Postsurgical Home Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis

Policy # 00386
Original Effective Date: 08/21/2013
Current Effective Date: 08/10/2020

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.

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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**.*

Policy Guidelines

This section reviews guidance on contraindications to using anticoagulants, determining risk for bleeding, determining risk for venous thromboembolism (VTE), and duration of treatment postoperatively.

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 uncommon. Intolerance may result from allergic reactions or adverse events. 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

American College of Chest Physicians (ACCP) guidelines on prevention of VTE in orthopedic surgery patients listed 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
- Surgical factors: history of or difficult-to-control surgical bleeding during the current operative procedure, extensive surgical dissection, and revision surgery."

The guidelines indicated, 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 (see Table PG1) (Kearon et al, 2016).

"Recent publication (2018, Palareti) questioned predictive value of ACCP score for bleeding and suggested that new predictions tools for bleeding risk during anticoagulation treatments are needed."

Risk factors include (1 point per risk factor):

- "Age >65 y
- Age >75 y
- 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."

Table PG1. Guidelines for Risk of Bleeding

Risk Factors	Estimated Absolute Risk of Major Bleeding		
	Low Risk (0 Risk Factors)	***Moderate Risk (1 Risk Factor)***	***High Risk (≥2 Risk Factors)***
Anticoagulation 0-3 mo, %			
Baseline risk	0.6	1.2	4.8
Increased risk	1.0	2.0	8.0
Total risk	1.6	3.2	12.8
Anticoagulation after first 3 mo, %/y			
Baseline risk	0.3	0.6	≥2.5
Increased risk	0.5	1.0	≥4.0
Total risk	0.8	1.6	≥6.5

Adapted from Kearon et al (2016).

Clinical guidelines from the American Academy of Orthopaedic Surgeons (Mont et al, 2011) have indicated that:

> "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 (total hip arthroplasty, total knee arthroplasty, hip fracture surgery), ACCP guidelines are consistent with use of intermittent limb compression devices for 10 to 14 days after surgery (Falck-Ytter et al, 2012). 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 guidelines on VTE prophylaxis in patients undergoing nonorthopedic surgery, the standard duration or "limited duration" of prophylaxis was not defined. However, "extended duration" pharmacologic prophylaxis was defined as 4 weeks, which 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 Determining Risk Level for Nonorthopedic Surgery

The ACCP guidelines on prevention of VTE in nonorthopedic surgery patients included the following discussion of risk levels (Gould et al, 2012):

> "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 > 60 years, prior VTE, and cancer; age ≥ 60 years, prior VTE, anesthesia ≥2 h, and bed rest ≥ 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 > 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."

In 2007 (reaffirmed in 2012), the American College of Obstetricians and Gynecologists revised its risk classification for VTE in patients undergoing major gynecologic surgery (American College of Obstetricians and Gynecologists, 2007):

> "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 aged 40 to 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 hypercoagulable state."

Background/Overview

Risk of Venous Thromboembolism

Orthopedic Surgery

Antithrombotic prophylaxis is recommended for surgical patients 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 with an increased risk of VTE include abdominal surgery, pelvic surgery, cancer surgery, and surgery for major trauma. For these types of surgeries, the risk varies. 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 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

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 the 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, are considered to have a contraindication to anticoagulants. There are a few surgeries for which anticoagulants are contraindicated or avoided, most notably some neurosurgical 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 a high-risk of DVT due to venous stasis of the lower limbs as a consequence of immobility during and after surgery. Also, 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 acute DVT is PE, which can be fatal. PE occurs when a DVT blood clot detaches and migrates to the lungs. Also, 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 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% to 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 by the ACCP (2012) recommended that one of several pharmacologic agents or mechanical prophylaxis be provided rather than no thromboprophylaxis. The guidelines further recommended 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 home use.

Limb Compression Prophylaxis
The ACCP guidelines have also noted that compliance is a major issue with the home use of limb compression devices for thromboprophylaxis and recommended 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 a day. A 2009 nonrandomized study found that there was better compliance with a portable battery-operated limb compression device than with a nonmobile device when used by patients in the hospital following hip or knee replacement surgery.

Nonorthopedic Surgery

Pharmacologic and Limb Compression Prophylaxis
The ACCP (2012) 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, the ACCP has recommended prophylaxis with pharmacologic agents or intermittent pneumatic compression rather than no prophylaxis. For patients at low-risk for VTE (≈1.5%), the guidelines have suggested mechanical prophylaxis. Unlike the guidelines on major orthopedic surgery, which recommends a minimum of 10 to 14 days of VTE prophylaxis, the guidelines on nonorthopedic surgery patients do not include a general timeframe for prophylaxis. They have, however, defined "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, and who are not otherwise at high-risk for major bleeding complications.

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

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

A large number of pneumatic and peristaltic limb compression devices have been cleared for marketing by the U.S. FDA through the 510(k) process for indications including prevention of DVT. Portable devices cleared by the FDA include (FDA product code: JOW):

- 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): This device is battery-powered and strapped to the leg below the knee.
- ActiveCare®‡+S.F.T. 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 the use of a single-celled foot sleeve. Calf and thigh compression requires the use of a 3-celled cuff sleeve.
- Restep®‡ DVT System (Stortford Medical): This lightweight device uses 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-powered option.
- PlasmaFlow™‡ (ManaMed): This system is portable, to be used at home or in a clinical setting.

Rationale/Source

Antithrombotic prophylaxis is recommended for surgical patients at moderate-to-high risk of postoperative venous thromboembolism (VTE), including deep vein thrombosis (DVT) and pulmonary embolism, based on the surgical procedure and/or patient characteristics. For some types of surgery (eg, 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 events and allergic reactions. Limb compression devices have been used as an adjunct or alternative to anticoagulation in the home setting for patients in the postoperative 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 a limb compression device as an adjunct to anticoagulation, the evidence includes no randomized controlled trials (RCTs) assessing any incremental benefit of home use of a limb compression device, plus pharmacologic agents. The relevant outcomes are overall survival, symptoms, morbid events, and treatment-related morbidity. Four meta-analyses of RCTs have compared medication plus intermittent pneumatic compression with medication alone in surgical patients in the hospital setting. These trials do not permit inferences to the post discharge home setting. Results of the meta-analyses have suggested that in-hospital addition of limb compression devices to pharmacologic management improves DVT prophylaxis. Limitations are: not distinguishing between asymptomatic and symptomatic DVT; sparse data on pulmonary embolism; and results generally not stratified by patient risk or specific intervention. Moreover, the post discharge setting differs in important respects from the hospital setting. Discharged patients tend to be healthier than those in the hospital. Factors such as treatment consistency, duration, and application errors in use differ in the home. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have moderate-to-high postsurgical risk of VTE and a contraindication to pharmacologic prophylaxis who receive home use of a limb compression device, the evidence includes a meta-analysis of inpatients and a study comparing the use of post discharge limb compression in the home setting to no prophylaxis. The relevant outcomes are overall survival, symptoms, morbid events, and treatment-related morbidity. The meta-analysis showed significantly fewer incidence of DVT (40 RCTs) and pulmonary embolism (26 RCTs) with limb compression.

Despite limitations related to stratification of patient risk and pharmacologic prophylaxis, the meta-analysis showed that limb compression is superior to no prophylaxis. A study of the post discharge use of a limb compression device combined with home visits showed that home use is feasible. With post discharge planning and support, home use of limb compression devices 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 a meaningful improvement in the net health outcome.

Supplemental Information

Practice Guidelines and Position Statements

American College of Chest Physicians

In 2016, the American College of Chest Physicians (ACCP) (updated its 2012 evidence-based guideline on antithrombotic therapy and prevention of thrombosis. The 2016 update, which addressed antithrombotic therapy for venous thromboembolism (VTE), outlined risk factors for bleeding with anticoagulant therapy and estimated the risks of major bleeding for patients in various risk categories (see Table 1).

Risk factors include (1 point per factor):

- "Age >65 y
- Age >75 y
- 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."

Table 1. Guidelines for Risk of Bleeding

Risk Factors	Estimated Absolute Risk of Major Bleeding		
	Low Risk (0 Risk Factors)	***Moderate Risk (1 Risk Factor)***	***High Risk (≥2 Risk Factors)***
Anticoagulation 0-3 mo, %			
Baseline risk	0.6	1.2	4.8
Increased risk	1.0	2.0	8.0
Total risk	1.6	3.2	12.8
Anticoagulation after first 3 mo, %/y			
Baseline risk	0.3	0.6	≥2.5
Increased risk	0.5	1.0	≥4.0
Total risk	0.8	1.6	≥6.5

Adapted from Kearon et al (2016).

In a 2017 review of ACCP 2012 and American Academy of Orthopaedic Surgeons 2011 guidelines on antithrombotic therapy and prevention of VTE in patients undergoing orthopedic and nonorthopedic surgery, the ACCP recommended use of limb compression devices in orthopedic surgical patients:

2.1.1 "In patients undergoing total hip arthroplasty (THA) or total knee arthroplasty (TKA), we recommend use of one of the following for a minimum of 10 to 14 days rather than no antithrombotic prophylaxis: low-molecular-weight heparin (LMWH), fondaparinux, apixaban, dabigatran, rivaroxaban, low-dose unfractionated heparin (LDUH), adjusted-

dose vitamin K antagonist (VKA), aspirin (all Grade 1B), or an intermittent pneumatic compression device (IPCD) (Grade 1C)."

2.5 "In patients undergoing major orthopedic surgery, we suggest using dual prophylaxis with an antithrombotic agent and an IPCD during the hospital stay (Grade 2C)."

2.6 "In patients undergoing major orthopedic surgery and increased risk of bleeding, we suggest using an IPCD or no prophylaxis rather than pharmacologic treatment (Grade 2C)."

"The efficacy of mobile mechanical compression devices alone has not been compared with any chemoprophylaxis agent in an appropriately powered randomized trial. In addition, concerns have arisen with regard to patient compliance after hospital discharge and the high cost of these devices."

In 2012, the ACCP recommendations on the use of limb compression devices in nonorthopedic general and abdominal-pelvic surgical patients, stratified by patient risk of VTE and risk of bleeding are listed in Table 2.

Table 2. Recommendations on Limb Compression Device Use in Nonorthopedic General and Abdominal-Pelvic Surgical Patients

Patient Risk Group	Recommendation	GOR
Very low risk (<0.5%)	"[W]e recommend that no specific pharmacologic or mechanical prophylaxis be used other than early ambulation."	1B 2C
Low risk for VTE (»1.5%)	"[W]e suggest mechanical prophylaxis, preferably with intermittent pneumatic compression (IPC), over no prophylaxis."	2C
Moderate risk for VTE (»3%) and not at high risk of bleeding	"[W]e suggest low-molecular-weight heparin (LMWH), low-dose unfractionated heparin, or mechanical prophylaxis with IPC over no prophylaxis."	2B 2B 2C

Patient Risk Group	Recommendation	GOR
Moderate risk for VTE (»3%) and high risk for major bleeding complications or in whom bleeding consequences would be particularly severe	"We suggest mechanical prophylaxis, preferably with IPC, over no prophylaxis."	2C
High risk for VTE (»6.0%) and not at high risk of bleeding	"[W]e recommend pharmacologic prophylaxis with LMWH or low-dose unfractionated heparin over no prophylaxis. In these patients, we suggest adding mechanical prophylaxis with elastic stockings or IPC to pharmacologic prophylaxis."	1B 1B 2C
High risk for VTE (»6.0%) and high risk for major bleeding complications or in whom bleeding consequences would be particularly severe	"[W]e suggest use of mechanical prophylaxis, preferably with IPC, over no prophylaxis until the risk of bleeding diminishes and pharmacologic prophylaxis may be initiated."	2C
High risk for VTE, both LMWH and unfractionated heparin contraindicated or unavailable and not at high risk for major bleeding complications:	"[W]e suggest low-dose aspirin, fondaparinux, or mechanical prophylaxis, preferably with IPC, over no prophylaxis."	2C
High risk for VTE, undergoing abdominal or pelvic surgery for cancer and not otherwise at high risk for major bleeding complications	"[W]e recommend extended-duration, postoperative, pharmacologic prophylaxis (4 weeks) with LMWH over limited-duration prophylaxis."	1B

GOR: grade of recommendation VTE: venous thromboembolism.

Note that a standard duration of prophylaxis was not defined. An "extended-duration" prophylaxis was defined as lasting four weeks.

American Academy of Orthopaedic Surgeons

In 2011, the American Academy of Orthopaedic Surgeons (2011) updated its guidelines on the prevention of VTE in patients undergoing elective hip and knee arthroplasty. The guidelines included the following recommendations relevant to this evidence review:

5. "The work group suggests the use of pharmacologic agents and/or mechanical compressive devices for the prevention of venous thromboembolism in patients undergoing elective hip or knee arthroplasty, and who are not at elevated risk beyond that of the surgery itself for venous thromboembolism or bleeding. (Grade of Recommendation: Moderate) Current evidence is unclear about which prophylactic strategy (or strategies) is/are optimal or suboptimal. Therefore, the work group is unable to recommend for or against specific prophylactics in these patients. (Grade of Recommendation: Inconclusive) In the absence of reliable evidence about how long to employ these prophylactic strategies, it is the opinion of this work group that patients and physicians discuss the duration of prophylaxis. (Grade of Recommendation: Consensus)

6. In the absence of reliable evidence, it is the opinion of this work group that patients undergoing elective hip or knee arthroplasty, and who have also had a previous venous thromboembolism, receive pharmacologic prophylaxis and mechanical compressive devices. (Grade of Recommendation: Consensus)

7. In the absence of reliable evidence, it is the opinion of this work group that patients undergoing elective hip or knee arthroplasty, and who also have a known bleeding disorder (e.g., hemophilia) and/or active liver disease, use mechanical compressive devices for preventing venous thromboembolism. (Grade of Recommendation: Consensus)"

American College of Obstetricians and Gynecologists

The 2007 (reaffirmed 2012) American College of Obstetricians and Gynecologists updated its practice bulletin on prevention of deep vein thrombosis and pulmonary embolism after gynecologic surgery. As with ACCP recommendations discussed above, prophylaxis recommendations varied by patient risk level. For patients at moderate and high-risk of deep vein thrombosis, intermittent pneumatic compression was one of the recommended options for deep vein thrombosis prophylaxis. For patients at highest risk (ie, >60 years plus prior VTE, cancer, or molecular hypocoagulable state), intermittent pneumatic compression or graduated compression stockings plus low-dose unfractionated heparin or low-molecular-weight heparin were recommended as prophylactic

options. For all but the highest risk patients, the practice bulletin stated that, when intermittent pneumatic compression devices were used, “the devices should be used continuously until ambulation and discontinued only at the time of hospital discharge.” For the highest risk patients, the bulletin stated that continuing prophylaxis for two to four weeks after discharge should be considered.

American Orthopaedic Foot and Ankle Society
In 2013, the American Orthopaedic Foot and Ankle Society published a position statement on VTE prophylaxis after foot and ankle surgery. It stated that: “There is currently insufficient data for the American Orthopaedic Foot & Ankle Society (AOFAS) to recommend for or against routine VTED prophylaxis for patients undergoing foot and ankle surgery. Further research in this field is necessary and is encouraged.”

American Society of Hematology
In 2019, the American Society of Hematology issued guidelines for the prevention and management and of venous thromboembolism in surgical hospitalized patients. Following are 2 suggestions for patients undergoing major surgery:

Recommendation 3: For those "who receive mechanical prophylaxis,...[use] intermittent compression devices over graduated compression stockings (conditional recommendation based on very low certainty in the evidence of effects)."

Recommendation 4: For those "who receive pharmacologic prophylaxis,...[use] combined prophylaxis with mechanical and pharmacological methods over prophylaxis with pharmacological agents alone (conditional recommendation based on very low certainty in the evidence of effects). Remark: For patients considered at high risk of VTE, combined prophylaxis is particularly favored over mechanical or pharmacological prophylaxis alone."

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 3.

Table 3. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT02987946[a]	Optimizing Anti Coagulant Therapy in Neurosurgical Interventions in Patients with an Increased Risk for Thrombo-embolic Complications	280	Dec 2019
Unpublished			
NCT01317160	Intermittent Pneumatic Compression Effects on Venous Thromboembolism Incidence and Healing of Achilles Tendon Rupture	150	Sep 2018 (updated 04/03/2019)

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

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Policy History

Original Effective Date: 08/21/2013
Current Effective Date: 08/10/2020

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

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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.
07/05/2018	Medical Policy Committee review
07/11/2018	Medical Policy Implementation Committee approval. Added policy guidelines.
07/03/2019	Medical Policy Committee review
07/18/2019	Medical Policy Implementation Committee approval. No change to coverage.
07/02/2020	Medical Policy Committee review
07/08/2020	Medical Policy Implementation Committee approval. No change to coverage.

Next Scheduled Review Date: 07/2021

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2019 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which

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contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

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, E0655, E0660, E0665, E0666, E0667, E0668, E0669, E0670, E0671, E0672, E0673, E0675, E0676
ICD-10 Diagnosis	All related diagnoses

*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:

A. 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
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:
    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.

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**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.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.