blue of california

Medical Policy

Postsurgical Outpatient Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis	
Type: Medical Necessity and Investigational / Experimental	**Policy Specific Section:** Durable Medical Equipment
Original Policy Date: September 27, 2013	**Effective Date:** July 14, 2014

Definitions of Decision Determinations

Medically Necessary: A treatment, procedure or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

Investigational/Experimental: A treatment, procedure or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California / Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a Split Evaluation, where a treatment, procedure or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Description

Patients undergoing major orthopedic surgery are at an increased risk of developing deep vein thrombosis (DVT) and pulmonary embolism (PE), together known as 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.

Policy

Outpatient use of limb compression devices (up to 30 days post-surgery) for venous thromboembolism prophylaxis may be considered **medically necessary** in **either** of the following situations:

- After major orthopedic surgery in patients with a contraindication to pharmacological agents (i.e., at high risk for bleeding)
- After major non-orthopedic surgery or non-major orthopedic surgery in patients who are at moderate or high risk of venous thromboembolism with a contraindication to pharmacological agents (i.e., at high risk for bleeding) (See Policy Guideline)

Outpatient use of limb compression devices for venous thromboembolism prophylaxis is considered **investigational** in **all** of the following situations:

- After major orthopedic surgery in patients without a contraindication to pharmacological prophylaxis
- After major non-orthopedic surgery or non-major orthopedic surgery in **either** of the following patients:
    - Those at moderate or high risk of venous thromboembolism without a contraindication to pharmacological prophylaxis
    - Those at low risk of venous thromboembolism
- After all other surgeries

Outpatient use of limb compression devices for venous thromboembolism prophylaxis for periods longer than 30 days post-surgery is considered **not medically necessary**.

Policy Guideline

For purposes of this policy, “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 American College of Chest Physicians (ACCP) guidelines on prevention of venous thromboembolism (VTE) in orthopedic surgery patients list 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

An Independent Member of the Blue Shield Association

- 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 (AAOS) (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 based on patient-specific and procedure-specific factors (Gould et al., 2012):

- **Procedure-Specific Risk Factors**:
  - Low risk: Laparoscopic cholecystectomy, appendectomy, transurethral prostatectomy, inguinal herniorrhaphy, and unilateral or bilateral mastectomy
  - High risk: Open abdominal and open-pelvic procedures
  - Highest risk: Abdominal or pelvic surgery for cancer
- **Patient-Specific Risk Factors** (as demonstrated in several relatively large studies of VTE in mixed surgical populations):

An Independent Member of the Blue Shield Association

- Age ≥ 60
- Anesthesia ≥ 2 hours
- Bed rest ≥ 4 days
- Central venous access
- Higher Charlson comorbidity score
- Inpatient hospital stay ≥ 2 days
- Male
- Malignancy
- Pregnancy or postpartum state
- Prior VTE
- Sepsis
- Surgical complications, including urinary tract infection, acute renal insufficiency, postoperative transfusion, perioperative myocardial infarction, and pneumonia

The American College of Obstetricians and Gynecologists (ACOG, 2007) proposed the following risk classification for VTE in patients undergoing major gynecological surgery:

- **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

Coding

Per the manufacturers, Venowave VW5 (Saringer Life Science Technologies Inc., Stouffville, Ontario, Canada) and ActiveCare®+S.F.T. (Synchronized Flow Technology) System (Medical Compression Systems LTD, Or Akiva, Israel) are billed using HCPCS code: E0676.

Internal Information

There is an MD Determination Form for this Medical Policy. It can be found on the following Web page:
http://myworkpath.com/healthcareservices/MedicalOperations/PSR_Determination_Pages.htm

Documentation Required for Clinical Review
• History and physical including: o Patient's risk for bleeding

An Independent Member of the Blue Shield Association

- Reason for contraindication to anticoagulation
- Reason for pneumatic compression device
- Type of surgery performed

- Operative report
- Prescription for pump and/or appliance

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available

Click here to view the appendix for this policy

An Independent Member of the Blue Shield Association