disease outlined risk factors for bleeding with anticoagulant therapy and estimated the risks of major bleeding for individuals in various risk categories (see [Table 1](#))

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 1. 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)
<b>Anticoagulation 0-3 mo, %</b>			
Baseline risk	0.6	1.2	4.8
Increased risk	1.0	2.0	8.0
Total risk	1.6	3.2	12.8
<b>Anticoagulation after first 3 mo, %/y</b>			
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).<sup>1</sup>

Clinical guidelines from the American Academy of Orthopaedic Surgeons (AAOS) have indicated that:

Individuals 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 individuals 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 individuals and, therefore, the work group is unable to recommend for or against using them to assess an individual's risk of bleeding. (Grade of Recommendation: Inconclusive)



## Guidance on Duration of Use

In individuals with contraindications to pharmacologic prophylaxis who are undergoing major orthopedic surgery (total hip arthroplasty, total knee arthroplasty, hip fracture surgery), ACCP guidelines are consistent with use of intermittent limb compression devices for 10 to 14 days after surgery. The ACCP suggestion on extended prophylaxis (up to 35 days) was a weak recommendation that did not mention limb compression devices as an option.

In the American College of Chest Physicians (ACCP) guidelines on VTE prophylaxis in individuals undergoing nonorthopedic surgery, the standard duration or “limited duration” of prophylaxis was not defined. However, “extended duration” pharmacologic prophylaxis was defined as four weeks, which was recommended only for individuals at high risk of VTE undergoing abdominal or pelvic surgery for cancer and not otherwise at high risk for major bleeding complications.

## Guidance on Determining Risk Level for Nonorthopedic Surgery

The ACCP guidelines on prevention of VTE in nonorthopedic surgery individuals included the following discussion of risk levels:

In individuals 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 individuals undergoing abdominal or pelvic surgery for cancer...

Patient-specific factors also determine the risk of VTE, as demonstrated in several relatively large studies of VTE in mixed surgical populations. Independent risk factors in these studies include: age > 60 years, prior VTE, and cancer; age  $\geq 60$  years, prior VTE, anesthesia  $\geq 2$  h, and bed rest  $\geq 4$  days; older age, male sex, longer length of hospital stay, and higher Charlson comorbidity score; and sepsis, pregnancy or postpartum state, central venous access, malignancy, prior VTE, and inpatient hospital stay > 2 days. In another study, most of the moderate to strong independent risk factors for VTE were surgical complications, including urinary tract infection, acute renal insufficiency, postoperative transfusion, perioperative myocardial infarction, and pneumonia.

The American College of Obstetricians and Gynecologists use the Caprini Risk Assessment Model to determine VTE risk level in individuals undergoing major gynecology surgery (see [Table 2](#)); this tool was used in developing the ACCP guidelines on VTE prevention. Caprini



scores of 1 to 2, 3 to 4, and 5 or higher indicate a low (1.5%), moderate (~3%), and high (~6%) risk of symptomatic VTE, respectively. The Caprini score is extensively used and has been validated in plastic surgery individuals and general surgery individuals, and the ACCP has defined each of these risk groups by the expected rate of VTE in a population of individuals undergoing general, abdominal-pelvic, bariatric, vascular, and plastic surgery without thromboprophylaxis.

**Table 2. Caprini Score to Assess Risk of Venous Thromboembolism**

Points	Risk Factors
1	<ul style="list-style-type: none"> <li>Abnormal pulmonary function</li> <li>Acute myocardial infarction</li> <li>Age 41–60 years</li> <li>BMI greater than 25 kg/m<sup>2</sup></li> <li>Congestive heart failure (less than 1 month)</li> <li>History of inflammatory bowel disease</li> <li>History of unexplained or recurrent pregnancy losses (greater than 3)</li> <li>Medical patient on bed rest</li> <li>Minor surgery</li> <li>Oral contraceptive, hormone replacement, or selective estrogen receptor modulator use*</li> <li>Pregnancy or postpartum state</li> <li>Sepsis (less than 1 month)</li> <li>Serious lung disease, including pneumonia (less than 1 month)</li> <li>Swollen legs</li> <li>Varicose veins</li> </ul>
2	<ul style="list-style-type: none"> <li>Age 61–74 years</li> <li>Central venous access</li> <li>Confined to bed (greater than 72 hours)</li> <li>Laparoscopic surgery (greater than 45 minutes)</li> <li>Major open surgery (greater than 45 minutes)</li> <li>Malignancy</li> </ul>
3	<ul style="list-style-type: none"> <li>Age 75 years or older</li> </ul>





Points	Risk Factors
	<ul style="list-style-type: none"> <li>Anticardiolipin antibodies</li> <li>Elevated serum homocysteine</li> <li>Factor V Leiden</li> <li>Family history of VTE</li> <li>Heparin-induced thrombocytopenia</li> <li>History of VTE</li> <li>Lupus anticoagulant</li> <li>Other congenital or acquired thrombophilia</li> <li>Prothrombin 20210A</li> </ul>
5	<ul style="list-style-type: none"> <li>Acute spinal cord injury (less than 1 month)</li> <li>Elective arthroplasty</li> <li>Hip, pelvis, or leg fracture</li> <li>Stroke (less than 1 month)</li> </ul>

Adapted from Gould et al (2012). BMI: body mass index; VTE: venous thromboembolism.

## Evidence Review

### Description

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



## Background

### Risk of Venous Thromboembolism

#### Orthopedic Surgery

Antithrombotic prophylaxis is recommended for surgical individuals at moderate-to-high risk of postoperative VTE, including DVT and PE. Individuals may be classified as moderate-to-high risk of VTE based on the surgical procedure and/or individual characteristics. For some types of surgery, such as major orthopedic surgery, there is a particularly high-risk of VTE due to the nature of the procedure and the prolonged immobility during and after surgery. The specific orthopedic procedures of concern are total knee arthroplasty, total hip arthroplasty, and hip fracture surgery. For these surgeries, all individuals undergoing the procedure are considered at high-risk for VTE.

Other surgeries with an increased risk of VTE include abdominal surgery, pelvic surgery, cancer surgery, and surgery for major trauma. For these types of surgeries, the risk varies. There are numerous individual-related risk factors such as increasing age, prior VTE, malignancy, pregnancy, and significant comorbidities that can be used in conjunction with the type of surgery to determine risk. There are tools for assessing VTE risk in surgical individuals, such as the modified Caprini Risk Assessment Model used in developing the 2012 American College of Chest Physicians (ACCP) guidelines on VTE prevention. However, in clinical practice, this and similar instruments are not regarded as definitive for the assessment of individual patient risk. Pharmacologic prophylaxis is indicated for individuals at moderate-to-high risk for VTE. As described in the ACCP guidelines, there are preferred antithrombotic prophylaxis regimens according to procedure and individual risk characteristics.<sup>2,3</sup>

#### Pharmacologic Prophylaxis

Pharmacologic prophylaxis is effective at reducing postoperative VTE but also has risks. The main risk is bleeding, although other adverse events such as allergic reactions and development of heparin antibodies can occur. Contraindications to pharmacologic prophylaxis include previous intolerance to these agents and increased risk of bleeding. Most individuals undergoing major surgery will not have an increased risk of bleeding precluding the use of anticoagulants, because these individuals would also likely have had a contraindication to the surgery itself and, thus, are likely to avoid the procedure. However, there are some cases in which individuals with a high bleeding risk will undergo major surgery, such as individuals with severe renal failure who require an essential procedure. Other individuals may develop



contraindications during the episode of care. For example, individuals who have excessive bleeding during or after surgery, or individuals who develop bleeding complications such as a gastrointestinal bleed, are considered to have a contraindication to anticoagulants. There are a few surgeries for which anticoagulants are contraindicated or avoided, most notably some neurosurgical procedures. Assessment and quantitation of bleeding risk can be performed using instruments such as the HAS-BLED scoring system,<sup>4</sup> although these tools were not developed specifically for the postoperative period.

Major orthopedic surgeries have a high-risk of DVT due to venous stasis of the lower limbs as a consequence of immobility during and after surgery. Also, direct venous wall damage associated with the surgical procedure itself may occur. DVTs are frequently asymptomatic and generally resolve when mobility is restored. However, some episodes of acute DVT can be associated with substantial morbidity and mortality. The most serious adverse consequence of acute DVT is PE, which can be fatal. 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%.<sup>5</sup> Other surgical individuals may be at increased risk of VTE during and after hospitalization. For example, it is estimated that rates of VTE without prophylaxis after gynecologic surgery are 15% to 40%.<sup>6</sup>

Thus, antithrombotic prophylaxis is recommended for individuals undergoing major orthopedic surgery and other surgical procedures who are at increased risk of VTE. For individuals undergoing major orthopedic surgery, clinical practice guidelines published by the ACCP (2012) recommended that one of several pharmacologic agents or mechanical prophylaxis be provided rather than no thromboprophylaxis.<sup>2</sup> The guidelines further recommended the use of pharmacologic prophylaxis during hospitalization, whether or not individuals are using a limb compression device. A minimum of 10 to 14 days of prophylaxis is recommended, a portion of which can be postdischarge home use.

### **Limb Compression Prophylaxis**

The ACCP guidelines have also noted that compliance is a major issue with the home use of limb compression devices for thromboprophylaxis and recommended that, if this prophylactic option is selected, use should be limited to portable, battery-operated devices. Moreover, ACCP recommended that devices be used for 18 hours a day. A 2009 nonrandomized study found that there was better compliance with a portable battery-operated limb compression device than



with a nonmobile device when used by individuals in the hospital following hip or knee replacement surgery.<sup>7</sup>

## Nonorthopedic Surgery

### Pharmacologic and Limb Compression Prophylaxis

The ACCP (2012) also issued guidelines on VTE prophylaxis in nonorthopedic surgery individuals.<sup>3</sup> For individuals undergoing general or abdominal-pelvic surgery who have a risk of VTE of 3% or higher, the ACCP has recommended prophylaxis with pharmacologic agents or intermittent pneumatic compression rather than no prophylaxis. For individuals at low-risk for VTE (~1.5%), the guidelines have suggested mechanical prophylaxis. Unlike the guidelines on major orthopedic surgery, which recommend a minimum of 10 to 14 days of VTE prophylaxis, the guidelines on nonorthopedic surgery individuals do not include a general timeframe for prophylaxis. They have, however, defined “extended duration” pharmacologic prophylaxis as lasting four weeks; the latter is recommended only for individuals at high-risk for VTE, undergoing abdominal or pelvic surgery for cancer, and who are not otherwise at high-risk for major bleeding complications.

National clinical guidelines have not specifically recommended the use of limb compression devices in the post discharge home setting. However, given the availability of portable, battery-operated devices, there is interest in the home use of limb compression devices for VTE prevention following discharge from the hospital for major orthopedic and nonorthopedic surgery.

## 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 individuals in the hospital setting. The relevant outcomes are overall survival (OS), 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



PE ; and results generally not being stratified by individual risk or specific intervention(s). Moreover, these trials do not permit inferences to the post discharge home setting, since the post-discharge setting differs in important respects from the hospital setting. Discharged individuals tend to be healthier than those in the hospital. Factors such as treatment consistency, duration, and application errors in use also differ in the home. 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 one 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 individuals in the hospital setting. The relevant outcomes are overall survival, symptoms, morbid events, and treatment-related morbidity. Results from meta-analyses suggest that in-hospital use of an IPC device improves VTE prophylaxis over no prophylaxis. Limitations include heterogeneity of participants and interventions; studies using a no prophylaxis control group might have included lower risk individuals and some studies involving higher risk individuals also included pharmacologic prophylaxis across groups. Nonetheless, the inference is supported that in individuals with a contraindication to pharmacologic prophylaxis, post-discharge use of an IPC device is superior for VTE prophylaxis compared with no prophylaxis. A study of the post discharge use of an IPC device combined with home visits showed that home use is feasible. With post discharge planning and support, home use of an IPC device in moderate-to-high risk individuals who have a contraindication to pharmacologic prophylaxis is likely to improve VTE prevention. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

### Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this policy are listed in [Table 3](#).

**Table 3. Summary of Key Trials**

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			



NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT03259204	Swedish Multicenter Trial of Outpatient Prevention of Leg Clots (StopLegClots)	1400	Dec 2025

NCT: national clinical trial.

## Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

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

### American Academy of Orthopaedic Surgeons

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

- “The work group suggests the use of pharmacologic agents and/or mechanical compressive devices for the prevention of venous thromboembolism in individuals 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 individuals. (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 individuals 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 individuals 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 individuals undergoing elective hip or knee arthroplasty, and who also have a known bleeding disorder (e.g., hemophilia) and/or active liver disease, use mechanical compressive devices for preventing venous thromboembolism. (Grade of Recommendation: Consensus)”

## American College of Chest Physicians

In 2016, the American College of Chest Physicians (ACCP) updated its 2012 evidence-based guideline<sup>19</sup> on antithrombotic therapy and prevention of thrombosis.<sup>1</sup> There was a second update to these guidelines in 2021, however, there was no new information for the prevention of thrombosis or mention of the use of limb compression devices.<sup>20</sup> The 2016 update, which addressed antithrombotic therapy for venous thromboembolism (VTE), outlined risk factors for bleeding with anticoagulant therapy and estimated the risks of major bleeding for individuals in various risk categories (see [Table 4](#)).

Risk factors include (1 point per factor):

- "Age >65 y
- Age >75 y
- Previous bleeding
- Cancer
- Metastatic cancer
- Renal failure
- Liver failure
- Thrombocytopenia
- Previous stroke
- Diabetes
- Anemia
- Antiplatelet therapy



- Poor anticoagulant control
- Comorbidity and reduced functional capacity
- Recent surgery
- Alcohol abuse
- Nonsteroidal anti-inflammatory drug.”

**Table 4. 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)
<b>Anticoagulation 0-3 mo, %</b>			
Baseline risk	0.6	1.2	4.8
Increased risk	1.0	2.0	8.0
Total risk	1.6	3.2	12.8
<b>Anticoagulation after first 3 mo, %/y</b>			
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).<sup>1</sup>

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

2.1.1 In individuals 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 individuals 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 individuals 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 individual compliance after hospital discharge and the high cost of these devices.”

In 2012, the ACCP recommendations on the use of limb compression devices in nonorthopedic general and abdominal-pelvic surgical individuals, stratified by individual risk of VTE and risk of bleeding are listed in [Table 5](#).<sup>3</sup>

**Table 5. 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	“[W]e suggest use of mechanical prophylaxis, preferably with IPC, over no prophylaxis until the risk of bleeding	2C



Patient Risk Group	Recommendation	GOR
bleeding consequences would be particularly severe	diminishes and pharmacologic prophylaxis may be initiated.”	
High risk for VTE, both LMWH and unfractionated heparin contraindicated or unavailable and not at high risk for major bleeding complications:	“[W]e suggest low-dose aspirin, fondaparinux, or mechanical prophylaxis, preferably with IPC, over no prophylaxis.”	2C
High risk for VTE, undergoing abdominal or pelvic surgery for cancer and not otherwise at high risk for major bleeding complications	“[W]e recommend extended-duration, postoperative, pharmacologic prophylaxis (4 weeks) with LMWH over limited-duration prophylaxis.”	1B

Adapted from Gould et al (2012)<sup>3</sup> GOR: grade of recommendation; IPC: intermittent pneumatic compression; LMWH: low molecular weight heparin; VTE: venous thromboembolism.

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

## American College of Obstetricians and Gynecologists

A 2007 American College of Obstetricians and Gynecologists (ACOG) practice bulletin on prevention of deep vein thrombosis (DVT) and pulmonary embolism (PE) after gynecologic surgery was replaced in 2021.<sup>21</sup> As with ACCP recommendations discussed above, prophylaxis recommendations varied by individual risk level based on the Caprini Risk Assessment Model. For individuals at moderate and high-risk of DVT, intermittent pneumatic compression (IPC) was one of the recommended options for DVT prophylaxis.

Relevant recommendations based on Level A evidence were as follows:

- “For gynecologic surgery individuals 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 individuals 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 individuals 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 individuals 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 individuals 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 individuals 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 individuals at high risk of VTE and major bleeding complications, and for whom both LMWH and low-dose unfractionated heparin are contraindicated or not available, mechanical prophylaxis alone (preferably with intermittent pneumatic compression) is recommended until the risk of bleeding diminishes and pharmacologic prophylaxis with fondaparinux can be added.”

## American Orthopaedic Foot and Ankle Society

In 2020, the American Orthopaedic Foot and Ankle Society re-approved a position statement on VTE prophylaxis after foot and ankle surgery. It stated that: “There is currently insufficient data for the American Orthopaedic Foot & Ankle Society (AOFAS) to recommend for or against routine venous thromboembolic (VTE) prophylaxis for individuals undergoing foot and ankle surgery. Further research in this field is necessary and is encouraged.”<sup>22</sup> The position statement further notes the following with regards to the use of mechanical prophylaxis: “Mechanical prophylaxis such as elastic compression stockings and sequential compression calf pumps or foot pumps on the contralateral extremity can be utilized intraoperatively and continued postoperatively through the duration of the hospital stay. While the true efficacy of this modality in foot and ankle surgery is unknown, complications are negligible and compression pumps may be considered in both the outpatient and inpatient setting. Whether there is a threshold duration of the surgical procedure for which these are beneficial is unknown, as is the optimal duration of their use post-operatively.”



## American Society of Clinical Oncology

In 2023, the American Society of Clinical Oncology (ASCO) released updates to the clinical practice guideline on VTE prophylaxis and treatment in individuals with cancer.<sup>23</sup> The guideline was unchanged from the previous 2019 guideline and makes the following recommendation for mechanical prophylaxis in this population: Recommendation 3.3. "Mechanical methods may be added to pharmacologic thromboprophylaxis but should not be used as monotherapy for VTE prevention unless pharmacologic methods are contraindicated because of active bleeding or high bleeding risk (Type: evidence based; Evidence quality: intermediate; Strength of recommendation: strong) "

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

## American Society of Hematology

In 2019, the American Society of Hematology (ASH) issued guidelines for the prevention and management of venous thromboembolism in surgical hospitalized individuals.<sup>24</sup> The following are two suggestions for individuals undergoing major surgery:

Recommendation 3: For those "who receive mechanical prophylaxis,...[use] intermittent compression devices over graduated compression stockings (conditional recommendation based on very low certainty in the evidence of effects)."

Recommendation 4: For those "who receive pharmacologic prophylaxis,...[use] combined prophylaxis with mechanical and pharmacological methods over prophylaxis with pharmacological agents alone (conditional recommendation based on very low certainty in the evidence of effects). Remark: For individuals considered at high risk of VTE, combined prophylaxis is particularly favored over mechanical or pharmacological prophylaxis alone."

## Medicare National Coverage

There is no national coverage determination.



## 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 individual's lower legs.
- Kendall SCD 700 Sequential Compression System (Covidien): This pneumatic compression device can be used in the clinic or at home; it has a battery-powered option.
- PlasmaFlow (ManaMed): This system is portable, to be used at home or in a clinical setting.

A full listing of products cleared by the FDA can be found at the following link: [510\(k\) Premarket Notification \(fda.gov\)](#) (Accessed April 10, 2024)

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## History

Date	Comments
03/11/13	New policy. New policy created with literature search through November 2012. Outpatient use of limb pneumatic compression devices after major orthopedic surgery is considered medically necessary in patients with a contraindication to pharmacological agents, i.e., at high-risk for bleeding. Outpatient use is considered medically necessary after major non-orthopedic surgery in patients who are at moderate or high risk of venous thromboembolism with a contraindication to pharmacological agents. Other outpatient uses are investigational and outpatient use beyond 30 days post-surgery is not medically necessary.
02/10/14	Replace policy. Title changed to include the word "Postsurgical" and delete the word "Pneumatic" in the title and policy statements. Policy statement for investigational indications changed to not medically necessary indications for outpatient use of limb compression devices to prevent VTE. Policy and policy guidelines reformatted for usability. Added definition of nonmajor orthopedic surgery to Policy Guidelines. Policy updated with literature search through November 2013. Kendall SCD device added to Regulatory Status. Reference 8 added; others renumbered. Policy statements changed as noted. ICD-9 and ICD-10 codes removed; they were provided for informational purposes only.
02/10/15	Annual Review. No change to policy statement.
06/01/16	Annual Review, approved May 10, 2016. No change to policy statement. Added references 15 and 17.



Date	Comments
03/01/17	Policy moved to new format. No change to policy statement.
06/01/17	Annual Review, approved May 16, 2017. Policy statement unchanged, however reorganized to include policy guidelines. Literature review through January 25, 2017. References 7 and 16-17 added. Removed HCPCS code E0218.
05/01/18	Annual Review, approved April 18, 2018. Policy updated with literature review through January 2018; references 20-24 added. Added the following to medical necessity criteria: prior history of VTE for major non-orthopedic surgery, and TURP to minor non-orthopedic surgery. Added Effient and Brilinta to antiplatelet medication examples; otherwise policy statements unchanged.
06/01/19	Annual Review, approved May 7, 2019. Policy updated with literature review through January 2019; one reference added. Minor edits to policy statements for greater clarity. Removed policy statement for minor non-orthopedic surgery. Removed HCPCS codes E1399, E0655, E0665, E0668, E0672 as only lower limbs are referenced in policy.
04/01/20	Delete policy 1.01.525, approved March 19, 2020, effective April 1, 2020. This policy is replaced with 1.01.28. Policy statements remain unchanged; this is effectively a policy renumber.
06/01/20	Annual Review, approved May 5, 2020. Policy updated with literature review through January 2020; references updated. Policy statements unchanged.
07/02/20	Coding update. HCPCS code E0675 removed. Related policy 1.01.10 removed; this will now be reviewed using InterQual criteria.
11/01/20	Added Related Policy 1.01.18 Pneumatic Compression Pumps for Treatment of Lymphedema and Venous Ulcers.
02/01/21	Correction made to clarify history summary of changes from 04/01/20: the policy statement was changed from not medically necessary to investigational for all other situations (e.g., major orthopedic and major nonorthopedic surgeries in patients without a contraindication for anticoagulation) – this was how the policy read when renumbered from 1.01.525 to 1.01.28 but the history section was recorded incorrectly. Additionally, the documentation requirements were updated to remove documentation of the need for confinement to a bed, chair, or wheelchair after surgery. No content changes were made.
06/01/21	Annual Review, approved May 20, 2021. Policy updated with literature review through January 25, 2021; references added. Medically necessary policy statements rewritten for greater ease of understanding; policy intent unchanged. Policy statement for postsurgical home use of limb compression devices in all other situations changed from is considered investigational to is considered not medically necessary. Removed HCPCS codes E0660, E0666, E0667, E0669, E0671. Added HCPCS code E0675.
10/01/21	New policy (renumbered to 1.01.525 from 1.01.28) approved September 14, 2021. This policy replaces 1.01.28 Postsurgical Home Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis. Deleted anti-inflammatories and antiplatelet





Date	Comments
	medications and added intolerance to heparin preparations as a contraindication to using standard anticoagulant medications policy statement.
06/01/22	Annual Review, approved May 23, 2022. Policy updated with literature review through January 13, 2022; guideline references updated. Policy statements unchanged.
06/01/23	Annual Review, approved May 5, 2023. Policy updated with literature review through January 24, 2023; references updated. Policy statement unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
06/15/23	Update to Related Policies. 1.01.26 is replaced with 1.01.538 Cooling Devices Used in the Outpatient Setting.
03/01/24	Interim Review, approved February 12, 2024. Reformatted and renamed policy criterion for contraindication to using standard anticoagulant medication as surgical factors: history of or difficult-to-control surgical bleeding during the current operative procedure, or extensive surgical dissection, or revision surgery for greater clarity.
06/01/24	Annual Review, approved May 13, 2024. Policy updated with literature review through February 7, 2024; guideline reference updated. Policy statements unchanged.
06/12/24	Minor edit to move content to a bullet point in the policy coverage criteria section.
12/01/24	Interim Review, approved November 12, 2024. Policy reformatted with policy statements emphasizing the type of surgery performed and if there is or is not a contraindication with use of standard anticoagulant medications. Risk of bleeding and moderate to high-risk of VTE reformatted to a guideline directed note. Policy intent unchanged. Removed HCPCS codes E0650, E0651, E0652, E0656, E0670, E0673, E0675 as they are not specific to the prevention of venous thromboembolism.

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