Postsurgical Home Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis

Policy #: 00386
Original Effective Date: 08/21/2013
Current Effective Date: 07/19/2017

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

When Services Are Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:
- Benefits are available in the member’s contract/certificate, and
- Medical necessity criteria and guidelines are met.

Based on review of available data, the Company may consider outpatient use of limb compression devices for venous thromboembolism (VTE) prophylaxis after major orthopedic surgery (total hip arthroplasty, total knee arthroplasty, hip fracture surgery) in patients with a contraindication to pharmacologic agents i.e., at high-risk for bleeding to be eligible for coverage.

Based on review of available data, the Company may consider outpatient use of limb compression devices for venous thromboembolism (VTE) prophylaxis after major non-orthopedic surgery or other orthopedic procedures in patients who are at moderate or high risk of venous thromboembolism (VTE) (see Background/Overview) with a contraindication to pharmacologic agents i.e., at high-risk for bleeding to be eligible for coverage.

When Services Are Considered Not Medically Necessary
Based on review on available data, the Company considers the use of outpatient use of limb compression devices for venous thromboembolism (VTE) prophylaxis for periods longer than 30 days post-surgery to be not medically necessary.**

When Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers outpatient use of limb compression devices for venous thromboembolism (VTE) prophylaxis after major orthopedic surgery (total hip arthroplasty, total knee arthroplasty, hip fracture surgery) in patients without a contraindication to pharmacologic prophylaxis to be investigational.*

Based on review of available data, the Company considers outpatient use of limb compression devices for venous thromboembolism (VTE) prophylaxis after major non-orthopedic surgery or other orthopedic procedures in patients who are at moderate or high risk of venous thromboembolism (VTE) without a contraindication to pharmacologic prophylaxis and in patients who are at low-risk of venous thromboembolism (VTE) to be investigational.*
Based on review of available data, the Company considers outpatient use of limb compression devices for venous thromboembolism (VTE) prophylaxis after all other surgeries to be **investigational**.

**Background/Overview**

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

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%.

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. 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 post discharge 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.

ACCP 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, ACCP recommends prophylaxis with pharmacologic agents or intermittent pneumatic compression rather than no prophylaxis. For patients at low risk for VTE (<1.5%), the guidelines suggest mechanical prophylaxis. Unlike the guidelines on major orthopedic surgery, which recommend a minimum of 10 to 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 4 weeks;
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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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
Various pneumatic and peristaltic limb compression devices, with indications including prevention of DVT, have been cleared for marketing by FDA through the 510(k) process. Portable devices that have been cleared by 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 3-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 2-pronged plug and is not battery-operated.

Centers for Medicare and Medicaid Services (CMS)
There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

Rationale/Source

Venous Thromboembolism Prophylaxis in Major Orthopedic Surgery Patients
Patients without a Contraindication to Prophylaxis Using Pharmaceutical Agents

Anticoagulation is the mainstay of DVT prophylaxis after major surgery and is sometimes continued into the outpatient setting. Treatment with limb compression devices may offer additional benefit when used in conjunction with anticoagulation in the inpatient setting but is not commonly used in the outpatient setting. The ideal study design to evaluate whether there is benefit in the outpatient setting would be a randomized controlled trial (RCT) comparing outpatient anticoagulation alone with anticoagulation plus a limb compression device. Key health outcomes include incidence of DVT and PE, as well as measures of functional status and/or quality of life associated with these outcomes.

Randomized Controlled Trials

No RCTs were identified comparing combined use of pneumatic compression and anticoagulants with anticoagulants alone that are specifically conducted in the outpatient setting. Several systematic reviews of
RCTs have addressed the issue of combined prophylaxis, but they did not focus on outpatient treatment. For example, in 2012, Kakkos et al published a meta-analysis of RCTs evaluating combined use of anticoagulation and mechanical DVT prophylaxis following joint replacement surgery; however, the study focused on inpatient thromboprophylaxis. The authors identified 4 trials that compared anticoagulation alone to anticoagulation plus use of limb compression devices. Three of the 4 studies used limb compression devices only until discharge from the hospital. In the fourth study, the article did not clearly state that the pump use was limited to the inpatient setting, but inpatient use was implied, eg, the article stated that staff checked several times a day to ensure correct use of the pump system. More recent systematic reviews were similar; the authors reviewed RCTs on compression for VTE prophylaxis and did not specifically describe outpatient use of pneumatic compression devices.

There are several reasons why the benefit of limb compression devices in the hospital setting may not extrapolate to benefit in the outpatient setting. First, the level of mobility is necessarily less in the hospital than in the outpatient setting, indicating a different risk for DVT. Also, the use of limb compression devices in the hospital can be more highly controlled and monitored. In the outpatient setting, there are questions about the degree of compliance with the devices, including the ability to correctly use them in the absence of professional supervision. No comparative studies were identified that focused on compliance with limb compression devices in the outpatient setting.

Nonrandomized Controlled Studies
A 2014 study by Colwell et al analyzed data from an industry-funded registry study on a mobile compression device (ActiveCare+SFT). The study compared outcomes of patients included in the registry with outcomes reported in previously published studies of thromboembolism prophylaxis using pharmacologic agents. Data were evaluated on 3060 patients at 10 U.S. sites who had undergone arthroplasty of a lower-extremity joint and used the mobile compression device for at least 10 days. The device was used both in the inpatient setting and after discharge; length of hospital stay was not reported. Twenty-eight (0.92%) of the 3060 patients developed symptomatic VTE. In other published studies, the rate of symptomatic VTE after lower-extremity joint arthroplasty was reported as 2.2% for warfarin, 1.1% for enoxaparin, 0.64% for rivaroxaban, and 1.2% for dabigatran. The mobile compression device was found to be noninferior using a predefined noninferiority 1% margin to pharmacologic prophylaxis. A limitation of the study was lack of randomization and including historical comparison groups. Moreover, it is unclear what proportion of time the mobile compression devices were used in the outpatient setting.

Patients with a Contraindication to Prophylaxis Using Pharmaceutical Agents
Patients with contraindications to anticoagulants need to be treated with nonpharmacologic measures. The ideal study design for this question would be an RCT comparing prophylaxis with limb compression devices alone in the outpatient setting with no prophylaxis or to alternative methods of prophylaxis.

Randomized Controlled Trials
No RCTs using this comparison were identified. However, 1 recent RCT provided data that might be useful for answering the question of whether outpatient use of limb compression devices are beneficial in the absence of outpatient anticoagulant use. The study, reported in 2 publications, one in 2010 and the other in 2011, was conducted at multiple centers in the United States and included 395 patients undergoing total hip
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replacement. Individuals with a previous history of thrombosis, known coagulation disorder, solid malignant tumor, peptic ulcer disease or mental disorder were excluded. Patients were randomized to 10 days of DVT prophylaxis using either low-molecular-weight heparin (LMWH) or a mobile limb compression device (ActiveCare+SFT). Treatment continued until 10 days after surgery in both groups; patients received a variable portion of their treatment after hospital discharge. Patients in the compression device group could also receive aspirin if recommended by their doctor. Patients were examined with bilateral duplex ultrasound on day 10 to 12 after surgery. The mean length of hospital stay was 3.2 days in both groups. Length of hospital stay ranged from 2 days to 10 days; thus, patients had between 0 days and 8 days of outpatient use of their assigned method of prophylaxis. According to ultrasound findings, 8 of 196 (4.1%) in the limb compression group and 8 of 190 (4.2%) in the LMWH group had a DVT. In addition, 2 pulmonary emboli were detected in each group. The incidence of VTE events did not differ significantly between groups. However, the rate of major bleeding was significantly higher in the LMWH group. A total of 11 (6%) of patients in the LMWH group had a major bleeding event compared with no patients in the limb compression group (p<0.001). Rates of minor bleeding were similar in the 2 groups; 78 (40%) in the LMWH group and 74 (37%) in the limb compression group. In addition, compliance with the mobile compression devices was monitored using internal timers in the device. According to these data, patients used the device for a mean of 11 days (range, 1-15 days) and for a mean of 20 hours per day. Mean use of the device was 83% of possible usable time. Findings on compliance were not reported separately for inpatient and outpatient use of the devices.

Section Summary
There is very little published evidence on the efficacy of outpatient use of limb compression devices for DVT prophylaxis after major orthopedic surgery. There are no RCTs that evaluate outpatient use of limb compression as an adjunct to pharmacologic prophylaxis in patients without a contraindication to anticoagulants. Some RCTs have evaluated the inpatient use of limb compression as an adjunct to pharmacologic agents, but the results of these trials might not be able to be extrapolated to the outpatient setting. There is also a lack of evidence on compliance with limb compression devices in the outpatient setting. National clinical guidelines support the use of limb compression devices DVT prophylaxis after major orthopedic surgery in patients who are not candidates for pharmacologic prophylaxis due to a high risk of bleeding. In addition, 1 RCT that reported similar rates of postoperative DVT in patients who received limb compression devices or LMWH provides some evidence in support of limb compression devices as the sole intervention in the outpatient setting. This study was limited in that much of the treatment occurred in the hospital, and patients with a known coagulation disorder were excluded from participation.

VTE Prophylaxis in Major Nonorthopedic Surgery Patients
Patients with and without a Contraindication to Prophylaxis Using Pharmaceutical Agents

Randomized Controlled Trials
No RCTs were identified that specifically addressed the comparison between inpatient-only and inpatient and outpatient use of limb compression devices as an adjunct to anticoagulant use in patients undergoing major nonorthopedic surgery. Moreover, no RCTs were identified that compared intermittent pneumatic compression (IPC) in the outpatient setting with no prophylaxis beyond inpatient use in patients with contraindications to pharmaceutical agents. Two systematic reviews of RCTs on VTE prophylaxis in...
patients undergoing major nonorthopedic surgery were examined, one a Cochrane review on VTE prevention in high-risk patients and the other on VTE prevention after gynecologic surgery; neither meta-analysis included RCTs relevant to the research question being considered.

However, an RCT by Sobieraj-Teague et al may contribute some relevant data. The nonblinded study, conducted in Canada, compared inpatient and outpatient use of Venowave, a portable battery-operated IPC device, to usual care only in 150 adult patients undergoing cranial or spinal neurosurgery. As part of usual care, all patients were prescribed graduated compression stockings and early mobilization. Patients could also receive pharmacologic treatment at the discretion of their physician. A total of 19 of 75 patients (25%) in the Venowave group and 26 of 75 patients (35%) in the control group received anticoagulants (unfractionated or LMWH) and an additional 4 (5%) in the Venogram group and 7 (9%) in the control group used aspirin. In the Venowave group, devices were worn until development of VTE, patient refusal, until undergoing a screening bilateral venogram at day 9 (±2 days) or earlier if patients were discharged from the hospital earlier and were unwilling to return for a venogram. The median day of hospital discharge was day 4. Patients who continued using the Venowave device at home received home visits at least daily to optimize compliance. Eight patients did not undergo screening venography. Mean time to screening was 7.3 days in the Venowave group and 7.5 days in the control group. The primary efficacy outcome was a composite of asymptomatic DVTs and symptomatic PEs. VTE occurred in 3 patients (4%) in the Venowave group and 14 (19%) in the control group. The difference between groups was statistically significant (risk ratio, 0.21; 95% confidence interval, 0.05 to 0.75). Most of the VTEs were asymptomatic, and there were no PEs. Two patients in the control group and none in the Venowave group experienced a symptomatic DVT. Among the 75 evaluable patients in the Venogram group, 17 (23.3%) were continuous users, 39 (53.4%) were intermittent users, and 17 (23.3%) discontinued use of the device before their venogram assessment. Compliance might have been lower if patients had not received daily home visits.

The Sobieraj-Teague study did not specifically exclude patients with a contraindication to pharmaceutical agents. Moreover, only about 30% of participants were prescribed heparin or aspirin. This suggests that study findings might be applicable to patients who are not taking pharmaceutical agents, ie, including those with a contraindication. Generalizability of study findings is not clear, however, as the authors did not report VTE prevalence among patients who did or did not take anticoagulants or aspirin.

Section Summary
There is very little published evidence on the efficacy of outpatient use of limb compression devices for DVT prophylaxis after major nonorthopedic surgery. There are no RCTs that evaluate outpatient use of limb compression as an adjunct to pharmacologic prophylaxis in patients without a contraindication to anticoagulants. There is also a lack of evidence on compliance with limb compression devices in the outpatient setting. National clinical guidelines support the use of limb compression devices for DVT prophylaxis after major nonorthopedic surgery in individuals at moderate and high risk of DVT. Moreover, 1 RCT, which found significantly fewer VTEs in patients undergoing cranial or neurosurgery who used a portable IPC than those receiving usual care; treatment occurred in both the inpatient and outpatient settings.
Summary of Evidence

Patients undergoing major surgery, particularly orthopedic surgery, are at high risk for VTE, and VTE prophylaxis for high-risk patients may be indicated beyond the period of hospitalization. Pharmacologic prophylaxis is the mainstay of treatment, but some patients have contraindications to anticoagulation, such as a high bleeding risk. For these patients who are undergoing major orthopedic surgery or other high-risk surgeries, limb compression devices are a reasonable alternative when prophylaxis is indicated in the outpatient setting. This is based on support in clinical practice guidelines, evidence from randomized controlled trials on different populations, and the lack of other good alternatives. Therefore, the use of limb compression devices for outpatient VTE prophylaxis may be considered medically necessary when prophylaxis is indicated but there are contraindications to anticoagulation.

For patients who do not have contraindications to anticoagulation, the evidence is not sufficient to determine whether limb compression devices offer additional benefit. There is a lack of studies that evaluate the incremental benefit of limb compression devices in addition to anticoagulants and a lack of evidence on outpatient compliance. Therefore, outpatient use of limb compression devices for VTE prophylaxis after major orthopedic surgery in patients who do not have a contraindication to pharmacologic prophylaxis is considered investigational.

References

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

Next Scheduled Review Date: 07/2018

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A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. FDA and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
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A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

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

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