

# **FEP Medical Policy Manual**

# FEP 1.01.28 Postsurgical Home Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis

Effective Policy Date: July 1, 2023

Original Policy Date: December 2013

**Related Policies:** 

1.01.18 - Pneumatic Compression Pumps for Treatment of Lymphedema and Venous Ulcers

## Postsurgical Home Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis

## **Description**

## **Description**

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), 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.

#### **OBJECTIVE**

The objective of this evidence review is to determine whether the use of limb compression devices in the home setting improves the net health outcome for patients at risk of VTE in the postsurgical period.

#### POLICY STATEMENT

Postsurgical home use of limb compression devices for 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 postsurgery is considered **not medically necessary**.

Postsurgical home use of limb compression devices for venous thromboembolism (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 individuals 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 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 the 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

The American College of Chest Physicians (ACCP) guidelines on prevention of VTE in orthopedic surgery patients listed the following general risk factors for bleeding

- "Previous major bleeding (and previous bleeding risk similar to current risk)
- Severe renal failure
- · Concomitant antiplatelet agent
- Surgical factors: a 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).

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<br>Factors)              | Moderate Risk (1 Risk<br>Factor) | High Risk (≥2 Risk<br>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). 1,

Clinical guidelines from the American Academy of Orthopaedic Surgeons (AAOS) 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 of 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."

The American College of Obstetricians and Gynecologists use the Caprini Risk Assessment Model to determine VTE risk level in patients undergoing major gynecology surgery (see Table PG2); this tool was used in developing the ACCP guidelines on VTE prevention. Caprini scores of 1 to 2, 3 to 4, and 5 or higher indicate a low (1.5%), moderate (~3%), and high (~6%) risk of symptomatic VTE, respectively. The Caprini score is extensively used and has been validated in plastic surgery patients and general surgery patients, and the ACCP has defined each of these risk groups by the expected rate of VTE in a population of patients undergoing general, abdominal-pelvic, bariatric, vascular, and plastic surgery without thromboprophylaxis.

#### Table PG2. Caprini Score to Assess Risk of Venous Thromboembolism

| Points | Risk factors   |
|--------|--|
| 1      | Age 41 - 60 years Minor surgery BMI greater than 25 kg/m² Swollen legs Varicose veins Pregnancy or postpartum state History of unexplained or recurrent pregnancy losses (greater than 3) Oral contraceptive, hormone replacement, or selective estrogen receptor modulator use* Sepsis (less than 1 month) Serious lung disease, including pneumonia (less than 1 month) Abnormal pulmonary function Acute myocardial infarction Congestive heart failure (less than 1 month) History of inflammatory bowel disease Medical patient on bed rest |

| 2 | Age 61 - 74 years Major open surgery (greater than 45 minutes) Laparoscopic surgery (greater than 45 minutes) Malignancy Confined to bed (greater than 72 hours) Central venous access   |
|---|--|
| 3 | Age 75 years or older History of VTE Family history of VTE Factor V Leiden Prothrombin 20210A Lupus anticoagulant Anticardiolipin antibodies Elevated serum homocysteine Heparin-induced thrombocytopenia Other congenital or acquired thrombophilia |
| 5 | Stroke (less than 1 month) Elective arthroplasty Hip, pelvis, or leg fracture Acute spinal cord injury (less than 1 month)   |

Adapted from Gould et al (2012).

BMI: body mass index; VTE: venous thromboembolism.

#### BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

#### FDA REGULATORY STATUS

A large number of pneumatic and peristaltic limb compression devices have been cleared for marketing by the FDA through the 510(k) process for indications including prevention of DVT. A sample of 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.

A full listing of products cleared by the FDA can be found at the following link: 510(k) Premarket Notification (fda.gov)

#### **RATIONALE**

### **Summary of Evidence**

For individuals who have a moderate-to-high postsurgical risk of venous thromboembolism (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 deep vein thrombosis (DVT); sparse data on pulmonary embolism (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.

#### SUPPLEMENTAL INFORMATION

#### **Practice Guidelines and Position Statements**

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

## **American Academy of Orthopaedic Surgeons**

In 2011, the American Academy of Orthopaedic Surgeons (AAOS) updated its guidelines on the prevention of venous thromboembolism (VTE) in patients undergoing elective hip and knee arthroplasty. 18, 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 Chest Physicians**

In 2016, the American College of Chest Physicians (ACCP) updated its 2012 evidence-based guideline<sup>19,</sup> on antithrombotic therapy and prevention of thrombosis.<sup>1,</sup> There was a second update to these guidelines in 2021, however, there was no new information for the prevention of thrombosis or mention of the use of limb compression devices. <sup>20,</sup> The 2016 update, which addressed antithrombotic therapy for 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<br>Factors)              | Moderate Risk (1 Risk<br>Factor) | High Risk (≥2 Risk<br>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). 1,

In the 2012 guidelines for the prevention of VTE in orthopaedic surgery patients, the ACCP recommended the use of limb compression devices in orthopedic surgical patients ]<sup>2</sup>,:

- 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.<sup>3</sup>,

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<br>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-<br>dose unfractionated heparin, or mechanical prophylaxis<br>with IPC over no prophylaxis."  | 2B<br>2B<br>2C |
| 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<br>1B<br>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<br>mechanical prophylaxis, preferably with IPC, over no<br>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 |

Adapted from Gould et al (2012)<sup>3</sup>,

GOR: grade of recommendation; IPC: intermittent pneumatic compression; LMWH: low molecular weight heparin; VTE: venous thromboembolism.

Note that a standard duration of prophylaxis was not defined. An "extended-duration" prophylaxis was defined as lasting 4 weeks.

### **American College of Obstetricians and Gynecologists**

A 2007 American College of Obstetricians and Gynecologists (ACOG) practice bulletin on prevention of deep vein thrombosis (DVT) and pulmonary embolism (PE) after gynecologic surgery was replaced in 2021.<sup>21,</sup> As with ACCP recommendations discussed above, prophylaxis recommendations varied by patient risk level based on the Caprini Risk Assessment Model. For patients at moderate and high-risk of DVT, intermittent pneumatic compression (IPC) was one of the recommended options for DVT prophylaxis.

Relevant recommendations based on Level A evidence were as follows:

- "For gynecologic surgery patients who are at high risk of VTE and average risk of bleeding complications, dual thromboprophylaxis with a combination of mechanical prophylaxis (preferably with intermittent pneumatic compression) and pharmacologic prophylaxis (low-dose unfractionated heparin or LMWH) is recommended."
- "For patients at high risk of VTE who are undergoing cancer surgery, in-hospital dual thromboprophylaxis and extended-duration pharmacologic prophylaxis with LMWH after hospital discharge are recommended."

Relevant recommendations based on Level B evidence were as follows:

- "For gynecologic surgery patients who are at moderate risk of VTE and not at increased risk of bleeding complications, mechanical thromboprophylaxis (preferably with intermittent pneumatic compression) or pharmacologic thromboprophylaxis (with low-dose unfractionated heparin or LMWH) is recommended."
- "For gynecologic surgery patients who are at moderate risk of VTE and high risk of major bleeding complications, mechanical prophylaxis (preferably with intermittent pneumatic compression) is recommended."
- "For gynecologic surgery patients who are at high risk of both VTE and bleeding complications, mechanical prophylaxis (preferably with intermittent pneumatic compression) is recommended until the risk of bleeding decreases and pharmacologic prophylaxis can be added."
- "For gynecologic surgery patients at high risk of VTE for whom both LMWH and low-dose unfractionated heparin are contraindicated or not available and who are not at high risk of major bleeding complications, fondaparinux, mechanical prophylaxis (preferably with intermittent pneumatic compression), or both is recommended."
- "For gynecologic surgery patients at high risk of VTE and major bleeding complications, and for whom both LMWH and low-dose unfractionated
  heparin are contraindicated or not available, mechanical prophylaxis alone (preferably with intermittent pneumatic compression) is
  recommended until the risk of bleeding diminishes and pharmacologic prophylaxis with fondaparinux can be added."

For all but the highest risk patients, the practice bulletin stated that, when IPC 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 2 to 4 weeks after discharge should be considered.

### **American Orthopaedic Foot and Ankle Society**

In 2020, the American Orthopaedic Foot and Ankle Society re-approved 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 VTE prophylaxis for patients undergoing foot and ankle surgery. Further research in this field is necessary and is encouraged." <sup>22,</sup> The position statement further notes the following with regards to the use of mechanical prophylaxis: "Mechanical prophylaxis such as elastic compression stockings and sequential compression calf pumps or foot pumps on the contralateral extremity can be utilized intraoperatively and continued postoperatively through the duration of the hospital stay. While the true efficacy of this modality in foot and ankle surgery is unknown, complications are negligible and compression pumps may be considered in both the outpatient and inpatient setting. Whether there is a threshold duration of the surgical procedure for which these are beneficial is unknown, as is the optimal duration of their use post-operatively."

### **American Society of Clinical Oncology**

In 2019, the American Society of Clinical Oncology (ASCO) released updates to the clinical practice guideline on VTE prophylaxis and treatment in patients with cancer.<sup>23,</sup> The guideline makes the following recommendation for mechanical prophylaxis in this patient population:

Recommendation 3.3. "Mechanical methods may be added to pharmacologic thromboprophylaxis but should not be used as monotherapy for VTE prevention unless pharmacologic methods are contraindicated because of active bleeding or high bleeding risk (Type: evidence based; Evidence quality: intermediate; Strength of recommendation: strong) "

Recommendation 3.4. "A combined regimen of pharmacologic and mechanical prophylaxis may improve efficacy, especially in the highest-risk patients (Type: evidence-based; Evidence quality: intermediate; Strength of recommendation: moderate)"

### American Society of Hematology

In 2019, the American Society of Hematology (ASH) issued guidelines for the prevention and management of VTE in surgical hospitalized patients.<sup>24</sup>,The 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.

#### REFERENCES

- 1. Kearon C, Akl EA, Ornelas J, et al. Antithrombotic Therapy for VTE Disease: CHEST Guideline and Expert Panel Report. Chest. Feb 2016; 149(2): 315-352. PMID 26867832
- Falck-Ytter Y, Francis CW, Johanson NA, et al. Prevention of VTE in orthopedic surgery patients: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. Chest. Feb 2012; 141(2 Suppl): e278S-e325S. PMID 22315265
- 3. Gould MK, Garcia DA, Wren SM, et al. Prevention of VTE in nonorthopedic surgical patients: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. Chest. Feb 2012; 141(2 Suppl): e227S-e277S. PMID 22315263
- MD+CALC. HAS-BLED Score for Major Bleeding Risk. http://www.mdcalc.com/has-bled-score-for-major- bleeding-risk/. Accessed January 24, 2023.
- 5. Fisher WD. Impact of venous thromboembolism on clinical management and therapy after hip and knee arthroplasty. Can J Surg. Oct 2011; 54(5): 344-51. PMID 21774881
- 6. Committee on Practice Bulletins--Gynecology, American College of Obstetricians and Gynecologists. ACOG Practice Bulletin No. 84: Prevention of deep vein thrombosis and pulmonary embolism. Obstet Gynecol. Aug 2007; 110(2 Pt 1): 429-40. PMID 17666620
- 7. Froimson MI, Murray TG, Fazekas AF. Venous thromboembolic disease reduction with a portable pneumatic compression device. J Arthroplasty. Feb 2009; 24(2): 310-6. PMID 18534456
- 8. Kakkos SK, Caprini JA, Geroulakos G, et al. Combined intermittent pneumatic leg compression and pharmacological prophylaxis for prevention of venous thromboembolism. Cochrane Database Syst Rev. Sep 07 2016; 9(9): CD005258. PMID 27600864
- 9. Kakkos S, Kirkilesis G, Caprini JA, et al. Combined intermittent pneumatic leg compression and pharmacological prophylaxis for prevention of venous thromboembolism. Cochrane Database Syst Rev. Jan 28 2022; 1(1): CD005258. PMID 35089599
- 10. O'Connell S, Bashar K, Broderick BJ, et al. The Use of Intermittent Pneumatic Compression in Orthopedic and Neurosurgical Postoperative Patients: A Systematic Review and Meta-analysis. Ann Surg. May 2016; 263(5): 888-9. PMID 26720432
- 11. Zareba P, Wu C, Agzarian J, et al. Meta-analysis of randomized trials comparing combined compression and anticoagulation with either modality alone for prevention of venous thromboembolism after surgery. Br J Surg. Aug 2014; 101(9): 1053-62. PMID 24916118
- 12. Sobieraj DM, Coleman CI, Tongbram V, et al. Comparative effectiveness of combined pharmacologic and mechanical thromboprophylaxis versus either method alone in major orthopedic surgery: a systematic review and meta-analysis. Pharmacotherapy. Mar 2013; 33(3): 275-83. PMID 23401017
- 13. Fan C, Jia L, Fang F, et al. Adjunctive Intermittent Pneumatic Compression in Hospitalized Patients Receiving Pharmacologic Prophylaxis for Venous Thromboprophylaxis: A Systematic Review and Meta-Analysis. J Nurs Scholarsh. 2020;52(4):397-405. doi:10.1111/jnu.12566
- 14. Ho KM, Tan JA. Stratified meta-analysis of intermittent pneumatic compression of the lower limbs to prevent venous thromboembolism in hospitalized patients. Circulation. Aug 27 2013; 128(9): 1003-20. PMID 23852609
- 15. Wang X, Zhang Y, Fang F, et al. Comparative efficacy and safety of pharmacological prophylaxis and intermittent pneumatic compression for prevention of venous thromboembolism in adult undergoing neurosurgery: a systematic review and network meta-analysis [published online ahead of print, 2020 Apr 16]. Neurosurg Rev. 2020;10.1007/s10143-020-01297-0. doi:10.1007/s10143-020-01297-0
- 16. Haykal T, Zayed Y, Dhillon H, et al. Meta-Analysis of the Role of Intermittent Pneumatic Compression of the Lower Limbs to Prevent Venous Thromboembolism in Critically III Patients. Int J Low Extrem Wounds. Mar 2022; 21(1): 31-40. PMID 32527203
- 17. Sobieraj-Teague M, Hirsh J, Yip G, et al. Randomized controlled trial of a new portable calf compression device (Venowave) for prevention of venous thrombosis in high-risk neurosurgical patients. J Thromb Haemost. Feb 2012; 10(2): 229-35. PMID 22188037
- 18. Mont MA, Jacobs JJ, Boggio LN, et al. Preventing venous thromboembolic disease in patients undergoing elective hip and knee arthroplasty. J Am Acad Orthop Surg. Dec 2011; 19(12): 768-76. PMID 22134209
- 19. Guyatt GH, Akl EA, Crowther M, et al. Introduction to the ninth edition: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. Chest. Feb 2012; 141(2 Suppl): 48S-52S. PMID 22315255
- 20. Stevens SM, Woller SC, Kreuziger LB, et al. Antithrombotic Therapy for VTE Disease: Second Update of the CHEST Guideline and Expert Panel Report. Chest. Dec 2021; 160(6): e545-e608. PMID 34352278
- 21. Clarke-Pearson DL, Barber EL, Landrum LM. Prevention of Venous Thromboembolism in Gynecologic Surgery: ACOG Practice Bulletin, Number 232. Obstet Gynecol. Jul 01 2021; 138(1): e1-e15. PMID 34259490
- 22. American Orthopaedic Foot & Ankle Society (AOFAS). Position Statement: The Use of VTED Prophylaxis in Foot and Ankle Surgery. 2020; https://www.aofas.org/docs/default-source/research-and-policy/vted-prophylaxis-in-foot-and-ankle-surgery-position-statement.pdf? sfvrsn=21490028 2. Accessed January 24, 2023.
- 23. Key NS, Khorana AA, Kuderer NM, et al. Venous Thromboembolism Prophylaxis and Treatment in Patients With Cancer: ASCO Clinical Practice Guideline Update. J Clin Oncol. Feb 10 2020; 38(5): 496-520. PMID 31381464
- 24. Anderson DR, Morgano GP, Bennett C, et al. American Society of Hematology 2019 guidelines for management of venous thromboembolism: prevention of venous thromboembolism in surgical hospitalized patients. Blood Adv. Dec 10 2019; 3(23): 3898-3944. PMID 31794602

# POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

| Date          | Action         | Description   |
|---------------|----------------|---|
| December 2013 | New policy     |   |
| March 2014    | Replace policy | Policy updated with literature review. "Pneumatic, removed from policy statements and policy title. Major non-orthopedic surgery changed to "major non-orthopedic surgery or non-major orthopedic surgery, in 3rd and 4th policy statements. "Post-surgical, added to policy. Reference 8 added.  |
| March 2015    | Replace policy | Policy updated with literature review. References 7 and 10 added. No change to policy statements.   |
| June 2018     | Replace policy | Policy updated with literature review through January 8, 2018; references 3, 7, 11, 13-14, 16-17, and 20-24 added. Policy statements and Policy Guidelines rewritten for clarity; intent of statements is unchanged. In title, "Outpatient, deleted and "Home, added.   |
| June 2019     | Replace policy | Policy updated with literature review through January 6, 2019; reference updated. Policy statements unchanged.  |
| June 2020     | Replace policy | Policy updated with literature review through January 13, 2020; no references added. Policy statements unchanged.   |
| June 2021     | Replace policy | Policy updated with literature review through January 25, 2021; references added. Policy statements unchanged. In title, "Outpatient" deleted and "Home" added per 2016 policy history.   |
| June 2022     | Replace policy | Policy updated with literature review through January 13, 2022; guideline references updated. Policy statements unchanged.  |
| June 2023     | Replace policy | Policy updated with literature review through January 24, 2023; references updated. Policy statement regarding postsurgical home use of limb compression devices for VTE prophylaxis for periods longer than 30 days postsurgery was changed from "not medically necessary" to "investigational." Editorial refinements to remaining policy statements; intent unchanged. |