Protocol

Postsurgical Outpatient Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis

(10128)

(Formerly Outpatient Use of Limb Pneumatic Compression Devices for Venous Thromboembolism Prophylaxis)

Medical Benefit		**Effective Date**: 07/01/14	**Next Review Date**: 03/15
Preauthorization	No	**Review Dates**: 03/13, 03/14	

The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. ***Preauthorization is not required.*** *Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

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

Patients undergoing major surgery are at increased risk of developing deep vein thrombosis (DVT) and pulmonary embolism (PE), together known as venous thromboembolism (VTE). Patients who are having major orthopedic surgery (defined here as total hip arthroplasty [THA], total knee arthroplasty [TKA] and hip fracture surgery [HFS]) are at particularly high risk. Risk of DVT is increased 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% to 57% after total hip replacement, and the risk of PE is approximately 1% to 28%. (1) 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 is about 15% to 40%. (2)

Thus, antithrombotic prophylaxis is recommended for patients undergoing major orthopedic surgery and other surgical patients 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. (3) 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 outpatient use.

The ACCP guidelines noted that compliance is a major issue with limb compression devices used for thromboprophylaxis and recommend that, if this prophylactic option is selected, use should be limited to portable, battery-operated devices. Moreover, it is recommended that devices be used for 18 hours per day. A 2009 nonrandomized study found that there was better compliance with a portable battery-operated limb compression device compared to a nonmobile device when used by patients in the hospital following hip or knee replacement surgery. (4)

The ACCP also issued guidelines on VTE prophylaxis in nonorthopedic surgery patients. (5) 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 guideline on nonorthopedic surgery patients does not include a general timeframe for prophylaxis. They do, however, define "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 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 outpatient setting. However, especially with the availability of portable, battery-operated devices, there is interest in use of outpatient limb compression devices for DVT following discharge from the hospital for major orthopedic and nonorthopedic 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:

Venowave™ VW5 (Venowave Inc., Stouffville, Ontario, Canada): The device is a peristaltic pump that is strapped to the leg below the knee. It is powered using a single NiMH AA battery.

ActiveCare+SFT® System (Medical Compression Systems Ltd, or Akiva, Israel): 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 three-celled cuff sleeve.

Restep® DVT System (Stortford Medical LLC, West Windsor, NJ): 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, Mansfield, MA): This pneumatic compression device can be used in the clinic or at home. It has a two-pronged plug and is not battery-operated.

Related Protocol

Pneumatic Compression Pumps for Treatment of Lymphedema and Venous Ulcers

Policy (Formerly Corporate Medical Guideline)

Outpatient use of limb compression devices for venous thromboembolism (VTE) prophylaxis after major orthopedic surgery may be considered **medically necessary** in patients with a contraindication to pharmacological agents, i.e., at high-risk for bleeding.

Outpatient use of limb compression devices for VTE prophylaxis after major orthopedic surgery is considered **investigational** in patients without a contraindication to pharmacological prophylaxis.

Outpatient use of limb compression devices for VTE prophylaxis after major nonorthopedic surgery or nonmajor orthopedic surgery may be considered **medically necessary** in patients who are at moderate or high risk of VTE (see Policy Guidelines) with a contraindication to pharmacological agents, i.e., at high-risk for bleeding.

Outpatient use of limb compression devices for VTE prophylaxis after major nonorthopedic surgery or nonmajor orthopedic surgery is considered **investigational** in patients who are at moderate or high risk of VTE without a contraindication to pharmacological prophylaxis and in patients who are at low-risk of VTE.

Outpatient use of limb compression devices for VTE prophylaxis after all other surgeries is considered **investigational**.

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

Policy Guideline

For purposes of this Protocol, "major orthopedic surgery" includes total hip arthroplasty (THA), total knee arthroplasty (TKA), or hip fracture surgery (HFS).

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 (3):

- 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."

A clinical guideline from the American Academy of Orthopaedic Surgeons (2011) states (6):

"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. (3) 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 four 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 (5):

"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, and inguinal herniorrhaphy. 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 two hours, and bed rest at least four 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 two 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.

Benefit Application

For general business, the existence of Legislative Mandates, such as Federal Legislation which is regarding complications after a mastectomy, may impact whether a service could be considered not medically necessary or investigational.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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12. Kakkos SK, Caprini JA, Geroulakos G et al. Combined intermittent pneumatic leg compression and pharmacological prophylaxis for prevention of venous thromboembolism in high-risk patients. Cochrane Database Syst Rev 2008; (4):CD005258.
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