Postsurgical Home Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis

Policy # 00386
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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**.

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).
Risk factors include (1 point per risk factor):

- "Age >65 y
- Age >75y
- 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 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 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, 2012 clinical practice guidelines published by ACCP 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 postdischarge 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

ACCP also issued guidelines (2012) 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 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 recommend 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 4 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 postdischarge 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):

- 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.

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

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be

adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

MODERATE-TO-HIGH POSTSURGICAL RISK OF VENOUS THROMBOEMBOLISM AND NO CONTRAINDICATION TO PHARMACOLOGIC PROPHYLAXIS

This section focuses on evidence that postdischarge use of limb compression devices in addition to pharmacologic agents provide an incremental benefit to the net health outcome compared with pharmacologic agents alone. The ideal study design to address patients with moderate-to-high postsurgical risk of VTE and no contraindication to pharmacologic prophylaxis is a superiority RCT comparing VTE prophylaxis plus pharmaceutical agents and limb compression devices with pharmacologic agents alone. No RCTs with this study design were identified for patients discharged after major orthopedic surgery or other types of major surgery. There are, however, RCTs and meta-analyses of RCTs comparing medication plus compression devices with medication alone in surgical patients in the hospital setting. These studies may not permit inferences to the postdischarge home setting. Meta-analyses of RCTs are described next.

Kakkos et al (2016) reported on a Cochrane review that compared the efficacy of combined intermittent pneumatic compression (IPC) plus pharmacologic prophylaxis with single therapies alone in preventing VTE, updating a review initially published in 2008. Overall, 22 trials (total N=9137 patients) were included, of which 15 were RCTs (n=7762). For the comparison of IPC plus pharmacologic therapy with pharmacologic therapy alone, 10 studies evaluated the effect of combined therapies on the incidence of symptomatic PE, 11 studies evaluated the effect on the incidence of DVT, and 5 studies evaluated the effect on the incidence of symptomatic DVT. The primary pooled study results are summarized in Table 1.

Table 1. IPC Plus Pharmacologic Therapy vs Pharmacologic Therapy

Outcome	Trials	N	IPC + Pharmacologic Tx[a]	Pharmacologic Tx[a]	Pooled OR	95% CI	I^2
Pulmonary embolus	10	3544	1.20% (22/1833)	2.92% (50/1711)	0.39	0.23 to 0.64	0%
DVT	11	2866	2.9% (41/1414)	6.2% (90/1452)	0.42	0.18 to 1.03	68%
Symptomatic DVT	5	2312	0.43% (5/1155)	0.43% (5/1157)	1.02	0.29 to 3.54	0%

Adapted from Kakkos et al (2016).
CI: confidence interval; DVT: deep vein thrombosis; IPC: intermittent pneumatic compression; OR: odds ratio; Tx: treatment.
[a] Values are % (n/N).

These findings were similar in subgroup analyses by surgical type, including orthopedic surgeries. The risk of bias in the selected studies was generally unclear or high. Overall, reviewers concluded that combined modalities for VTE prophylaxis were more effective than single modalities. Although the risks for bias were high, the findings of the meta-analysis were consistent with those of previous studies.

A meta-analysis by O'Connell et al (2016) included 9 RCTs (total N=3347 patients) comparing IPC, with or without pharmacologic therapy, to pharmacologic agent alone in orthopedic and neurologic surgical

patients. Six studies included patients undergoing major orthopedic surgery. In a pooled analysis of all 9 trials, significantly fewer patients in the IPC group (38/1680 [2.3%]) were diagnosed with DVT than in the control group (89/1667 [5.3%]) (pooled relative risk [RR], 0.49; 95% confidence interval [CI], 0.25 to 0.96; I^2=60%). A pooled analysis of 8 studies did not find a significant difference in the rate of PE in the IPC and control groups; however, the total number of events was low (5 [0.6%] in the IPC group vs 7 [0.9%] in the control group), and 5 studies had no PE (pooled RR=0.71; 95% CI, 0.22 to 2.24; I^2=2%).

Zareba et al (2014) published a meta-analysis of RCTs comparing compression plus pharmacologic prophylaxis with either intervention alone for postsurgical VTE prevention. Twenty-five studies met inclusion criteria: 13 on orthopedic surgery, 7 on abdominal surgery, 3 on neurosurgery, and 1 on cardiac surgery (the population in the remaining study was not reported). Eleven RCTs (total N=4866 patients) compared pharmacologic prophylaxis plus compression with pharmacologic prophylaxis alone. IPC was used in 5 studies and graduated compression stockings in the other 6. A pooled analysis of 10 studies found that the risk of DVT with pharmacologic prophylaxis plus compression was significantly lower than with pharmacologic prophylaxis alone (5.1% vs 10.4%; RR=0.51; 95% CI, 0.36 to 0.73; I^2=11%). In addition, there was a significant between-group difference in the risk of PE (9 studies; RR=0.43; 95% CI, 0.27 to 0.66; I^2=0%). Reviewers noted that the PE analysis was heavily weighted by a large (N=2786 patients) study of patients undergoing cardiac surgery, which provided 69 of 89 total PE events. Four studies reported on symptomatic DVT. A pooled analysis did not find a significant difference between groups in risk of symptomatic DVT (4 studies; pooled RR=0.39; 95% CI, 0.05 to 2.90; I^2=0%).

A systematic review and meta-analysis by Sobieraj et al (2013) included RCTs comparing pharmacologic and mechanical prophylaxis with either treatment alone in patients undergoing major orthopedic surgery. Six trials (total N=961 patients) were identified, five of which compared combination prophylaxis with pharmacologic prophylaxis alone. Mechanical prophylaxis included IPCs, venous foot pumps, and graduated compression stockings. A pooled analysis of 4 RCTs found a significantly lower risk of DVT with combination prophylaxis than with pharmacologic prophylaxis alone (RR=0.48; 95% CI, 0.32 to 0.72). In other pooled analyses, there were no significant differences between groups in risk of PE (2 studies), proximal DVT (3 studies), or distal DVT (2 studies).

A meta-analysis by Kakkos et al (2012) focused on patients undergoing hip and knee replacement. Six RCTs (total N=1399 patients) were included; four of them compared pharmacologic plus mechanical prophylaxis with pharmacologic prophylaxis alone. Three studies included both hip and knee replacement patients and the fourth included only hip replacement patients. A pooled analysis of 3 trials on total knee replacement found a significantly lower rate of DVT in the combined prophylaxis group (3.7%) than in the pharmacologic prophylaxis only group (18.7%; RR=0.27; 95% CI, 0.08 to 0.89; I^2=42%). Similarly, there was a significantly lower risk of DVT with combined prophylaxis when pooling findings of 4 studies on hip replacement (0.9% vs 9.7%; RR=0.17; 95% CI, 0.06 to 0.46; I^2=0%).

Section Summary: Moderate-to-High Postsurgical Risk of Venous Thromboembolism and No Contraindication to Pharmacologic Prophylaxis
Findings from meta-analyses have suggested that the in-hospital addition of limb compression devices to pharmacologic management improves VTE prophylaxis, especially for prevention of DVTs. Findings related to the risk of PE are more limited because analyses might have been underpowered due to the small number of PE events. RCTs varied regarding patient populations (eg, orthopedic surgery, nonorthopedic surgery, medical patients), compression devices (IPCs, foot pumps, sequential compression devices), cointerventions (eg, compression stockings), duration of follow-up, and outcomes reported. The meta-analyses reported on the risk of DVT, but some did not distinguish between symptomatic DVT, which is more clinically relevant, and asymptomatic (imaging-detected) DVT.

The available evidence also does not address the question of interest to this review: Is there an incremental benefit in the postdischarge setting by adding limb compression devices to pharmacologic prophylaxis? The postdischarge setting has important characteristics that preclude making inferences from the inpatient setting. Patient characteristics vary because discharged patients tend to be healthier than those in the hospital. Characteristics of home use also vary (eg, treatment consistency, duration, application errors in use). RCTs evaluating the addition of limb compression devices to pharmacologic management postdischarge in the home setting are needed to permit conclusions about the incremental benefit of this technology on VTE prophylaxis.

MODERATE-TO-HIGH POSTSURGICAL RISK OF VTE AND A CONTRAINDICATION TO PHARMACOLOGIC PROPHYLAXIS
This section addresses whether postdischarge limb compression device use in moderate-to-high risk patients with a contraindication to pharmacologic prophylaxis improves the net health outcome compared with no postdischarge VTE prophylaxis. The ideal study design is an RCT comparing limb compression devices with no prophylaxis after hospital discharge. However, there may be ethical and practical barriers to conducting such a study, especially in higher risk patients. Alternatively, a network meta-analysis could indirectly compare outcomes of limb compression device use with no VTE prophylaxis. No RCTs or network meta-analyses of postdischarge use in patients with contraindication to pharmacologic prophylaxis were identified.

There is, however, a meta-analysis of RCTs comparing IPC use with placebo in the hospital setting. The meta-analysis was published by Ho and Tan (2013). It included RCTs comparing IPC with no prophylaxis or another type of prophylaxis in hospitalized surgical and nonsurgical patients. As with the meta-analyses reviewed above, there was heterogeneity of participants and interventions. Studies using a no prophylaxis control group might have included lower risk patients and some studies involving higher risk patients also included pharmacologic prophylaxis in both groups. A pooled analysis of 40 RCTs found a significantly lower rate of DVT with IPCs (7.3%) than with placebo (16.7%; RR=0.43; 95% CI, 0.36 to 0.52). Similarly, a pooled analysis of 26 trials found a significantly lower rate of PE with IPC (1.2%) than with placebo (2.8%; RR=0.48; 95% CI, 0.33 to 0.69). Results of the Ho and Tan meta-analysis suggested that IPC devices can be beneficial for VTE prophylaxis in patients with a contraindication to medication.

To draw inferences about the benefit of limb compression devices postdischarge in these patients, the feasibility of home use should be considered. An unblinded RCT by Sobieraj-Teague et al (2012) compared the use of a portable battery-operated IPC device with usual care alone in patients undergoing cranial or spinal neurosurgery. All patients were also prescribed graduated compression stockings and 20% to 25% used anticoagulants. Patients were evaluated at 9 days postsurgery, and those discharged earlier were permitted to use an IPC at home (median duration of hospitalization, 4 days). Patients who used the IPC device postdischarge received home visits at least daily to optimize compliance. Three (4%) of 75 patients in the IPC group and 14 (19%) of 75 patients in the usual care group developed VTE; the difference between groups was statistically significant (p=0.008). Among evaluable patients in the IPC group, 23.3% were continuous users, 53.4% were intermittent users, and 23.3% discontinued use (this includes both inpatient and outpatient use). The mean duration of IPC use was 6.6 days. Findings would suggest that in-home use of IPC devices is feasible with adequate postdischarge planning and support.

Section Summary: Moderate-to-High Postsurgical Risk of VTE and a Contraindication to Pharmacologic Prophylaxis

A meta-analysis has supported the conclusion that the use of limb compression devices is superior to placebo for VTE prevention in hospitalized patients. Notably, the incidences of both DVT and PE were significantly lower among patients receiving limb compression. A limitation of the meta-analysis is that it did not stratify patients by risk level, nor was pharmacologic prophylaxis absent in all cases. Nonetheless, the inference is supported that in patients with a contraindication to pharmacologic prophylaxis, postdischarge use of limb compression devices is superior for VTE prophylaxis compared with no prophylaxis.

Results of an unblinded RCT, which only enrolled 150 patients and evaluated a single approach to patient support in the home (ie, daily visits by care provider), were consistent with the feasibility of postdischarge home use of limb compression devices. In the U.S. health care system, appropriate postdischarge planning and transition are recognized as critical to reducing readmissions. When appropriate postdischarge planning and support are in place, the use of limb compression devices in the home in moderate-to-high risk patients with a contraindication to pharmacologic prophylaxis is likely to improve VTE prevention.

SUMMARY OF EVIDENCE

For individuals who have a 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 RCTs assessing any incremental benefit of home use of a limb compression device, plus pharmacologic agents. 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 postdischarge 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 postdischarge 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 a 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 postdischarge limb compression in the home setting to no prophylaxis. 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 postdischarge use of a limb compression device combined with home visits showed that home use is feasible. With postdischarge 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.

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Policy History

Original Effective Date: 08/21/2013
Current Effective Date: 07/11/2018

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.
07/05/2018	Medical Policy Committee review
07/11/2018	Medical Policy Implementation Committee approval. Added policy guidelines.

Next Scheduled Review Date: 07/2019

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 2017 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.

Postsurgical Home Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis

Policy # 00386
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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, 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. 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.

**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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