Corporate Medical Policy

Postsurgical Home Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis

File Name: postsurgical_home_use_of_limb_ compression_devices_for_VTE_prophylaxis
Origination: 5/2013
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Description of Procedure or Service

Description
Patients undergoing major orthopedic surgery are at increased risk for venous thromboembolism (VTE). Patients undergoing other types of surgery may also be at increased risk of VTE. Limb compression devices are one option for thromboprophylaxis and are commonly used in the hospital setting. Outpatient use of compression devices following hospitalization, with or without pharmacologic prophylaxis, has also been proposed.

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

Other surgeries that have increased risk of VTE include abdominal surgery, pelvic surgery, cancer surgery, and surgery for major trauma. For these types of surgeries, the risk is variable. 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 that was 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.

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 use of anticoagulants, because these patients would also likely have had a contraindication to the surgery itself and, thus, are likely to avoid the procedure. However, there are some cases in which patients with a high bleeding risk will undergo major surgery, such as patients with severe renal failure who require an essential procedure. Other patients may develop contraindications during the episode of care. For example, patients who have excessive bleeding during or after surgery, or patients who develop bleeding complications such as a gastrointestinal bleed, will subsequently have a contraindication to anticoagulants. There are a few surgeries for which anticoagulants are contraindicated or avoided, most notably some neurosurgery procedures.

Assessment and quantitation of bleeding risk can be performed using instruments such as HAS-BLED scoring system, although these tools were not developed specifically for the postoperative period.

Major orthopedic surgeries have high risk of DVT due to venous stasis of the lower limbs as a consequence of immobility during and after surgery. In addition, direct venous wall damage associated with the surgical procedure itself may occur. DVTs are frequently asymptomatic and generally resolve when mobility is restored. However, some episodes of acute DVT can be associated with substantial morbidity and mortality. The most serious adverse consequence of an acute DVT is a PE which can be fatal; this occurs when the DVT detaches and migrates to the lungs. In addition, DVT may produce long-term vascular damage that leads to chronic venous insufficiency. Without thromboprophylaxis, the incidence of venographically detected DVT is approximately 42-57% after total hip replacement, and the risk of pulmonary embolism is approximately 1-28%. Other surgical patients may also be at increased risk of VTE during and after hospitalization. For example, it is estimated that rates of VTE without prophylaxis after gynecologic surgery are 15-40%.

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 in 2012 by the American College of Chest Physicians (ACCP) recommend that one of several pharmacologic agents or mechanical prophylaxis be provided rather than no thromboprophylaxis. The guidelines further recommend the use of pharmacologic prophylaxis during hospitalization, whether or not patients are using a limb compression device. A minimum of 10 to 14 days of prophylaxis is recommended, a portion of which can be postdischarge home use.

The ACCP guidelines noted that compliance is a major issue with home use of limb compression devices for thromboprophylaxis and recommend that, if this prophylactic option is selected, use should be limited to portable, battery-operated devices. Moreover, ACCP recommended that devices be used for 18 hours per day. A 2009 non-randomized study found that there was better compliance with a portable battery-operated limb compression device compared to a non-mobile device when used by patients in the hospital following hip or knee replacement surgery.

The ACCP also issued guidelines on VTE prophylaxis in non-orthopedic surgery patients. For patients undergoing general or abdominal-pelvic surgery who have a risk of VTE of 3% or higher, the ACCP recommends prophylaxis with pharmacologic agents or intermittent pneumatic compression rather than no prophylaxis. For patients at low risk for VTE (about 1.5%), the guidelines suggest mechanical prophylaxis. Unlike the guidelines on major orthopedic surgery, which recommend a minimum of 10-14 days of VTE prophylaxis, the guidelines on non-orthopedic surgery patients do not include a general timeframe for prophylaxis. They do, however, define “extended duration” pharmacologic prophylaxis as lasting 4 weeks; the latter is recommended only for patients at high risk for VTE, undergoing abdominal or pelvic surgery for cancer, and who are not otherwise at high risk for major bleeding complications.

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

Regulatory Status

Various pneumatic and peristaltic limb compression devices, with indications including prevention of DVT, have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. Portable devices that have been cleared by the FDA include:

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 Inc.): This device is battery powered and strapped to the leg below the knee.

ActiveCare+SFT® 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 use of a single-celled foot sleeve. Calf and thigh compression requires use of a 3-celled cuff sleeve.

Restep® DVT System (Stortford Medical): This is a lightweight device that utilizes 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-operated option.

PlasmaFlow™ (ManaMed): This system is portable, to be used at home or in a clinical setting.

Related Policies
Pneumatic Compression Pumps for Treatment of Lymphedema and Venous Ulcers

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

BCBSNC will provide coverage for postsurgical home use of limb compression devices when they are determined to be medically necessary because the medical criteria and guidelines noted below are met.

Benefits Application

Please refer to certificate for availability of benefit. See Covered Services section for Durable Medical Equipment.

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

Limb compression devices require a physician prescription to rent or purchase to be eligible for coverage.

The individual certificate should be reviewed to verify eligibility requirements and any prior approval or preauthorization necessary for the rental/purchase of equipment.

The DME supplier must meet eligibility and/or credentialing requirements as defined by the Plan to be eligible for reimbursement.

Postsurgical Home Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis

When Postsurgical Home Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis is covered

Postsurgical home use of limb compression devices for venous thromboembolism (VTE) prophylaxis may be considered **medically necessary** in individuals 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 individuals who are at moderate or high risk of VTE (see Policy Guidelines).

When Postsurgical Home Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis is not covered

Postsurgical home use of limb compression devices for 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 individuals without a contraindication for anticoagulation; OR
- After major nonorthopedic surgery or other orthopedic procedures in individuals without a contraindication for anticoagulation who are at moderate or high risk of VTE (see Policy Guidelines).

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

Policy Guidelines

For purposes of this policy, "major orthopedic surgery" includes total hip arthroplasty, total knee arthroplasty, or hip fracture surgery.

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 this is uncommon. Intolerance may result from allergic reactions or adverse eventts. 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 ACCP guidelines on prevention of VTE in orthopedic surgery patients list the following general risk factors for bleeding:

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

The guidelines note, 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. Risk factors include (1 point per risk factor):

- "Age >65 y
- Age >75y
- Previous bleeding
- Cancer
- Metastatic cancer
- Renal failure
- Liver failure
- Thrombocytopenia
- Previous stroke
- Diabetes
- Anemia
- Antiplatelet therapy
- Poor anticoagulant control
- Comorbidity and reduced functional capacity
- Recent surgery
- Alcohol abuse
- Nonsteroidal anti-inflammatory drug."

A clinical guideline from the American Academy of Orthopaedic Surgeons (2011) states:

"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 (THA, TKA or HFS), the ACCP guidelines are consistent with use of intermittent limb compression devices for 10-14 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 guideline on VTE prophylaxis in patients undergoing non-orthopedic surgery, the length of standard duration or "limited duration" prophylaxis was not defined. However, "extended duration" pharmacologic prophylaxis was defined as 4 weeks; this 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 risk level for patients undergoing non-orthopedic surgery
The ACCP guidelines on prevention of VTE in non-orthopedic surgery patients included the following discussion of risk levels:

"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 at least 60 years, prior VTE, and cancer; age >60 years, prior VTE, anesthesia at least 2 hours, and bed rest at least 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 more than 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 (ACOG) proposed the following risk classification for VTE in patients undergoing major gynecological surgery (available online at: http://guidelines.gov/content.aspx?id=11429):

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 age 40-60 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 molecular hypercoagulable state.

Summary

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

For individuals who have moderate-to-high postsurgical risk of VTE and no contraindication to pharmacologic prophylaxis who receive home use of an intermittent pneumatic compression device as an adjunct to anticoagulation, there are no randomized controlled trials (RCTs) assessing the incremental benefit of home use of an intermittent pneumatic compression device. Multiple meta-analyses of RCTs have compared medication plus an intermittent pneumatic compression device with medication alone in surgical patients in the hospital setting. Relevant outcomes are overall survival, symptoms, morbid events, and treatment-related morbidity. Results of these meta-analyses have suggested that in-hospital addition of intermittent pneumatic compression devices to pharmacologic management improves VTE 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(s). Moreover, the postdischarge setting differs in important respects from the hospital setting. Discharged patients tend to be healthier than those in hospital. Factors such as treatment consistency, duration, and application errors in use differ in the home. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have moderate-to-high postsurgical risk of VTE and contraindication to pharmacologic prophylaxis who receive home use of an intermittent pneumatic compression device, there is one RCT assessing the benefit and feasibility of home use of an intermittent pneumatic compression device. Meta-analyses of RCTs have compared VTE prophylaxis with an intermittent pneumatic compression device to no prophylaxis in surgical patients 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 intermittent pneumatic compression device improves VTE prophylaxis over no prophylaxis. Limitations include heterogeneity of participants and interventions; studies using a no prophylaxis control group might have included lower risk patients and some studies involving higher risk patients also included pharmacologic prophylaxis across groups. Nonetheless, the inference is supported that in patients with a contraindication to pharmacologic prophylaxis, post-discharge use of an intermittent pneumatic compression device is superior for VTE prophylaxis compared with no prophylaxis. A study of the post-discharge use of an intermittent pneumatic compression device combined with home visits showed that home use is feasible. With post-discharge planning and support, home use of an intermittent pneumatic compression device in moderate-to-high risk patients who have a contraindication to pharmacologic prophylaxis is likely to improve VTE prevention. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: *E0650, E0651, E0652, E0655, E0656, E0657, E0660, E0665, E0666, E0667, E0668, E0669, E0670, E0671, E0672, E0673, E0676*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.28, 12/13/12

Specialty Matched Consultant Advisory Panel – 11/2013

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.28, 12/12/13

Specialty Matched Consultant Advisory Panel – 11/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.28, 12/11/14

Specialty Matched Consultant Advisory Panel – 11/2015

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.28, 4/14/2016

Specialty Matched Consultant Advisory Panel – 11/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.28, 3/9/2017

Specialty Matched Consultant Advisory Panel – 11/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.28, 3/8/2018

Specialty Matched Consultant Advisory Panel – 11/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.28, 3/14/2019

Specialty Matched Consultant Advisory Panel – 11/2019

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.28, 3/12/2020

Specialty Matched Consultant Advisory Panel – 11/2020

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.28, 3/11/2021

Specialty Matched Consultant Advisory Panel – 11/2021

Specialty Matched Consultant Advisory Panel – 11/2022

Policy Implementation/Update Information

5/28/13 New policy adopted. Outpatient use of limb pneumatic compression devices after major orthopedic surgery is considered medically necessary in patients with a contraindication to pharmacological agents i.e., at high-risk for bleeding. Outpatient use is considered medically necessary after major non-orthopedic surgery in patients who are at moderate or high risk of venous thromboembolism with a contraindication to pharmacological agents. Other outpatient uses are investigational and outpatient use beyond 30 days post-surgery is not medically necessary. Senior Medical Director review. Notification given 5/28/13 for policy effective date 8/27/13. (sk)

1/14/14 Specialty Matched Consultant Advisory Panel review 11/20/13. No change to Policy statement. (sk)

2/25/14 Reference added. "Pneumatic" removed from policy statements and policy title. Major nonorthopedic surgery changed to "major nonorthopedic surgery or nonmajor orthopedic surgery" in 2nd covered policy statement and 2nd non covered policy statement. "Postsurgical" added to policy title. Senior Medical Director review. No change to coverage guidelines. (sk)

12/9/14 Specialty Matched Consultant Advisory Panel review 11/24/14. No change to Policy statement. (sk)

4/28/15 Reference added. (sk)

12/30/15 Specialty Matched Consultant Advisory Panel review 11/18/2015. (sk)

5/31/16 Reference added. Description section and Policy Guidelines updated. Policy statements rewritten for better clarity. Intent of Policy statements unchanged. Deleted "Outpatient" from policy title and added "Home" in its place. (sk)

12/30/16 Specialty Matched Consultant Advisory Panel review 11/30/2016. (sk)

5/26/17 Reference added. 2016 ACCP Guidelines added to Policy Guidelines section. Policy Guidelines updated. (sk)

12/15/17 Specialty Matched Consultant Advisory Panel review 11/29/2017. (sk)

4/13/18 Reference added. (sk)

1/15/19 Specialty Matched Consultant Advisory Panel review 11/28/2018. (sk)

7/1/19 Reference added. (sk)

12/10/19 Specialty Matched Consultant Advisory Panel review 11/20/2019. (sk)

5/12/20 Reference added. Regulatory Status section updated. (bb)

12/8/20 Specialty Matched Consultant Advisory Panel review 11/18/2020. (sk)

11/30/21 Reference added. Policy Guidelines updated. Specialty Matched Consultant Advisory Panel review 11/17/2021. (sk)

5/2/23 Policy review. Policy Guidelines updated. Specialty Matched Consultant Advisory Panel review 11/16/2022. (sk)