MEDICAL POLICY – 1.01.28

Postsurgical Home Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis

BCBSA Ref. Policy: 1.01.28
Effective Date: June 1, 2020
Last Revised: July 2, 2020
Replaces: 1.01.525

RELATED MEDICAL POLICIES:
1.01.26 Cooling Devices Used in the Outpatient Setting

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POLICY CRITERIA  |  DOCUMENTATION REQUIREMENTS  |  CODING
RELATED INFORMATION  |  EVIDENCE REVIEW  |  REFERENCES  |  HISTORY

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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

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Medical Necessity</th>
</tr>
</thead>
</table>
| Postsurgical home use of limb compression devices for VTE prophylaxis    | Postsurgical home use of limb compression devices for VTE prophylaxis may be considered medically necessary in patients with a contraindication to pharmacologic agents (see Policy Guidelines), in the following situations:  
  - After major orthopedic surgery (total hip arthroplasty, total knee arthroplasty, hip fracture surgery)  
  OR  
  - After major nonorthopedic surgery or other orthopedic procedures in patients who are at moderate or high risk of VTE (see Table 2).  

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

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Investigational</th>
</tr>
</thead>
</table>
| Postsurgical home use of limb compression devices for VTE prophylaxis    | Postsurgical home use of limb compression devices for venous thromboembolism (VTE) prophylaxis is considered investigational in all other situations, including but not limited to:  
  - After major orthopedic surgery (total hip arthroplasty, total knee arthroplasty, hip fracture surgery) in patients without a contraindication for anticoagulation  
  OR  
  - After major nonorthopedic surgery or other orthopedic procedures in patients without a contraindication for anticoagulation who are at moderate or high risk of VTE (see Table 2) |

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**Documentation Requirements**

The patient’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
  - Member will be confined to a bed, chair, or wheelchair after surgery

**Coding**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCPCS</td>
<td></td>
</tr>
<tr>
<td>E0650</td>
<td>Pneumatic compression, nonsegmental home model</td>
</tr>
<tr>
<td>E0651</td>
<td>Pneumatic compressor, segmental home model without calibrated gradient pressure</td>
</tr>
<tr>
<td>E0652</td>
<td>Pneumatic compressor, segmental home model with calibrated gradient pressure</td>
</tr>
<tr>
<td>E0656</td>
<td>Segmental pneumatic appliance for use with pneumatic compressor, trunk</td>
</tr>
<tr>
<td>E0660</td>
<td>Nonsegmental pneumatic appliance for use with pneumatic compressor, full leg</td>
</tr>
<tr>
<td>E0666</td>
<td>Nonsegmental pneumatic appliance for use with pneumatic compressor, half leg</td>
</tr>
<tr>
<td>E0667</td>
<td>Segmental pneumatic appliance for use with pneumatic compressor, full leg</td>
</tr>
<tr>
<td>E0669</td>
<td>Segmental pneumatic appliance for use with pneumatic compressor, half leg</td>
</tr>
<tr>
<td>E0670</td>
<td>Segmental pneumatic appliance for use with pneumatic compressor, integrated, 2 full legs and trunk</td>
</tr>
<tr>
<td>E0671</td>
<td>Segmental gradient pressure pneumatic appliance, full leg</td>
</tr>
<tr>
<td>E0673</td>
<td>Segmental gradient pressure pneumatic appliance, half leg</td>
</tr>
<tr>
<td>E0676</td>
<td>Intermittent limb compression device (includes all accessories), not otherwise specified</td>
</tr>
</tbody>
</table>

**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 patients listed the following general risk factors for bleeding (Falck-Ytter et al, 2012):

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

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

The 2016 ACCP guidelines addressing antithrombotic therapy for VTE disease outlined risk factors for bleeding with anticoagulant therapy and estimated the risks of major bleeding for patients in various risk categories (see Table 2) (Kearon et al, 2016).

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.”

Clinical guidelines from the American Academy of Orthopaedic Surgeons (Mont et al, 2011) have indicated that:

Patients undergoing elective hip or knee arthroplasty are at risk for bleeding and bleeding-associated complications. In the absence of reliable evidence, it is the opinion of this work group that patients be assessed for known bleeding disorders like hemophilia and for the presence of active liver disease which further increase the risk for bleeding and bleeding-associated complications. (Grade of Recommendation: Consensus) Current evidence is not clear about whether factors other than the presence of a known bleeding disorder or active liver disease increase the chance of bleeding in these patients and, therefore, the work group is unable to recommend for or against using them to assess a patient’s risk of bleeding. (Grade of Recommendation: Inconclusive)
Guidance on Duration of Use

In patients with contraindications to pharmacologic prophylaxis who are undergoing major orthopedic surgery (total hip arthroplasty, total knee arthroplasty, hip fracture surgery), ACCP guidelines are consistent with use of intermittent limb compression devices for 10 to 14 days after surgery (Falck-Ytter et al, 2012). The ACCP suggestion on extended prophylaxis (up to 35 days) was a weak recommendation that did not mention limb compression devices as an option.

In the ACCP guidelines on VTE prophylaxis in patients undergoing nonorthopedic surgery, the standard duration or “limited duration” of prophylaxis was not defined. However, “extended duration” pharmacologic prophylaxis was defined as 4 weeks, which was recommended only for patients at high risk for VTE undergoing abdominal or pelvic surgery for cancer and not otherwise at high risk for major bleeding complications.

Guidance on Determining Risk Level for Nonorthopedic Surgery

The ACCP guidelines on prevention of VTE in nonorthopedic surgery patients included the following discussion of risk levels (Gould et al, 2012):

In patients undergoing general and abdominal-pelvic surgery, the risk of VTE varies depending on both patient-specific and procedure-specific factors. Examples of relatively low-risk procedures include laparoscopic cholecystectomy, appendectomy, transurethral prostatectomy, inguinal herniorrhaphy, and unilateral or bilateral mastectomy. Open-abdominal and open-pelvic procedures are associated with a higher risk of VTE. VTE risk appears to be highest for patients undergoing abdominal or pelvic surgery for cancer....

Patient-specific factors also determine the risk of VTE, as demonstrated in several relatively large studies of VTE in mixed surgical populations. Independent risk factors in these studies include age > 60 years, prior VTE, and cancer; age³ 60 years, prior VTE, anesthesia³ 2 h, and bed rest³ 4 days; older age, male sex, longer length of hospital stay, and higher Charlson comorbidity score; and sepsis, pregnancy or postpartum state, central venous access, malignancy, prior VTE, and inpatient hospital stay > 2 days. In another study, most of the moderate to strong independent risk factors for VTE were surgical complications, including urinary tract infection, acute renal insufficiency, postoperative transfusion, perioperative myocardial infarction, and pneumonia.

In 2007 (reaffirmed in 2012), the American College of Obstetricians and Gynecologists revised its risk classification for VTE in patients undergoing major gynecologic surgery (American College of Obstetricians and Gynecologists, 2007):
Low: Surgery lasting less than 30 minutes in patients younger than 40 years with no additional risk factors.

Moderate: Surgery lasting less than 30 minutes in patients with additional risk factors; surgery lasting less than 30 minutes in patients aged 40 to 60 years with no additional risk factors; major surgery in patients younger than 40 years with no additional risk factors.

High: Surgery lasting less than 30 minutes in patients older than 60 years or with additional risk factors; major surgery in patients older than 40 years or with additional risk factors.

Highest: Major surgery in patients older than 60 years plus prior venous thromboembolism, cancer, or hypercoagulable state.

Evidence Review

Description

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

Background

Risk of Venous Thromboembolism

Orthopedic Surgery

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

Other surgeries with an increased risk of VTE include abdominal surgery, pelvic surgery, cancer surgery, and surgery for major trauma. For these types of surgeries, the risk varies. There are numerous patient-related risk factors such as increasing age, prior VTE, malignancy, pregnancy, and significant comorbidities that can be used in conjunction with the type of surgery to determine risk. There are tools for assessing VTE risk in surgical patients, such as the modified Caprini Risk Assessment Model used in developing the 2012 American College of Chest Physicians (ACCP) guidelines on VTE prevention. However, in clinical practice, this and similar instruments are not regarded as definitive for assessment of individual patient risk. Pharmacologic prophylaxis is indicated for patients at moderate-to-high risk for VTE. As described in the ACCP guidelines, there are preferred antithrombotic prophylaxis regimens according to procedure and patient risk characteristics.\textsuperscript{1,2}

**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 patients undergoing major surgery will not have an increased risk of bleeding precluding the use of anticoagulants, because these patients would also likely have had a contraindication to the surgery itself and, thus, are likely to avoid the procedure. However, there are some cases in which patients with a high bleeding risk will undergo major surgery, such as patients with severe renal failure who require an essential procedure. Other patients may develop contraindications during the episode of care. For example, patients who have excessive bleeding during or after surgery, or patients who develop bleeding complications such as a gastrointestinal bleed, are considered to have a contraindication to anticoagulants. There are a few surgeries for which anticoagulants are contraindicated or avoided, most notably some neurosurgical procedures. Assessment and quantitation of bleeding risk can be performed using instruments such as HAS-BLED scoring system,\textsuperscript{3} 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%. Other surgical patients may be at increased risk of VTE during and after hospitalization. For example, it is estimated that rates of VTE without prophylaxis after gynecologic surgery are 15% to 40%.

Thus, antithrombotic prophylaxis is recommended for patients undergoing major orthopedic surgery and other surgical procedures who are at increased risk of VTE. For patients undergoing major orthopedic surgery, 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 patients are using a limb compression device. A minimum of 10 to 14 days of prophylaxis is recommended, a portion of which can be postdischarge home use.

**Limb Compression Prophylaxis**

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

National clinical guidelines have not specifically recommended 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 moderate-to-high postsurgical risk of VTE and no contraindication to pharmacologic prophylaxis who receive home use of a limb compression device as an adjunct to anticoagulation, the evidence includes no RCTs assessing any incremental benefit of home use of a limb compression device, plus pharmacologic agents. The relevant outcomes are overall survival (OS), symptoms, morbid events, and treatment-related morbidity. Four meta-analyses of RCTs have compared medication plus intermittent pneumatic compression with medication alone in surgical patients in the hospital setting. These trials do not permit inferences to the post discharge home setting. Results of the meta-analyses have suggested that in-hospital addition of limb compression devices to pharmacologic management improves DVT prophylaxis. Limitations are: not distinguishing between asymptomatic and symptomatic DVT; sparse data on PE; and results generally not stratified by patient risk or specific intervention. Moreover, the post discharge setting differs in important respects from the hospital setting. Discharged patients tend to be healthier than those in the hospital. Factors such as treatment consistency, duration, and application errors in use differ in the home. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have moderate-to-high postsurgical risk of VTE and a contraindication to pharmacologic prophylaxis who receive home use of a limb compression device, the evidence includes a meta-analysis of inpatients and a study comparing the use of post discharge limb compression in the home setting to no prophylaxis. The relevant outcomes are OS, symptoms, morbid events, and treatment-related morbidity. The meta-analysis showed significantly fewer
incidence of DVT (40 RCTs) and PE (26 RCTs) with limb compression. Despite limitations related to stratification of patient risk and pharmacologic prophylaxis, the meta-analysis showed that limb compression is superior to no prophylaxis. A study of the post discharge use of a limb compression device combined with home visits showed that home use is feasible. With post discharge planning and support, home use of limb compression devices in moderate-to-high risk patients who have a contraindication to pharmacologic prophylaxis is likely to improve VTE prevention. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02987946*</td>
<td>Optimizing Anti Coagulant Therapy in Neurosurgical Interventions in Patients with an Increased Risk for Thrombo-embolic Complications</td>
<td>280</td>
<td>Dec 2019</td>
</tr>
<tr>
<td><strong>Unpublished</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT01317160</td>
<td>Intermittent Pneumatic Compression Effects on Venous Thromboembolism Incidence and Healing of Achilles Tendon Rupture</td>
<td>150</td>
<td>Sep2018 (updated 04/03/2019)</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

* Denotes industry-sponsored or cosponsored trial.

Practice Guidelines and Position Statements

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. The 2016 update, which addressed antithrombotic therapy for venous thromboembolism (VTE), outlined risk factors for
bleeding with anticoagulant therapy and estimated the risks of major bleeding for patients in various risk categories (see Table 2).

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 2. Guidelines for Risk of Bleeding

<table>
<thead>
<tr>
<th>Risk Factors</th>
<th>Estimated Absolute Risk of Major Bleeding</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Low Risk (0 Risk Factors)</td>
</tr>
<tr>
<td>Anticoagulation 0-3 mo, %</td>
<td></td>
</tr>
<tr>
<td>Baseline risk</td>
<td>0.6</td>
</tr>
<tr>
<td>Increased risk</td>
<td>1.0</td>
</tr>
<tr>
<td>Total risk</td>
<td>1.6</td>
</tr>
<tr>
<td>Anticoagulation after first 3 mo, %/y</td>
<td></td>
</tr>
<tr>
<td>Baseline risk</td>
<td>0.3</td>
</tr>
<tr>
<td>Increased risk</td>
<td>0.5</td>
</tr>
<tr>
<td>Total risk</td>
<td>0.8</td>
</tr>
</tbody>
</table>

Adapted from Kearon et al (2016).16

In a 2017 review of ACCP 2012 and American Academy of Orthopaedic Surgeons 2011 guidelines on antithrombotic therapy and prevention of VTE in patients undergoing orthopedic and nonorthopedic surgery, the ACCP recommended use of limb compression devices in orthopedic surgical patients17,1:

2.1.1 In patients undergoing total hip arthroplasty (THA) or total knee arthroplasty (TKA), we recommend use of one of the following for a minimum of 10 to 14 days rather than no antithrombotic prophylaxis: low-molecular-weight heparin (LMWH), fondaparinux, apixaban, dabigatran, rivaroxaban, low-dose unfractionated heparin (LDUH), adjusted-dose vitamin K antagonist (VKA), aspirin (all Grade 1B), or an intermittent pneumatic compression device (IPCD) (Grade 1C).”

2.5 “In patients undergoing major orthopedic surgery, we suggest using dual prophylaxis with an antithrombotic agent and an IPCD during the hospital stay (Grade 2C).”

2.6 “In patients undergoing major orthopedic surgery and increased risk of bleeding, we suggest using an IPCD or no prophylaxis rather than pharmacologic treatment (Grade 2C).”

“The efficacy of mobile mechanical compression devices alone has not been compared with any chemoprophylaxis agent in an appropriately powered randomized trial. In addition, concerns
have arisen with regard to patient compliance after hospital discharge and the high cost of these devices.”

In 2012, the ACCP recommendations on the use of limb compression devices in nonorthopedic general and abdominal-pelvic surgical patients, stratified by patient risk of VTE and risk of bleeding are listed in Table 3.²

### Table 3. Recommendations on Limb Compression Device Use in Nonorthopedic General and Abdominal-Pelvic Surgical Patients

<table>
<thead>
<tr>
<th>Patient Risk Group</th>
<th>Recommendation</th>
<th>GOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very low risk (&lt;0.5%)</td>
<td>“[W]e recommend that no specific pharmacologic or mechanical prophylaxis be used other than early ambulation.”</td>
<td>1B   2C</td>
</tr>
<tr>
<td>Low risk for VTE (&gt;1.5%)</td>
<td>“[W]e suggest mechanical prophylaxis, preferably with intermittent pneumatic compression (IPC), over no prophylaxis.”</td>
<td>2C</td>
</tr>
<tr>
<td>Moderate risk for VTE (&gt;3%) and not at high risk of bleeding</td>
<td>“[W]e suggest low-molecular-weight heparin (LMWH), low-dose unfractionated heparin, or mechanical prophylaxis with IPC over no prophylaxis.”</td>
<td>2B   2B  2C</td>
</tr>
<tr>
<td>Moderate risk for VTE (&gt;3%) and high risk for major bleeding complications or in whom bleeding consequences would be particularly severe</td>
<td>“We suggest mechanical prophylaxis, preferably with IPC, over no prophylaxis.”</td>
<td>2C</td>
</tr>
<tr>
<td>High risk for VTE (≥6.0%) and not at high risk of bleeding</td>
<td>“[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.”</td>
<td>1B   1B  2C</td>
</tr>
<tr>
<td>High risk for VTE (≥6.0%) and high risk for major bleeding complications or in whom bleeding consequences would be particularly severe</td>
<td>“[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.”</td>
<td>2C</td>
</tr>
<tr>
<td>High risk for VTE, both LMWH and unfractionated heparin contraindicated or unavailable and not at high risk for major bleeding complications:</td>
<td>“[W]e suggest low-dose aspirin, fondaparinux, or mechanical prophylaxis, preferably with IPC, over no prophylaxis.”</td>
<td>2C</td>
</tr>
</tbody>
</table>
### Patient Risk Group | Recommendation | GOR
---|---|---
High risk for VTE, undergoing abdominal or pelvic surgery for cancer and not otherwise at high risk for major bleeding complications | “[W]e recommend extended-duration, postoperative, pharmacologic prophylaxis (4 weeks) with LMWH over limited-duration prophylaxis.” | 1B

GOR: grade of recommendation. VTE: venous thromboembolism.

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

### American Academy of Orthopaedic Surgeons

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

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

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

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

The American College of Obstetricians and Gynecologists (2007; reaffirmed 2012) updated its practice bulletin on prevention of deep vein thrombosis and pulmonary embolism after gynecologic surgery.5 As with ACCP recommendations discussed above, prophylaxis recommendations varied by patient risk level. For patients at moderate and high-risk of deep vein thrombosis, intermittent pneumatic compression was one of the recommended options for deep vein thrombosis prophylaxis. For patients at highest risk (ie, >60 years plus prior VTE, cancer, or molecular hypocoagulable state), intermittent pneumatic compression or graduated compression stockings plus low-dose unfractionated heparin or low-molecular-weight heparin were recommended as prophylactic options. For all but the highest risk patients, the practice bulletin stated that, when intermittent pneumatic compression devices were used, “the devices should be used continuously until ambulation and discontinued only at the time of hospital discharge.” For the highest risk patients, the bulletin stated that continuing prophylaxis for two to four weeks after discharge should be considered.

American Orthopaedic Foot and Ankle Society

In 2013, the American Orthopaedic Foot and Ankle Society published a position statement on VTE prophylaxis after foot and ankle surgery. It stated that: “There is currently insufficient data for the American Orthopaedic Foot & Ankle Society (AOFAS) to recommend for or against routine VTE prophylaxis for patients undergoing foot and ankle surgery. Further research in this field is necessary and is encouraged.”19

American Society of Hematology

In 2019, the American Society of Hematology issued guidelines for the prevention and management of venous thromboembolism in surgical hospitalized patients.20 Following are 2 suggestions for patients undergoing major surgery:

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

Recommendation 4: For those “who receive pharmacologic prophylaxis,...[use] combined prophylaxis with mechanical and pharmacological methods over prophylaxis with pharmacological agents alone (conditional recommendation based on very low certainty in the
evidence of effects). Remark: For patients considered at high risk of VTE, combined prophylaxis is particularly favored over mechanical or pharmacological prophylaxis alone.\textsuperscript{20}

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 U.S. Food and Drug Administration through the 510(k) process for indications including prevention of DVT. Portable devices cleared by the Food and Drug Administration include (Food and Drug Administration 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.
- **AeroDVxTM System** (Sun Scientific Inc): This device is for hospital or outpatient use.
- **VenaPro™ Vascular Therapy System** (InnovaMed Health): This device is battery-powered.
- **Venowave™ VW5** (Venowave): This device is battery-powered and strapped to the leg below the knee.
- **ActiveCare® +S.F.T. System** (Medical Compression Systems): The device applies sequential pneumatic compression to the lower limb; it has the option of being battery-operated. Foot compression is achieved with the use of a single-celled foot sleeve. Calf and thigh compression requires the use of a 3-celled cuff sleeve.
- **Restep® DVT System** (Stortford Medical): This lightweight device uses single-chamber pressure cuffs attached to the patient’s lower legs.
- **Kendall SCD™ 700 Sequential Compression System** (Covidien): This pneumatic compression device can be used in the clinic or at home; it has a battery-powered option.
PlasmaFlow™ (ManaMed): This system is portable, to be used at home or in a clinical setting.

References


### History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>03/11/13</td>
<td>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, ie, 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.</td>
</tr>
<tr>
<td>02/10/14</td>
<td>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.</td>
</tr>
<tr>
<td>02/10/15</td>
<td>Annual Review. No change to policy statement.</td>
</tr>
<tr>
<td>06/01/16</td>
<td>Annual Review, approved May 10, 2016. No change to policy statement. Added references 15 and 17.</td>
</tr>
<tr>
<td>03/01/17</td>
<td>Policy moved to new format. No change to policy statement.</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
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<td>------------</td>
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</tr>
<tr>
<td>05/01/18</td>
<td>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.</td>
</tr>
<tr>
<td>06/01/19</td>
<td>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.</td>
</tr>
<tr>
<td>04/01/20</td>
<td>New policy number (1.01.28), approved March 19, 2020, effective April 1, 2020. This policy replaces 1.01.525. Policy statements remain unchanged; this is effectively a policy renumber.</td>
</tr>
<tr>
<td>07/02/20</td>
<td>Coding update. HCPCS code E0675 removed. Related policy 1.01.10 removed; this will now be reviewed using InterQual criteria.</td>
</tr>
</tbody>
</table>

**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2020 Premera All Rights Reserved.

**Scope:** Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.
Discrimination is Against the Law

Premera Blue Cross complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

Premera:
• Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  • Qualified sign language interpreters
  • Written information in other formats (large print, audio, accessible electronic formats, other formats)
• Provides free language services to people whose primary language is not English, such as:
  • Qualified interpreters
  • Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:
Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-4535, Fax 425-918-5592, TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at: U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
Email AppealsDepartmentInquiries@Premera.com

Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost.

Call 800-722-1471 (TTY: 800-842-5357).

Arabic (Arabic):
يحضي هذا الإشعار معلومات هامة. قد يحوي هذا الإشعار معلومات مهمة يخصك بشكل أو بأخرى. قد تكون هناك تأثيرات رمزية على خاصيتك الصحية أو الخصخصة في هذا الإشعار. نعم، إذا كنت لا تزال تحتاج إلى مزيد من المعلومات على تطبيقها الصالحة للإشراف على تطبيقها الصالحة للإشراف.

Call 800-722-1471 (TTY: 800-842-5357) أو

Chinese (Chinese):
本通知有重要的訊息。本通知可能有關於您透過Premera Blue Cross 提交的申請或保單的重要訊息。本通知內可能有重要日期。您可能需要在截止日期之前採取行動，以保留您的健康保障或費用補貼。您有權利免費以您的母語得到本訊息和幫助。請撥電話800-722-1471 (TTY: 800-842-5357)

Oromoo (Cushite):
Oromoo (Cushite):

Français (French):
Appelez le 800-722-1471 (TTY: 800-842-5357).

Kreyòl ayisyen (Creole):

Deutsche (German):

Hmoob (Hmong):

Ilokano (Ilocano):
Daytoy a Pakdaara ket naglaon iti Napateg nga Impormasion. Daytoy a pakdaara mabalini nga adda ket naglaon iti napateg nga impormasion maipanggep i aplikasyonowo nyo coverage babaen iti Premera Blue Cross. Daytoy kel mabalini dagiti importante a pesla iti daytoy a pakdaara. Mabalini nga adda rumbang nga aramidenyo nga addang sakbay dagiti partikular a naituding nga adda tawao tapno mapatgalinedyo a ti coverage ti salun-atyo wolung kadatit gastos. Adda karbenganyo a mangala iti daytoy nga impormasion ken tulgong iti bukddyog a pagasasao nga awan ti bayadanyo. Tumawag ti numero nga osa 800-722-1471 (TTY: 800-842-5357).

Italiano (Italian):
Questo avviso contiene informazioni importanti. Questo avviso può contenere informazioni importanti sulla tua domanda o copertura attraverso Premera Blue Cross. Potrebbero esserci date chiave in questo avviso. Potrebbe essere necessario un tuo intervento entro una scadenza determinata per consentirti di mantenere la tua copertura o sovvenzione. Hai il diritto di ottenere queste informazioni e assistenza nella tua lingua gratuitamente.
Chiamate 800-722-1471 (TTY: 800-842-5357).
日本語 (Japanese):
この通知には重要な情報が含まれています。この通知には、Premera Blue Crossの申請または補償範囲に関する重要な情報が含まれています。この通知に記載されている情報は、特定の事例において役立つでしょう。

한국어 (Korean):
본 통지서에는 중요한 정보가 들어 있습니다. 이 통지서는 Premera Blue Cross 를 통해 커버지에 관한 정보를 포함하고 있습니다. 본 통지서는 관심 있는 사람들에게 있어 유용할 수 있습니다.

Română (Romanian):

Русский (Russian):
Настоящее уведомление содержит важную информацию. Это уведомление может содержать важную информацию о вашем заявлении или страховом покрытии через Premera Blue Cross. В настоящем уведомлении могут быть указаны ключевые даты. Вам, возможно, потребуется привыкнуть к определенным предельным срокам для сохранения страховочного покрытия или помощи с расходами. Вы имеете право на бесплатное получение этой информации и помощь на вашем языке. Звоните по телефону 800-722-1471 (TTY: 800-842-5357).

Español (Spanish):
Este Aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud o cobertura a través de Premera Blue Cross. Es posible que haya fechas clave en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costos alguno. Llame al 800-722-1471 (TTY: 800-842-5357).

Polski (Polish):

Português (Portuguese):
Este aviso contém informações importantes. Este aviso poderá conter informações importantes a respeito de sua aplicação ou cobertura por meio do Premera Blue Cross. Poderão existir datas importantes neste aviso. Talvez seja necessário que você tome providências dentro de determinados prazos para manter sua cobertura de saúde ou ajuda de custos. Você tem o direito de obter esta informação e ajuda em seu idioma e sem custos. Ligue para 800-722-1471 (TTY: 800-842-5357).

Tiếng Việt (Vietnamese):
Thông báo này cũng khẳng định quyền của bạn. Nếu bạn không đồng ý với các điều khoản của thông báo này, bạn có thể không đồng ý với các điều khoản này. Bạn có thể liên hệ với chúng tôi để được hỗ trợ trong thời gian hợp lý.