

Home Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis

Policy # 00386

Original Effective Date: 08/21/2013

Current Effective Date: 02/10/2025

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider postsurgical home use of limb compression devices for venous thromboembolism (VTE) prophylaxis in individuals with a contraindication to pharmacologic agents (see Policy Guidelines), in the following situations to be **eligible for coverage:****

Patient Selection Criteria

Coverage eligibility will be considered when either of the following criteria are met:

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

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers postsurgical home use of limb compression devices for venous thromboembolism (VTE) prophylaxis for periods longer than 30 days post surgery to be **investigational.***

Based on review of available data, the Company considers home use of limb compression devices for venous thromboembolism (VTE) prophylaxis to be **investigational*** in all other situations, including but not limited to:

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

Home Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis

Policy # 00386

Original Effective Date: 08/21/2013

Current Effective Date: 02/10/2025

- After major nonorthopedic surgery or other orthopedic procedures in individuals without a contraindication for anticoagulation who are at moderate or high risk of venous thromboembolism (VTE) (see Policy Guidelines).

Policy Guidelines

This section reviews guidance on contraindications to using anticoagulants, determining risk for bleeding, determining risk for 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

The 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: 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 individuals in various risk categories (see Table PG1).

Risk factors include (1 point per risk factor):

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



Home Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis

Policy # 00386

Original Effective Date: 08/21/2013

Current Effective Date: 02/10/2025

- 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).

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 a patient's risk of bleeding. (Grade of Recommendation: Inconclusive)”

Home Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis

Policy # 00386

Original Effective Date: 08/21/2013

Current Effective Date: 02/10/2025

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 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 4 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 PG2); this tool was used in developing the ACCP guidelines on VTE prevention. Caprini scores of 1 to 2, 3 to 4, and 5 or higher indicate a low (1.5%), moderate (~3%), and high (~6%) risk of symptomatic VTE, respectively. The Caprini score is extensively used and has been validated in plastic surgery 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.



Home Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis

Policy # 00386

Original Effective Date: 08/21/2013

Current Effective Date: 02/10/2025

Table PG2. Caprini Score to Assess Risk of Venous Thromboembolism

Points	Risk factors
1	Age 41–60 years Minor surgery BMI greater than 25 kg/m ² Swollen legs Varicose veins Pregnancy or postpartum state History of unexplained or recurrent pregnancy losses (greater than 3) Oral contraceptive, hormone replacement, or selective estrogen receptor modulator use* Sepsis (less than 1 month) Serious lung disease, including pneumonia (less than 1 month) Abnormal pulmonary function Acute myocardial infarction Congestive heart failure (less than 1 month) History of inflammatory bowel disease Medical patient on bed rest
2	Age 61–74 years Major open surgery (greater than 45 minutes) Laparoscopic surgery (greater than 45 minutes) Malignancy Confined to bed (greater than 72 hours) Central venous access
3	Age 75 years or older History of VTE Family history of VTE Factor V Leiden Prothrombin 20210A Lupus anticoagulant Anticardiolipin antibodies Elevated serum homocysteine Heparin-induced thrombocytopenia Other congenital or acquired thrombophilia
5	Stroke (less than 1 month) Elective arthroplasty Hip, pelvis, or leg fracture Acute spinal cord injury (less than 1 month)

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



Home Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis

Policy # 00386

Original Effective Date: 08/21/2013

Current Effective Date: 02/10/2025

The efficacy of mechanical thromboprophylaxis (e.g., frequent left-lateral decubitus positioning during late pregnancy, graduated elastic compression stockings, and pneumatic compression devices) during pregnancy or the puerperium is unknown because there is a paucity of evidence. In a study of 10 pregnant females, venous Doppler ultrasound demonstrated that graduated compression stockings increased femoral vein flow velocity during late pregnancy. The use of mechanical prophylaxis for hospitalized females during pregnancy is considered safe.

Background/Overview

Risk of Venous Thromboembolism

Orthopedic Surgery

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). Individuals may be classified as moderate-to-high risk of VTE based on the surgical procedure and/or individuals 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 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.

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,



Home Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis

Policy # 00386

Original Effective Date: 08/21/2013

Current Effective Date: 02/10/2025

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, 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. Pulmonary embolism 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%. 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%.

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. 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 post-discharge 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.

Nonorthopedic Surgery

Pharmacologic and Limb Compression Prophylaxis

The ACCP (2012) also issued guidelines on VTE prophylaxis in nonorthopedic surgery individuals. 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



Home Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis

Policy # 00386

Original Effective Date: 08/21/2013

Current Effective Date: 02/10/2025

pneumatic compression (IPC) 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 4 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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

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 \(fda.gov\)](#)



Home Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis

Policy # 00386

Original Effective Date: 08/21/2013

Current Effective Date: 02/10/2025

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

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.

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. 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 (DVT); sparse data on pulmonary embolism (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 1 RCT assessing the benefit and feasibility of home use of an IPC device. Meta-analyses of RCTs have compared VTE prophylaxis with an IPC device to no prophylaxis in surgical individuals in the hospital setting. Relevant outcomes are overall survival, symptoms, morbid events, and treatment-related morbidity. Results from meta-analyses suggest that in-hospital use of an IPC device improves VTE prophylaxis



Home Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis

Policy # 00386

Original Effective Date: 08/21/2013

Current Effective Date: 02/10/2025

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.

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 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. The guidelines included the following recommendations relevant to this evidence review:

1. "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)
2. 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)
3. 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)"



Home Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis

Policy # 00386

Original Effective Date: 08/21/2013

Current Effective Date: 02/10/2025

American College of Chest Physicians

In 2016, the American College of Chest Physicians (ACCP) updated its 2012 evidence-based guideline on antithrombotic therapy and prevention of thrombosis. 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. The 2016 update, which addressed antithrombotic therapy for VTE, 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 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		
	<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



Home Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis

Policy # 00386

Original Effective Date: 08/21/2013

Current Effective Date: 02/10/2025

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>
Increased risk	0.5	1.0	≥ 4.0
Total risk	0.8	1.6	≥ 6.5

Adapted from Kearon et al (2016).

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

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 individuals, stratified by individual risk of VTE and risk of bleeding are listed in Table 2.

Table 2. Recommendations on Limb Compression Device Use in Nonorthopedic General and Abdominal-Pelvic Surgical Individuals

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



Home Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis

Policy # 00386

Original Effective Date: 08/21/2013

Current Effective Date: 02/10/2025

Patient Risk Group	Recommendation	GOR
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)
 GOR: grade of recommendation; IPC: intermittent pneumatic compression; LMWH: low molecular weight heparin; VTE: venous thromboembolism.

Note that a standard duration of prophylaxis was not defined. An “extended-duration” prophylaxis was defined as lasting 4 weeks.

American College of Obstetricians and Gynecologists

A 2007 American College of Obstetricians and Gynecologists (ACOG) practice bulletin on prevention of deep vein thrombosis (DVT) and pulmonary embolism (PE) after gynecologic surgery was replaced in 2021. As with ACCP recommendations discussed above, prophylaxis recommendations varied by individual risk level based on the Caprini Risk Assessment Model. For



Home Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis

Policy # 00386

Original Effective Date: 08/21/2013

Current Effective Date: 02/10/2025

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 patients who are at high risk of VTE and average risk of bleeding complications, dual thromboprophylaxis with a combination of mechanical prophylaxis (preferably with intermittent pneumatic compression) and pharmacologic prophylaxis (low-dose unfractionated heparin or LMWH) is recommended.”
- “For patients at high risk of VTE who are undergoing cancer surgery, in-hospital dual thromboprophylaxis and extended-duration pharmacologic prophylaxis with LMWH after hospital discharge are recommended.”

Relevant recommendations based on Level B evidence were as follows:

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

American Orthopaedic Foot and Ankle Society

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 individuals undergoing foot and ankle surgery. Further research in this field is necessary and is encouraged.” 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



Home Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis

Policy # 00386

Original Effective Date: 08/21/2013

Current Effective Date: 02/10/2025

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 patients with cancer. 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 patients (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 VTE in surgical hospitalized individuals. The following are 2 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.

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.



Home Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis

Policy # 00386

Original Effective Date: 08/21/2013

Current Effective Date: 02/10/2025

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 3.

Table 3. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT03259204	Swedish Multicenter Trial of Outpatient Prevention of Leg Clots (StopLegClots)	1400	December 2025

NCT: national clinical trial.

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Home Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis

Policy # 00386

Original Effective Date: 08/21/2013

Current Effective Date: 02/10/2025

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Home Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis

Policy # 00386

Original Effective Date: 08/21/2013

Current Effective Date: 02/10/2025

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Policy History

Original Effective Date: 08/21/2013

Current Effective Date: 02/10/2025

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|------------|---|
| 02/06/2014 | Medical Policy Committee review |
| 02/19/2014 | Medical Policy Implementation Committee approval. Title changed from “Outpatient Use of Limb Pneumatic Compression Devices for Venous Thromboembolism Prophylaxis” to “Post-Surgical Outpatient Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis”. “Pneumatic” removed from all coverage statements. “Major non-orthopedic surgery” changed to “major non-orthopedic surgery or non-major orthopedic surgery” in the second coverage statements in both the Eligible for Coverage and Investigational sections. |
| 04/02/2015 | Medical Policy Committee review |
| 04/20/2015 | Medical Policy Implementation Committee approval. No change to coverage. |
| 04/07/2016 | Medical Policy Committee review |
| 04/20/2016 | Medical Policy Implementation Committee approval. No change to coverage. |
| 01/01/2017 | Coding update: Removing ICD-9 Diagnosis Codes |
| 07/06/2017 | Medical Policy Committee review |
| 07/19/2017 | Medical Policy Implementation Committee approval. Major orthopedic surgery clarified. Non-major orthopedic surgery changed to other orthopedic procedures. The word Outpatient was replaced with Home in the title. |
| 07/05/2018 | Medical Policy Committee review |
| 07/11/2018 | Medical Policy Implementation Committee approval. Added policy guidelines. |
| 07/03/2019 | Medical Policy Committee review |
| 07/18/2019 | Medical Policy Implementation Committee approval. No change to coverage. |
| 07/02/2020 | Medical Policy Committee review |
| 07/08/2020 | Medical Policy Implementation Committee approval. No change to coverage. |
| 07/01/2021 | Medical Policy Committee review |
| 07/14/2021 | Medical Policy Implementation Committee approval. No change to coverage. |
| 07/07/2022 | Medical Policy Committee review |



Home Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis

Policy # 00386

Original Effective Date: 08/21/2013

Current Effective Date: 02/10/2025

07/13/2022 Medical Policy Implementation Committee approval. No change to coverage.
07/06/2023 Medical Policy Committee review
07/12/2023 Medical Policy Implementation Committee approval. Policy statement regarding postsurgical home use of limb compression devices for VTE prophylaxis for periods longer than 30 days post surgery was changed from "not medically necessary" to "investigational."
07/02/2024 Medical Policy Committee review
07/10/2024 Medical Policy Implementation Committee approval. No change to coverage.
09/18/2024 Coding update.
01/02/2025 Medical Policy Committee review
01/08/2025 Medical Policy Implementation Committee approval. Title changed from "Postsurgical Home Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis" to "Home Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis." The word "postsurgical" was removed from the second investigational statement. Policy Guidelines updated.

Next Scheduled Review Date: 01/2026

Coding

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Home Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis

Policy # 00386

Original Effective Date: 08/21/2013

Current Effective Date: 02/10/2025

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	No codes
HCPCS	E0650, E0651, E0652, E0655, E0660, E0665, E0666, E0667, E0668, E0669, E0670, E0671, E0672, E0673, E0675, E0676, E0683
ICD-10 Diagnosis	All related diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.



Home Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis

Policy # 00386

Original Effective Date: 08/21/2013

Current Effective Date: 02/10/2025

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NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

