



BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

Post-Surgical Outpatient Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis

Policy # 00386

Original Effective Date: 08/21/2013

Current Effective Date: 02/19/2014

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 in patients with a contraindication to pharmacological 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 non-major orthopedic surgery in patients who are at moderate or high risk of venous thromboembolism (VTE) (see Background/Overview) with a contraindication to pharmacological 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 in patients without a contraindication to pharmacological 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 non-major orthopedic surgery in patients who are at moderate or high risk of venous thromboembolism (VTE) without a contraindication to pharmacological 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**.



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Background/Overview

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 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."

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 pneumatic compression (IPC) 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 pneumatic 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:



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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. Venous thromboembolism 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 h, 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. (pp. 13-14)

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 VTE, cancer, or molecular hypercoagulable state.

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

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 THA, TKA and 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. Deep vein thromboses 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 PE is approximately 1-28%. Other surgical patients may also be at increased



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risk of VTE during and after hospitalization. For example, it is estimated that rates of VTE without prophylaxis after gynecologic surgery is about 15-40%.

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 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 pneumatic compression device. A minimum of 10-14 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 pneumatic 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 non-randomized study found that there was better compliance with a portable battery-operated pneumatic 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 IPC 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 recommends a minimum of 10-14 days of VTE prophylaxis, the guideline on non-orthopedic surgery patients does 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 who are not otherwise at high risk for major bleeding complications.

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



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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 two-pronged plug and is not battery-operated.

Centers for Medicare and Medicaid Services (CMS)

No national coverage determination was found for limb compression devices used to prevent DVT.

Rationale/Source

Venous thromboembolism prophylaxis in major orthopedic surgery patients

Patients without a contraindication to prophylaxis with pharmaceutical agents

Anticoagulation is the mainstay of DVT prophylaxis after major surgery and is sometimes continued into the outpatient setting. Treatment with pneumatic 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 to anticoagulation plus pneumatic compression devices. 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 with the above design were identified. In 2012, Kakkos and colleagues 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 pneumatic compression devices. Three of the 4 studies used pneumatic compression devices only until discharge from the hospital. In the fourth study, the article did not clearly state that that pump use was limited to the inpatient setting, but inpatient use was implied e.g., the article stated that staff checked several times a day to ensure correct use of the pump system. Meta-analyses found statistically significantly lower incidences of DVT in the group that used compression pumps in addition to anticoagulation compared to anticoagulation-only. In a pooled analysis of 4 trials on hip replacement, the incidence of DVT was 9.7% in the anticoagulation-only group and 0.9% in the combined treatment group (risk ratio [RR]: 0.17; 95% confidence interval [CI]: 0.06 to 0.46). Similarly, when findings from 2 trials on knee replacement were pooled, the incidence of DVT was 18.7% in the anticoagulation-only group and 3.7% in the combined treatment group (RR: 0.27; 95% CI: 0.08 to 0.89).

A 2013 systematic review and meta-analysis by Sobieraj and colleagues was similar to the Kakkos et al. study, described above. It reviewed studies comparing combined pharmacologic and mechanical



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prophylaxis to either method alone in patients undergoing major orthopedic surgery. Six RCTs were identified and these studies all focused on inpatient treatment. Most studies evaluating outcomes in the post-operative period. In 1 study that followed patients for 90 days, IPC continued only until hospital discharge.

There are several reasons why the benefit of pneumatic 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 pneumatic 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 pneumatic compression devices in the outpatient setting.

Case series:

A 2006 case series by Giannoni and colleagues in Italy included both inpatient and outpatient DVT prophylaxis with pneumatic compression devices and anticoagulants. The study included 34 patients who underwent total knee replacement (4 patients had bilateral replacements). All patients used a pneumatic compression device (A-V Impulse foot pump system) for 15 days. The mean hospital stay was 7 days, and the range was 5 to 12 days. The compression devices were worn for an average of 14 hours per day (range 8 to 18 hours). Patients were also treated with low-molecular-weight heparin (LMWH), beginning after surgery and continuing until the operated leg was completely weight bearing (15-30 days). Ultrasonography detected DVTs in 3 of 34 (8.8%) patients; all were distal DVTs. One symptomatic developed on the 4th post-operative day, and there were 2 subclinical DVTs detected at the routine 1 month ultrasonographic examination. This study did not include a comparison group of patients who did not use a pneumatic compression device. In addition, given the range of length of hospital stay, some patients received their entire course of prophylactic treatment as inpatients. Compliance with pneumatic compression devices was not reported.

Patients with a contraindication to prophylaxis with pharmaceutical agents

Patients with contraindications to anticoagulants need to be treated with non-pharmacologic measures. The ideal study design for this question would be an RCT comparing prophylaxis with pneumatic compression devices alone in the outpatient setting to no prophylaxis or to alternative methods of prophylaxis.

Randomized controlled trials:

No RCTs using this design were identified. However, one recent RCT provided data that might be useful for answering the question of whether outpatient use of pneumatic compression devices are beneficial in the absence of outpatient anticoagulant use. The study, reported on 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 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 LMWH or a mobile pneumatic 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



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recommended by their doctor. Patients were examined with bilateral duplex ultrasound on day 10-12 following 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 pneumatic 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 venous thromboembolic 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 to no patients in the pneumatic compression group ($p = 0.0004$). Rates of minor bleeding were similar in the 2 groups; 78 (40%) in the LMWH group and 74 (37%) in the pneumatic 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 to 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 pneumatic compression devices for DVT prophylaxis after major orthopedic surgery. There are no RCTs that evaluate outpatient use of pneumatic compression as an adjunct to pharmacologic prophylaxis in patients without a contraindication to anticoagulants. Some RCTs have evaluated the inpatient use of pneumatic 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 pneumatic compression devices in the outpatient setting. National clinical guidelines support the use of pneumatic 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, one RCT that reported similar rates of post-operative DVT in patients who received pneumatic compression devices or low-molecular-weight evidence provides some evidence in support of pneumatic 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.

Venous Thromboembolism prophylaxis in major non-orthopedic surgery patients

Patients with and without a contraindication to prophylaxis with pharmaceutical agents

Randomized controlled trials: No RCTs were identified that specifically addressed the comparison between inpatient-only and inpatient and outpatient use of pneumatic compression devices as an adjunct to anticoagulant use in patients undergoing major non-orthopedic surgery. Moreover, no RCTs were identified that compared IPC in the outpatient setting to no prophylaxis beyond inpatient use in patients with contraindications to pharmaceutical agents. Two systematic reviews of RCTs on VTE prophylaxis in patients undergoing major non-orthopedic 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 and colleagues may contribute some relevant data. The non-blinded study, conducted in Canada, compared inpatient and outpatient use of Venowave, a portable battery-



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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 LMW heparin) 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. Venous thromboembolism occurred in 3 patients (4%) in the Venowave group and 14 (19%) in the control group. The difference between groups was statistically significant (RR: 0.21, 95% CI: 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 i.e., 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 pneumatic compression devices for DVT prophylaxis after major non-orthopedic surgery. There are no RCTs that evaluate outpatient use of pneumatic 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 pneumatic compression devices in the outpatient setting. National clinical guidelines support the use of pneumatic compression devices DVT prophylaxis after major non-orthopedic surgery in individuals at moderate- and high-risk of DVT. Moreover, one 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

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, pneumatic compression devices are a reasonable alternative when prophylaxis is indicated in the



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outpatient setting. This is based on support in clinical practice guidelines, evidence from RCTs on different populations, and the lack of other good alternatives. Therefore, the use of pneumatic 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 pneumatic compression devices offer additional benefit. There is a lack of studies that evaluate the added benefit of pneumatic compression devices in addition to anticoagulants and a lack of evidence on outpatient compliance. Therefore, outpatient use of limb pneumatic compression devices for VTE prophylaxis after major orthopedic surgery in patients who do not have a contraindication to pharmacologic prophylaxis is considered investigational.

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Coding

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	No codes
HCPCS	E0650, E0651, E0652, E0660, E0666, E0667, E0669, E0670, E0671, E0673, E0676
ICD-9 Diagnosis	All relative diagnoses
ICD-9 Procedure	No codes

Policy History

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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.

Next Scheduled Review Date: 02/2015

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (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
- 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

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Post-Surgical Outpatient Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis

Policy # 00386

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of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
2. credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. reference to federal regulations.

****Medically Necessary (or "Medical Necessity")** - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- 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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