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Postsurgical Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis

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Related Policies (if applicable)
DME101.000: DME Introduction
MED202.060: Pneumatic Compression Pumps for Treatment of Lymphedema and Venous Ulcers

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NOTE 1: Coverage of DME items is for home/place of residence use only. DME items utilized in a facility setting (hospital, outpatient surgery, physician office, other) are not separately billable and are considered part of the facility/office charge.

Postsurgical use of limb compression devices for venous thromboembolism prophylaxis **may be considered medically necessary** in individuals with a contraindication for 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 non-orthopedic surgery or other orthopedic procedures in patients who are at moderate or high risk of venous thromboembolism.

Postsurgical use of limb compression devices for venous thromboembolism prophylaxis for periods longer than 30 days post-surgery (when meeting medically necessary criteria noted above) **is considered not medically necessary**.

Postsurgical use of limb compression devices for venous thromboembolism prophylaxis **is considered experimental, investigational and/or unproven** 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 non-orthopedic surgery or other orthopedic procedures in individuals without a contraindication for anticoagulation who are at moderate or high risk of venous thromboembolism; OR
- Treatment of peripheral artery disease/arterial insufficiency.

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

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 Factors)	***Moderate Risk (1 Risk Factor)***	***High Risk (≥2 Risk Factors)***
Anticoagulation 0-3 months, %			
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 months, %/year			
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 Orthopedic Surgeons 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 individuals with contraindications to pharmacologic prophylaxis who are undergoing major orthopedic surgery (total hip arthroplasty, total knee arthroplasty, hip fracture surgery), the 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 individuals undergoing non-orthopedic 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 individuals 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 Non-Orthopedic Surgery

The ACCP guidelines on prevention of VTE in non-orthopedic surgery individuals 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 (hours), 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 individuals 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/m^2 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). (3)
BMI: body mass index; VTE: venous thromboembolism.

Description

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 the 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. (2, 3)

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 individuals undergoing major surgery will not have an increased risk of bleeding precluding the use of anticoagulants, because these individuals 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 individuals with a high bleeding risk will undergo major surgery, such as individuals with

severe renal failure who require an essential procedure. Other individuals may develop contraindications during the episode of care. For example, individuals who have excessive bleeding during or after surgery, or individuals 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 (4), 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 a venographically detected DVT is approximately 42% to 57% after total hip replacement, and the risk of PE is approximately 1% to 28%. (5) 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%. (6)

Thus, antithrombotic prophylaxis is recommended for individuals undergoing major orthopedic surgery and other surgical procedures who are at increased risk of VTE. For individuals undergoing major orthopedic surgery, clinical practice guidelines published by the ACCP (2012) recommended that one of several pharmacologic agents or mechanical prophylaxis be provided rather than no thromboprophylaxis. (2) The guidelines further recommended the use of pharmacologic prophylaxis during hospitalization, whether or not individuals 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 individuals in the hospital following hip or knee replacement surgery. (7)

Non-orthopedic Surgery

Pharmacologic and Limb Compression Prophylaxis

The ACCP (2012) also issued guidelines on VTE prophylaxis in non-orthopedic surgery individuals. (3) For individuals undergoing general or abdominal-pelvic surgery who have a risk

of VTE of 3% or higher, the ACCP has recommended prophylaxis with pharmacologic agents or intermittent pneumatic compression (IPC) 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 non-orthopedic surgery individuals 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 individuals 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 non-orthopedic 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. 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 individual'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: <https://www.accessdata.fda.gov>.

Rationale

Medical policies assess the clinical evidence to determine whether the use of 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 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 technology, two 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

Clinical Context and Therapy Purpose

The purpose of home use of a limb compression device as an adjunct to anticoagulation is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as anticoagulation only, in individuals with moderate-to-high postsurgical risk of venous thromboembolism (VTE) and no contraindication to pharmacologic prophylaxis.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals with moderate-to-high postsurgical risk of VTE and no contraindication to pharmacologic prophylaxis.

Interventions

The therapy being considered is home use of a limb compression device as an adjunct to anticoagulation.

Comparators

Comparators of interest include anticoagulation only. Treatments include an anticoagulation regimen and conventional therapy.

Outcomes
The general outcomes of interest are overall survival, symptoms, morbid events, and treatment-related morbidity.

The existing literature evaluating home use of a limb compression device as an adjunct to anticoagulation as a treatment for moderate-to-high postsurgical risk of VTE and no contraindication to pharmacologic prophylaxis has varying lengths of follow-up. While studies described below all reported at least one outcome of interest, longer follow-up was necessary to fully observe outcomes.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

This section focuses on evidence that post-discharge use of limb compression devices (commonly referred to in the literature as intermittent pneumatic compression [IPC] 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 individuals with moderate-to-high postsurgical risk of VTE and no contraindication to pharmacologic prophylaxis is a superiority RCT comparing VTE prophylaxis consisting of pharmaceutical agents plus limb compression devices with pharmacologic agents alone. No RCTs with this study design were identified for individuals 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 individuals in the hospital setting. These studies may not permit inferences to the post discharge home setting; they are briefly summarized for informational purposes below.

Systematic Reviews
Multiple meta-analyses of RCTs have compared pharmacological VTE prophylaxis plus an IPC device with medication alone in surgical patients in the hospital setting. (8-13) Surgical populations represented in these analyses include patients undergoing abdominal, cardiac, neurologic, and orthopedic surgery. Commonly reported outcomes include the occurrence of deep vein thrombosis (DVT), symptomatic DVT, and pulmonary embolism (PE). In addition to an IPC device, cointerventions with other mechanical prophylaxis strategies (graduated compression stockings, etc.) have also been reported in some analyses. Overall, findings from

meta-analyses suggest that the in-hospital addition of an IPC device to pharmacologic management improves VTE prophylaxis, especially for the prevention of DVT. Findings related to the risk of PE are more limited because analyses might have been underpowered due to the small number of PE events.

The post-discharge setting has important characteristics that preclude making inferences from the inpatient setting. Individual characteristics vary because discharged individuals tend to be healthier than those in the hospital. Characteristics of home use also vary (e.g., treatment consistency, duration, application errors in use).

Section Summary: Moderate-to-High Postsurgical Risk of VTE and No Contraindication to Pharmacologic Prophylaxis

For individuals who have moderate-to-high postsurgical risk of VTE and no contraindication to pharmacologic prophylaxis who receive home use of an IPC device as an adjunct to anticoagulation, there are no RCTs assessing the incremental benefit of home use of an IPC device. Meta-analyses of RCTs have compared medication plus an IPC device with medication alone in surgical individuals in the hospital setting. Relevant outcomes are overall survival, symptoms, morbid events, and treatment-related morbidity. Results of these meta-analyses suggest that the 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 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 individuals tend to be healthier than those in the hospital. Factors such as treatment consistency, duration, and application errors in use differ in the home.

Moderate-to-High Postsurgical Risk of Venous Thromboembolism and a Contraindication to Pharmacologic Prophylaxis

Clinical Context and Therapy Purpose

The purpose of home use of a limb compression device is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as no outpatient venous prophylaxis or other methods of mechanical prophylaxis, in individuals with a moderate-to-high postsurgical risk of VTE and a contraindication to pharmacologic prophylaxis.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest are individuals with a moderate-to-high postsurgical risk of VTE and a contraindication to pharmacologic prophylaxis.

Interventions

The therapy being considered is the home use of a limb compression device.

Comparators
Comparators of interest include no outpatient venous prophylaxis or other methods of mechanical prophylaxis. Treatment includes conventional therapy.

Outcomes
The general outcomes of interest are overall survival, symptoms, morbid events, and treatment related morbidity.

The existing literature evaluating home use of a limb compression device as a treatment for moderate-to-high postsurgical risk of VTE and a contraindication to pharmacologic prophylaxis has varying lengths of follow-up. While studies described below all reported at least one outcome of interest, longer follow-up was necessary to fully observe outcomes.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

This section addresses whether post-discharge limb compression device (commonly referred to in the literature as an IPC device) use in moderate-to-high risk patients with a contraindication to pharmacologic prophylaxis improves the net health outcome compared with no post-discharge 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 individuals. Alternatively, a network meta-analysis could indirectly compare outcomes of limb compression device use with no VTE prophylaxis. One RCT of post-discharge use in individuals with contraindication to pharmacologic prophylaxis was identified. Briefly summarized below are data from inpatients comparing limb compression device use to no prophylaxis.

Systematic Reviews
A few meta-analyses of RCTs have compared IPC devices to no prophylaxis in the hospital setting. (14-16) Populations include surgical and nonsurgical patients, including critically ill patients in a medical or surgical intensive care unit (ICU). Commonly reported outcomes include the occurrence of DVT and PE. 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 individuals and some studies involving higher risk individuals also included pharmacologic prophylaxis in both groups. Overall, findings from meta-analyses suggest that the in-hospital addition of an IPC device improves VTE prophylaxis over no

prophylaxis, especially for the prevention of DVT; 2 of the 3 meta-analyses also saw statistically significant reductions in the incidence of PE.

Randomized Controlled Trials

To draw inferences about the benefit of limb compression devices post-discharge in these individuals, 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 intermittent pneumatic compression device with usual care alone in patients undergoing cranial or spinal neurosurgery. (17) All individuals were also prescribed graduated compression stockings and 20% to 25% used anticoagulants. Individuals were evaluated at 9 days post-surgery, and those discharged earlier were permitted to use an intermittent pneumatic compression at home (median duration of hospitalization, 4 days). Individuals who used the intermittent pneumatic compression device post-discharge received home visits at least daily to optimize compliance. Three (4%) of 75 individuals in the IPC group and 14 (19%) of 75 individuals in the usual care group developed VTE; the difference between groups was statistically significant (p=0.008). Among evaluable individuals in the intermittent pneumatic compression 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 intermittent pneumatic compression use was 6.6 days. Findings would suggest that in-home use of intermittent pneumatic compression devices is feasible with adequate post-discharge planning and support.

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

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 incremental benefit of home use of an IPC device. A few meta-analyses of RCTs have compared VTE prophylaxis with an IPC device to no prophylaxis in surgical individuals in the hospital setting, and 1 RCT evaluated the feasibility of post-discharge home use of an IPC. 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 individuals and some studies involving higher risk individuals also included pharmacologic prophylaxis across groups. Nonetheless, the inference is supported that in individuals 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 individuals who have 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 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 intermittent pneumatic compression device with medication alone in surgical individuals 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; and results generally not stratified by individual risk or specific intervention(s). Moreover, these trials do not permit inferences to the post-discharge home setting differs in important respects from the hospital setting. Discharged individuals 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 that the technology results in an improvement in the net health outcome.

For individuals who have a moderate-to-high post-surgical 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 individuals 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 individuals and some studies involving higher risk individuals also included pharmacologic prophylaxis across groups. Nonetheless, the inference is supported that in individuals 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 individuals 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.

Practice Guidelines and Position Statements

American Academy of Orthopaedic Surgeons

In 2011, the American Academy of Orthopaedic Surgeons (AAOS) updated its guidelines on the prevention of VTE in individuals undergoing elective hip and knee arthroplasty. (18) The guidelines included the following recommendations relevant to this medical policy:

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 (19) on antithrombotic therapy and prevention of thrombosis. (1) 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. (20) 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):

1. "Age >65 y;
2. Age >75 y;
3. Previous bleeding;
4. Cancer;
5. Metastatic cancer;
6. Renal failure;
7. Liver failure;
8. Thrombocytopenia;
9. Previous stroke;
10. Diabetes;
11. Anemia;
12. Antiplatelet therapy;
13. Poor anticoagulant control;
14. Comorbidity and reduced functional capacity;
15. Recent surgery;
16. Alcohol abuse;
17. Nonsteroidal anti-inflammatory drug."

Table 1. Guidelines for Risk of Bleeding

Risk Factors	Estimated Absolute Risk of Major Bleeding		
	Low Risk (0 Risk Factors)	Moderate Risk (1 Risk Factor)	High Risk (≥2 Risk Factors)
Anticoagulation 0-3 months., %			
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 months., %/years			
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. (2):

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 non-orthopedic general and abdominal-pelvic surgical patients, stratified by patient risk of VTE and risk of bleeding are listed in Table 2. (3)

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

Patient Risk Group	Recommendation	GOR
Very low risk (<0.5%)	"[W]e recommend that no specific pharmacologic or mechanical prophylaxis be used other than early ambulation."	1B 2C
Low risk for VTE (~1.5%)	"[W]e suggest mechanical prophylaxis, preferably with intermittent pneumatic compression (IPC), over no prophylaxis."	2C
Moderate risk for VTE (~3%) and not at high risk of bleeding	"[W]e suggest low-molecular-weight heparin (LMWH), low-dose unfractionated heparin, or mechanical prophylaxis with IPC over no prophylaxis."	2B 2B 2C
Moderate risk for VTE (~3%) and high risk for major bleeding complications or in whom bleeding consequences would be particularly severe	"We suggest mechanical prophylaxis, preferably with IPC, over no prophylaxis."	2C
High risk for VTE (~6.0%) and not at high risk of bleeding	"[W]e recommend pharmacologic prophylaxis with LMWH or low-dose unfractionated heparin over no prophylaxis. In these patients, we suggest adding mechanical prophylaxis with elastic stockings or IPC to pharmacologic prophylaxis."	1B 1B 2C
High risk for VTE (~6.0%) and high risk for major bleeding complications or in whom bleeding consequences would be particularly severe	"[W]e suggest use of mechanical prophylaxis, preferably with IPC, over no prophylaxis until the risk of bleeding diminishes and pharmacologic prophylaxis may be initiated."	2C
High risk for VTE, both LMWH and unfractionated heparin contraindicated or unavailable and not at high risk for major bleeding complications:	[W]e suggest low-dose aspirin, fondaparinux, or mechanical prophylaxis, preferably with IPC, over no prophylaxis."	2C
High risk for VTE, undergoing abdominal or pelvic surgery for cancer and not otherwise at high risk for major bleeding complications	"[W]e recommend extended-duration, postoperative, pharmacologic prophylaxis (4 weeks) with LMWH over limited-duration prophylaxis."	1B

Adapted from Gould et al. (2012) (3)
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 four 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. (21) 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."

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 venous thromboembolic disease (VTED) prophylaxis for patients undergoing foot and ankle surgery. Further research in this field is necessary and is encouraged.” (22) 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 2023 the American Society of Clinical Oncology (ASCO) released updates to the clinical practice guideline on VTE prophylaxis and treatment in patients with cancer. (23) The guideline was unchanged from the previous 2019 guideline and 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 issued guidelines for the prevention and management and of venous thromboembolism in surgical hospitalized patients. (24) The following are 2 suggestions for individuals 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.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished and published trials that might influence this review are listed in Table 3.

Table 3. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT03259024	Swedish Multicenter Trial of Outpatient Prevention of Leg Clots (StopLegClots)	1400	December 2025

NCT: national clinical trial.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	None
HCPCS Codes	A4600, E0650, E0651, E0652, E0655, E0656, E0657, E0660, E0665, E0666, E0667, E0668, E0669, E0670, E0671, E0672, E0673, E0675, E0676, E0683

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

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A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
02/01/2025	Document updated with literature review. Coverage unchanged. No new references added.
02/01/2024	Document updated with literature review. Coverage unchanged. References 9, 20, 21, and 23 added; others removed.
08/15/2022	Reviewed. No changes.
12/01/2021	Document updated with literature review. The following changes were made to Coverage: 1) Added NOTE 1; 2) Removed “home” from all coverage statements; 3) Added Treatment of peripheral artery disease/arterial insufficiency to the postsurgical use of limb compression devices for venous thromboembolism prophylaxis experimental, investigational and/or

	unproven coverage statement. References 13 and 15-16 were added. Title changed from: Postsurgical Outpatient Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis.
01/15/2021	New medical document. Outpatient home use of limb compression devices for venous thromboembolism prophylaxis may be considered medically necessary when criteria in the policy are met. Coverage previously addressed on MED202.060 Pneumatic Compression Pumps for Treatment of Lymphedema and Venous Ulcers (previously Outpatient Use of Pneumatic Compression Devices).