MEDICAL POLICY

POLICY TITLE	**POSTSURGICAL HOME USE OF LIMB COMPRESSION DEVICES FOR VENOUS THROMBOEMBOLISM PROPHYLAXIS**
POLICY NUMBER	**MP 6.053**

CLINICAL BENEFIT	☐ MINIMIZE SAFETY RISK OR CONCERN. ☐ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☒ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	**10/1/2024**

I. POLICY

Postsurgical home use of limb compression devices for venous thromboembolism (VTE) prophylaxis may be considered **medically necessary** in individuals with a contraindication to pharmacologic agents (see Policy Guidelines), in the following situations:

- After major orthopedic surgery (total hip arthroplasty, total knee arthroplasty, hip fracture surgery); OR
- After major nonorthopedic surgery or other orthopedic procedures in individuals who are at moderate or high risk of VTE (see Policy Guidelines)

Postsurgical home use of limb compression devices for VTE prophylaxis for periods longer than 30 days post-surgery is **not medically necessary**.

Postsurgical home use of limb compression devices for VTE prophylaxis is considered **investigational** in all other situations, including but not limited to:

- After major orthopedic surgery (total hip arthroplasty, total knee arthroplasty, hip fracture surgery) in patients without a contraindication for anticoagulation; OR
- After major nonorthopedic surgery or other orthopedic procedures in individuals without a contraindication for anticoagulation who are at moderate or high risk of VTE (see Policy Guidelines)

POLICY GUIDELINES

This section reviews guidance on contraindications to use of 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 not an absolute threshold at which anticoagulants cannot be used. Rather there is a risk/benefit continuum that weighs the benefit of treatment vs risks of bleeding. There may also be intolerance to specific agents, although this is uncommon. Intolerance may occur due to allergic reactions or intolerable adverse effects. Finally, when heparin preparations are used, there can be the development of serum antibodies and heparin-induced thrombocytosis that precludes further use of heparin products.

Guidance on Determining High Risk for Bleeding
The American College of Chest Physicians (ACCP) guidelines on prevention of venous thromboembolism (VTE) in orthopedic surgery patients list the following 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 indicated, however, that "…specific thresholds for using mechanical compression devices or no prophylaxis instead of anticoagulant thromboprophylaxis have not been established."

The 2021 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)

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

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. 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):

> "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 2018), 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."

Cross-reference:

MP 6.013 Pneumatic Compression Devices for Treatment of Lymphedema and Chronic Venous Insufficiency

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at:
https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies

III. DESCRIPTION/BACKGROUND

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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 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, 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 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.

Most bariatric surgery patients are considered high risk for venous thromboembolism (VTE) given the prevalence of risk factors that promote VTE, including obesity, obstructive sleep apnea/hypoventilation syndrome, and exposure to general anesthesia. Nevertheless, there is considerable variability among bariatric surgeons in the approach to thromboprophylaxis because of a lack of consensus regarding the optimal thromboprophylaxis strategy for this population. The current American Society of Bariatric and Metabolic Surgeons (ASMBS) guidelines regarding VTE prophylaxis state that all bariatric patients receive mechanical prophylaxis and are recommended to ambulate early in the postoperative period. Additionally, the surgeon may routinely utilize chemical prophylaxis.

Patients who are considered at a higher level of risk for VTE, such as patients with hypercoagulable disorders, history of previous VTE, or body mass index greater than 60 kg/m^2, may be considered for extended administration of VTE prophylaxis; there is no consensus regarding indications for extended prophylaxis for patients undergoing bariatric surgery.

REGULATORY STATUS

A large number of pneumatic and peristaltic limb compression devices have been cleared for marketing by the U.S. Food and Drug Administration (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.

IV. RATIONALE

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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 an intermittent pneumatic compression (IPC) device as an adjunct to anticoagulation, there are no randomized controlled trials (RCTs) assessing the incremental benefit of home use of an IPC device. Multiple meta-analyses of RCTs have compared medication plus an IPC device with medication alone in surgical patients in the hospital setting. Relevant outcomes are overall survival, symptoms, morbid events, and treatment-related morbidity. Results of these meta-analyses suggest that in-hospital addition of an IPC device to pharmacologic management improves VTE prophylaxis. Limitations of these meta-analyses include not distinguishing between asymptomatic and symptomatic DVT; sparse data on PE; and results generally not being stratified by patient risk or specific intervention(s). Moreover, these trials do not permit inferences to the post-discharge home setting, since 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 also differ in the home. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have a moderate-to-high postsurgical risk of VTE and a contraindication to pharmacologic prophylaxis who receive home use of an IPC device, there is 1 RCT assessing the benefit and feasibility of home use of an IPC device. Meta-analyses of RCTs have compared VTE prophylaxis with an IPC device to no prophylaxis in surgical patients in the hospital setting. Relevant outcomes are overall survival, symptoms, morbid events, and treatment-related morbidity. Results from meta-analyses suggest that in-hospital use of an IPC device improves VTE prophylaxis over no prophylaxis. Limitations include 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 across groups. Nonetheless, the inference is supported that in patients with a contraindication to pharmacologic prophylaxis, post-discharge use of an IPC device is superior

for VTE prophylaxis compared with no prophylaxis. A study of the post-discharge use of an IPC device combined with home visits showed that home use is feasible. With post-discharge planning and support, home use of an IPC device 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 an improvement in the net health outcome.

V. DEFINITIONS

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N/A

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits, and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

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Capital Blue Cross' medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

POLICY TITLE	POSTSURGICAL HOME USE OF LIMB COMPRESSION DEVICES FOR VENOUS THROMBOEMBOLISM PROPHYLAXIS
POLICY NUMBER	MP 6.053

Procedure Codes							
E0650	E0651	E0652	E0660	E0666	E0667	E0669	E0671
E0673	E0676						

ICD-10-CM Diagnosis Codes	Description
Z47.1	Aftercare following joint replacement surgery
Z96.641	Presence of right artificial hip joint
Z96.642	Presence of left artificial hip joint
Z96.643	Presence of artificial hip joint, bilateral
Z96.649	Presence of unspecified artificial hip joint
Z96.651	Presence of right artificial knee joint
Z96.652	Presence of left artificial knee joint
Z96.653	Presence of artificial knee joint, bilateral
Z96.659	Presence of unspecified artificial knee joint

IX. REFERENCES

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X. POLICY HISTORY

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MP 6.053	**05/01/2020 Consensus Review**. No change to policy statement. Policy Guidelines, Description/Background, References, and Rationale updated. Coding reviewed.
	05/17/2021 Consensus Review. No change to policy statement. Coding and References reviewed.
	06/08/2022 Consensus Review. No change to policy statement. FEP, background, rationale, references updated. Coding reviewed, no changes.
	07/20/2023 Consensus Review. No change to policy statement. References updated. Coding reviewed, no changes.
	06/27/2024. Consensus Review. No change to policy statement. Updated background and references.

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