

POLICY TITLE	OUTPATIENT USE OF LIMB PNEUMATIC COMPRESSION DEVICES FOR VENOUS THROMBOEMBOLISM PROPHYLAXIS
POLICY NUMBER	MP- 6.053

Original Issue Date (Created):	September 24, 2013
Most Recent Review Date (Revised):	September 24, 2013
Effective Date:	February 1, 2014

I. POLICY

Outpatient use of limb pneumatic compression devices for venous thromboembolism prophylaxis is considered **medically necessary** for the following indications.

- After major orthopedic surgery in patients with a contraindication to pharmacological agents i.e., at high-risk for bleeding. (For purposes of this policy, “major orthopedic surgery” includes total hip arthroplasty, total knee arthroplasty, or hip fracture surgery only.)
- After non-major orthopedic surgery of the lower extremity in patients who are at moderate or high risk of venous throboembolism (see Policy Guidelines) with a contraindication to pharmacological agents i.e., at high risk for bleeding.
- After major non-orthopedic surgery in patients who are at moderate or high risk of venous thromboembolism (see Policy Guidelines) with a contraindication to pharmacological agents i.e., at high-risk for bleeding.

Outpatient use of limb pneumatic compression devices for venous thromboembolism prophylaxis is considered **investigational** for the following indications

- After major orthopedic surgery in patients without a contraindication to pharmacological prophylaxis.
- After non-major orthopedic surgery of the lower extremity in patients who are at moderate or high risk of venous throboembolism without a contraindication to pharmacological prophylaxis.
- After major non-orthopedic surgery in patients who are at moderate or high risk of venous thromboembolism without a contraindication to pharmacological prophylaxis
- In patients who are at low-risk of venous thromboembolism
- After all other surgeries

Outpatient use of limb pneumatic compression devices for venous thromboembolism prophylaxis for periods longer than 30 days post-surgery is **not medically necessary**.

POLICY TITLE	OUTPATIENT USE OF LIMB PNEUMATIC COMPRESSION DEVICES FOR VENOUS THROMBOEMBOLISM PROPHYLAXIS
POLICY NUMBER	MP- 6.053

POLICY GUIDELINES

For purposes of this policy, “major orthopedic surgery” includes total hip arthroplasty, total knee arthroplasty, or hip fracture surgery.

Guidance on determining high risk for bleeding

The ACCP guidelines on prevention of VTE in orthopedic surgery patients list the following general risk factors for bleeding (3):

- 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 note, however, that “specific thresholds for using mechanical compression devices or no prophylaxis instead of anticoagulant thromboprophylaxis have not been established.”

A clinical guideline from the American Academy of Orthopaedic Surgeons (2011) states (6):

"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 (THA, TKA or HFS), the ACCP guidelines are consistent with use of intermittent pneumatic compression devices for 10-14 days after surgery. (3) The ACCP suggestion on extended prophylaxis (up to 35 days) was a weak recommendation that did not mention pneumatic compression devices as an option.

In the ACCP guideline on VTE prophylaxis in patients undergoing non-orthopedic surgery, the length of standard duration or “limited duration” prophylaxis was not defined. However, “extended duration” pharmacologic prophylaxis was defined as 4 weeks; this was

POLICY TITLE	OUTPATIENT USE OF LIMB PNEUMATIC COMPRESSION DEVICES FOR VENOUS THROMBOEMBOLISM PROPHYLAXIS
POLICY NUMBER	MP- 6.053

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 risk level for patients undergoing non-orthopedic surgery

The ACCP guidelines on prevention of VTE in non-orthopedic surgery patients included the following discussion of risk levels (5): (pp. 13-14)

“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 at least 60 years, prior VTE, and cancer; age >60 years, prior VTE, anesthesia at least 2 h, and bed rest at least 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 more than 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 (ACOG) proposed the following risk classification for VTE in patients undergoing major gynecological surgery (available online at: <http://guidelines.gov/content.aspx?id=11429>):

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 age 40-60 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 molecular hypercoagulable state.

Cross-reference:

MP- 6.013 Pneumatic Compression Pumps for Treatment of Lymphedema and Venous Ulcers.

POLICY TITLE	OUTPATIENT USE OF LIMB PNEUMATIC COMPRESSION DEVICES FOR VENOUS THROMBOEMBOLISM PROPHYLAXIS
POLICY NUMBER	MP- 6.053

II. PRODUCT VARIATIONS

Key:

[N] = No product variation, policy applies as stated

[Y] = Standard product coverage varies from application of this policy, see below

[N] Capital Cares 4 Kids

[N] Indemnity

[N] PPO

[N] SpecialCare

[N] HMO

[N] POS

[N] SeniorBlue HMO

[Y] FEP PPO*

[N] SeniorBlue PPO

* The FEP program dictates that all drugs, devices or biological products approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational. Therefore, FDA-approved drugs, devices or biological products may be assessed on the basis of medical necessity.

III. DESCRIPTION/BACKGROUND

Patients undergoing major orthopedic surgery are at increased risk for venous thromboembolism (VTE). Patients undergoing other types of surgery may also be at increased risk of VTE. Limb pneumatic compression devices are one option for thromboprophylaxis and are commonly used in the hospital setting. Outpatient use of pneumatic compression devices following hospitalization, with or without pharmacologic prophylaxis, has also been proposed.

Patients undergoing major surgery are at increased risk of developing deep vein thrombosis (DVT) and pulmonary embolism (PE), together known as venous thromboembolism (VTE). Patients who are having major orthopedic surgery (defined here as total hip arthroplasty [THA], total knee arthroplasty [TKA] and hip fracture surgery [HFS]) are at particularly high risk. Risk of DVT is increased due to venous stasis of the lower limbs as a consequence of immobility during and after surgery. In addition, 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 an acute DVT is a PE which can be fatal; this occurs when the DVT detaches and migrates to the lungs. In addition, DVT may produce long-term vascular damage that leads to chronic venous insufficiency. Without thromboprophylaxis, the incidence of venographically detected DVT is approximately 42-57% after total hip replacement, and the risk of pulmonary embolism is approximately 1-28%. (1) Other surgical patients may also be at increased risk of VTE during

POLICY TITLE	OUTPATIENT USE OF LIMB PNEUMATIC COMPRESSION DEVICES FOR VENOUS THROMBOEMBOLISM PROPHYLAXIS
POLICY NUMBER	MP- 6.053

and after hospitalization. For example, it is estimated that rates of VTE without prophylaxis after gynecologic surgery is about 15-40%. (2)

Thus, antithrombotic prophylaxis is recommended for patients undergoing major orthopedic surgery and other surgical patients at increased risk of VTE. For patients undergoing major orthopedic surgery, clinical practice guidelines published in 2012 by the American College of Chest Physicians (ACCP) recommend that one of several pharmacologic agents or mechanical prophylaxis be provided rather than no thromboprophylaxis. (3) The guidelines further recommend the use of pharmacologic prophylaxis during hospitalization, whether or not patients are using a pneumatic compression device. The ACCP guidelines noted that compliance is a major issue with pneumatic compression devices used for thromboprophylaxis and recommend that, if this prophylactic option is selected, use should be limited to portable, battery-operated devices. Moreover, it is recommended that devices be used for 18 hours per day. A 2009 non-randomized study found that there was better compliance with a portable battery-operated pneumatic compression device compared to a non-mobile device when used by patients in the hospital following hip or knee replacement surgery. (4)

The ACCP also issued guidelines on VTE prophylaxis in non-orthopedic surgery patients. (5) For patients undergoing general or abdominal-pelvic surgery who have a risk of VTE of 3% or higher, the ACCP recommends prophylaxis with pharmacologic agents or intermittent pneumatic compression rather than no prophylaxis. For patients at low risk for VTE (about 1.5%), the guidelines suggest mechanical prophylaxis. Unlike the guidelines on major orthopedic surgery, which recommends a minimum of 10-14 days of VTE prophylaxis, the guideline on non-orthopedic surgery patients does not include a general timeframe for prophylaxis. They do, however, define “extended duration” pharmacologic prophylaxis as lasting 4 weeks; the latter is recommended only for patients at high risk for VTE, undergoing abdominal or pelvic surgery for cancer who are not otherwise at high risk for major bleeding complications.

National clinical guidelines have not specifically recommended use of pneumatic compression devices in the outpatient setting. However, especially with the availability of portable, battery-operated devices, there is interest in use of outpatient pneumatic compression devices for DVT following discharge from the hospital for major orthopedic and non-orthopedic surgery.

Regulatory Status

Multiple limb pneumatic compression devices, with indications including prevention of DVT, have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. Portable battery-operated devices that have been cleared by the FDA include: Venowave VW5 (Venowave Inc.; Stouffville, Ontario, Canada): The device is a portable unit that is strapped to the leg below the knee. Different models are available that have a different maximum number of wave plate cycles per minute.

POLICY TITLE	OUTPATIENT USE OF LIMB PNEUMATIC COMPRESSION DEVICES FOR VENOUS THROMBOEMBOLISM PROPHYLAXIS
POLICY NUMBER	MP- 6.053

ActiveCare+SFT® System (Medical Compression Systems LTD, Or Akiva, Israel): The device applies sequential pneumatic compression to the lower limb; it has the option of being battery-operated. Foot compression is achieved with use of a single-celled foot sleeve. Calf and thigh compression requires use of a 3-celled cuff sleeve.

Restep DVT System (Stortford Medical LLC, West Windsor, NJ): This is a lightweight device that utilizes single chamber pressure cuffs attached to the patient’s lower legs

IV. RATIONALE

The policy was created in November 2012 with a search of the MEDLINE database through October 2012. The key published literature is summarized below.

VTE prophylaxis in major orthopedic surgery patients

Patients without a contraindication to prophylaxis with pharmaceutical agents

Anticoagulation is the mainstay of deep vein thrombosis (DVT) prophylaxis after major surgery and is sometimes continued into the outpatient setting. Treatment with pneumatic compression devices may offer addition benefit when used in conjunction with anticoagulation in the inpatient setting but is not commonly used in the outpatient setting. The ideal study design to evaluate whether there is benefit in the outpatient setting would be a randomized controlled trial (RCT) comparing outpatient anticoagulation alone to anticoagulation plus pneumatic compression devices. Key health outcomes include incidence of DVT and pulmonary embolism (PE), as well as measures of functional status and/or quality of life associated with these outcomes.

Randomized controlled trials (RCT): No RCT with the above design was identified. In 2012, Kakkos and colleagues published a meta-analysis of RCTs evaluating combined use of anticoagulation and mechanical DVT prophylaxis following joint replacement surgery; however, the study focused on inpatient thromboprophylaxis. (7) The authors identified 4 trials that compared anticoagulation alone to anticoagulation plus use of pneumatic compression devices. Three of the 4 studies used pneumatic compression devices only until discharge from the hospital. In the fourth study, the article did not clearly state that that pump use was limited to the inpatient setting, but inpatient use was implied e.g., the article stated that staff checked several times a day to ensure correct use of the pump system. Meta-analyses found statistically significantly lower incidences of DVT in the group that used compression pumps in addition to anticoagulation compared to anticoagulation-only. In a pooled analysis of 4 trials on hip replacement, the incidence of DVT was 9.7% in the anticoagulation-only group and 0.9% in the combined treatment group (risk ratio [RR]: 0.17; 95% confidence interval [CI]: 0.06 to 0.46). Similarly, when findings from 2 trials on knee replacement were pooled, the incidence of DVT was 18.7% in the anticoagulation-only group and 3.7% in the combined treatment group (RR: 0.27; 95% CI: 0.08 to 0.89).

POLICY TITLE	OUTPATIENT USE OF LIMB PNEUMATIC COMPRESSION DEVICES FOR VENOUS THROMBOEMBOLISM PROPHYLAXIS
POLICY NUMBER	MP- 6.053

There are several reasons why the benefit of pneumatic compression devices in the hospital setting may not extrapolate to benefit in the outpatient setting. First, the level of mobility is necessarily less in the hospital than in the outpatient setting, indicating a different risk for DVT. Also, the use of pneumatic compression devices in the hospital can be more highly controlled and monitored. In the outpatient setting, there are questions about the degree of compliance with the devices, including the ability to correctly use them in the absence of professional supervision. No comparative studies were identified that focused on compliance with pneumatic compression devices in the outpatient setting.

Case series: A 2006 case series by Giannoni and colleagues in Italy included both inpatient and outpatient DVT prophylaxis with pneumatic compression devices and anticoagulants. (8) The study included 34 patients who underwent total knee replacement (4 patients had bilateral replacements). All patients used a pneumatic compression device (A-V Impulse foot pump system) for 15 days. The mean hospital stay was 7 days, and the range was 5 to 12 days. The compression devices were worn for an average of 14 hours per day (range 8 to 18 hours). Patients were also treated with LMWH, beginning after surgery and continuing until the operated leg was completely weight bearing (15-30 days). Ultrasonography detected DVTs in 3 of 34 (8.8%) patients; all were distal DVTs. One symptomatic DVT developed on the 4th post-operative day, and there were 2 subclinical DVTs detected at the routine 1 month ultrasonographic examination. This study did not include a comparison group of patients who did not use a pneumatic compression device. In addition, given the range of length of hospital stay, some patients received their entire course of prophylactic treatment as inpatients. Compliance with pneumatic compression devices was not reported.

Patients with a contraindication to prophylaxis with pharmaceutical agents

Patients with contraindications to anticoagulants need to be treated with non-pharmacologic measures. The ideal study design for this question would be an RCT comparing prophylaxis with pneumatic compression devices alone in the outpatient setting to no prophylaxis or to alternative methods of prophylaxis.

Randomized controlled trials: No RCTs using this design were identified. However, one recent RCT provided data that might be useful for answering the question of whether outpatient use of pneumatic compression devices are beneficial in the absence of outpatient anticoagulant use. The study, reported on in 2 publications, one in 2010 and the other in 2011, was conducted at multiple centers in the United States and included 395 patients undergoing total hip replacement. (9, 10) Individuals with a previous history of thrombosis, known coagulation disorder, solid malignant tumor, peptic ulcer disease or mental disorder were excluded. Patients were randomized to 10 days of DVT prophylaxis using either low-molecular-weight heparin (LMWH) or a mobile pneumatic compression device (ActiveCare+SFT). Treatment continued until 10 days after surgery in both groups; patients received a variable portion of their treatment after hospital discharge. Patients in the compression device group could also receive aspirin if recommended by their doctor. Patients were examined with bilateral duplex ultrasound on day 10-12 following surgery. The mean length of hospital stay was 3.2 days in both groups. Length

POLICY TITLE	OUTPATIENT USE OF LIMB PNEUMATIC COMPRESSION DEVICES FOR VENOUS THROMBOEMBOLISM PROPHYLAXIS
POLICY NUMBER	MP- 6.053

of hospital stay ranged from 2 days to 10 days; thus, patients had between 0 days and 8 days of outpatient use of their assigned method of prophylaxis. According to ultrasound findings, 8 of 196 (4.1%) in the pneumatic compression group and 8 of 190 (4.2%) in the LMWH group had a DVT. In addition, 2 pulmonary emboli were detected in each group. The incidence of venous thromboembolic events did not differ significantly between groups. However, the rate of major bleeding was significantly higher in the LMWH group. A total of 11 (6%) of patients in the LMWH group had a major bleeding event compared to no patients in the pneumatic compression group (p=0.0004). Rates of minor bleeding were similar in the 2 groups; 78 (40%) in the LMWH group and 74 (37%) in the pneumatic compression group. In addition, compliance with the mobile compression devices was monitored using internal timers in the device. According to these data, patients used the device for a mean of 11 days (range 1 to 15 days) and for a mean of 20 hours per day. Mean use of the device was 83% of possible usable time. Findings on compliance were not reported separately for inpatient and outpatient use of the devices.

Conclusions in patients undergoing major orthopedic surgery: There is very little published evidence on the efficacy of outpatient use of limb pneumatic compression devices for deep vein thrombosis prophylaxis after major orthopedic surgery. There are no RCTs that evaluate outpatient use of pneumatic compression as an adjunct to pharmacologic prophylaxis in patients without a contraindication to anticoagulants. Some RCTs have evaluated the inpatient use of pneumatic compression as an adjunct to pharmacologic agents, but the results of these trials might not be able to be extrapolated to the outpatient setting. There is also a lack of evidence on compliance with limb pneumatic compression devices in the outpatient setting. National clinical guidelines support the use of pneumatic compression devices DVT prophylaxis after major orthopedic surgery in patients who are not candidates for pharmacologic prophylaxis due to a high risk of bleeding. In addition, one RCT that reported similar rates of post-operative DVT in patients who received pneumatic compression devices or low-molecular-weight evidence provides some evidence in support of pneumatic compression devices as the sole intervention in the outpatient setting. This study was limited in that much of the treatment occurred in the hospital, and patients with a known coagulation disorder were excluded from participation.

VTE (venous thromboembolism) prophylaxis in major non-orthopedic surgery patients

Patients with and without a contraindication to prophylaxis with pharmaceutical agents

Randomized controlled trials: No RCTs were identified that specifically addressed the comparison between inpatient-only and inpatient and outpatient use of pneumatic compression devices as an adjunct to anticoagulant use in patients undergoing major non-orthopedic surgery. Moreover, no RCTs were identified that compared intermittent pneumatic compression (IPC) in the outpatient setting to no prophylaxis beyond inpatient use in patients with contraindications to pharmaceutical agents. Two systematic reviews of RCTs on VTE prophylaxis in patients undergoing major non-orthopedic surgery were examined, one a Cochrane review on VTE prevention in high-risk patients and the other on VTE prevention

POLICY TITLE	OUTPATIENT USE OF LIMB PNEUMATIC COMPRESSION DEVICES FOR VENOUS THROMBOEMBOLISM PROPHYLAXIS
POLICY NUMBER	MP- 6.053

after gynecologic surgery; neither meta-analysis included RCTs relevant to the research question being considered. (11, 12)

However, an RCT by Sobieraj-Teague and colleagues may contribute some relevant data. (13) The non-blinded study, conducted in Canada, compared inpatient and outpatient use of Venowave, a portable battery-operated IPC device, to usual care only in 150 adult patients undergoing cranial or spinal neurosurgery. As part of usual care, all patients were prescribed graduated compression stockings and early mobilization. Patients could also receive pharmacologic treatment at the discretion of their physician. A total of 19 of 75 patients (25%) in the Venowave group and 26 of 75 patients (35%) in the control group received anticoagulants (unfractionated or LMW heparin) and an additional 4 (5%) in the Venogram group and 7 (9%) in the control group used aspirin. In the Venowave group, devices were worn until development of VTE, patient refusal, until undergoing a screening bilateral venogram at day 9 (+/- 2 days) or earlier if patients were discharged from the hospital earlier and were unwilling to return for a venogram. The median day of hospital discharge was day 4. Patients who continued using the Venowave device at home received home visits at least daily to optimize compliance. Eight patients did not undergo screening venography. Mean time to screening was 7.3 days in the Venowave group and 7.5 days in the control group. The primary efficacy outcome was a composite of asymptomatic DVTs and symptomatic PEs. VTE occurred in 3 patients (4%) in the Venowave group and 14 (19%) in the control group. The difference between groups was statistically significant (RR: 0.21, 95% CI: 0.05 to 0.75). Most of the VTEs were asymptomatic, and there were no PEs. Two patients in the control group and none in the Venowave group experienced a symptomatic DVT. Among the 75 evaluable patients in the Venogram group, 17 (23.3%) were continuous users, 39 (53.4%) were intermittent users, and 17 (23.3%) discontinued use of the device before their venogram assessment. Compliance might have been lower if patients had not received daily home visits.

The Sobieraj-Teague study did not specifically exclude patients with a contraindication to pharmaceutical agents. Moreover, only about 30% of participants were prescribed heparin or aspirin. This suggests that study findings might be applicable to patients who are not taking pharmaceutical agents i.e., including those with a contraindication. Generalizability of study findings is not clear, however, as the authors did not report VTE prevalence among patients who did or did not take anticoagulants or aspirin.

Conclusions in patients undergoing major non-orthopedic surgery: There is very little published evidence on the efficacy of outpatient use of limb pneumatic compression devices for deep vein thrombosis prophylaxis after major non-orthopedic surgery. There are no RCTs that evaluate outpatient use of pneumatic compression as an adjunct to pharmacologic prophylaxis in patients without a contraindication to anticoagulants. There is also a lack of evidence on compliance with limb pneumatic compression devices in the outpatient setting. National clinical guidelines support the use of pneumatic compression devices DVT prophylaxis after major non-orthopedic surgery in individuals at moderate- and high-risk of DVT. Moreover, one RCT, which found significantly fewer VTEs in patients undergoing

POLICY TITLE	OUTPATIENT USE OF LIMB PNEUMATIC COMPRESSION DEVICES FOR VENOUS THROMBOEMBOLISM PROPHYLAXIS
POLICY NUMBER	MP- 6.053

cranial or neurosurgery who used a portable IPC than those receiving usual care; treatment occurred in both the inpatient and outpatient settings.

Summary

Patients undergoing major surgery, particularly orthopedic surgery, are at high risk for venous thromboembolism (VTE), and VTE prophylaxis for high-risk patients may be indicated beyond the period of hospitalization. Pharmacologic prophylaxis is the mainstay of treatment, but some patients have contraindications to anticoagulation, such as a high bleeding risk. For these patients who are undergoing major orthopedic surgery or high-risk non-orthopedic surgery, pneumatic compression devices are a reasonable alternative when prophylaxis is indicated in the outpatient setting. This is based on support in clinical practice guidelines, evidence from RCTs on different populations, and the lack of other good alternatives. Therefore, the use of pneumatic compression devices for outpatient VTE prophylaxis may be considered medically necessary when prophylaxis is indicated but there are contraindications to anticoagulation.

For patients who do not have contraindications to anticoagulation, the evidence is not sufficient to determine whether pneumatic compression devices offer additional benefit. There is a lack of studies that evaluate the added benefit of pneumatic compression devices in addition to anticoagulants and a lack of evidence on outpatient compliance. Therefore, outpatient use of limb pneumatic compression devices for VTE prophylaxis after major orthopedic surgery in patients who do not have a contraindication to pharmacologic prophylaxis is considered investigational.

Practice Guidelines and Position Statements

In 2012, the American College of Chest Physicians (ACCP) published updated evidence-based guidelines on prevention of VTE in orthopedic surgery and non-orthopedic surgical patients.

ACCP recommendations on use of limb compression devices in orthopedic surgical patients (3):

- “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).”
- “2.1.2 In patients undergoing hip fracture surgery (HFS), we recommend use of one of the following rather than no antithrombotic prophylaxis for a minimum of 10 to 14 days: LMWH, fondaparinux, LDUH, adjusted-dose VKA, aspirin (all Grade 1B) , or an 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).

POLICY TITLE	OUTPATIENT USE OF LIMB PNEUMATIC COMPRESSION DEVICES FOR VENOUS THROMBOEMBOLISM PROPHYLAXIS
POLICY NUMBER	MP- 6.053

- “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).”

For all of the above recommendations related to pneumatic compression pumps, the ACCP recommended only portable, battery-powered devices be used and stated that efforts should be made to ensure devices are worn for 18 hours per day. The authors noted that compliance is the biggest challenge associated with use of pneumatic compression devices.

ACCP recommendations on use of limb compression devices in non-orthopedic general and abdominal-pelvic surgical patients, stratified by patient risk of VTE and risk of bleeding (5):

Note: A recommended standard duration of prophylaxis was not defined. However, “extended duration” prophylaxis was defined as lasting 4 weeks.

Very low risk patients (<0.5%): “We recommend that no specific pharmacologic (Grade 1B) or mechanical (Grade 2C) prophylaxis be used other than early ambulation.”

Low risk for VTE (about 1.5%): “We suggest mechanical prophylaxis, preferably with intermittent pneumatic compression (IPC), over no prophylaxis (Grade 2C).”

Moderate risk for VTE (about 3%) and not at high risk of bleeding: “We suggest low-molecular-weight heparin (LMWH) (Grade 2B), low-dose unfractionated heparin (LDUH) (Grade 2B), or mechanical prophylaxis, preferably with IPC (Grade 2C), over no prophylaxis.”

Moderate risk for VTE (about 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 (Grade 2C).”

High risk for VTE (about 6.0%) and not at high risk of bleeding: “We recommend pharmacologic prophylaxis with LMWH (Grade 1B) or LDUH (Grade 1B) over no prophylaxis. We suggest that mechanical prophylaxis with elastic stockings (ES) or IPC should be added to pharmacologic prophylaxis (Grade 2C).”

High risk for VTE (about 6.0%) and high risk for major bleeding complications or in whom bleeding consequences would be particularly severe: “We suggest use of mechanical prophylaxis, preferably with IPC, over no prophylaxis until the risk of bleeding diminishes and pharmacologic prophylaxis may be initiated (Grade 2C).”

High-risk for VTE, both LMWH and unfractionated heparin contraindicated or unavailable and not at high risk for major bleeding complications: “We suggest low-dose aspirin (Grade 2C), fondaparinux (Grade 2C), or mechanical prophylaxis, preferably with IPC (Grade 2C), over no prophylaxis.”

High-risk for VTE, undergoing abdominal or pelvic surgery for cancer and not otherwise at high risk for major bleeding complications: “We recommend extended duration pharmacologic prophylaxis (4 weeks) with LMWH over limited-duration prophylaxis (Grade 1B).”

In 2011, the American Academy of Orthopaedic Surgeons (AAOS) published an updated guideline on prevention of venous thromboembolism in patients undergoing elective hip and

POLICY TITLE	OUTPATIENT USE OF LIMB PNEUMATIC COMPRESSION DEVICES FOR VENOUS THROMBOEMBOLISM PROPHYLAXIS
POLICY NUMBER	MP- 6.053

knee arthroplasty. (6) The guideline included the following recommendations relevant to this policy:

- “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)
- 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)
- 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)”

In 2007, the American College of Obstetricians-Gynecologists (ACOG) published a practice bulletin on prevention of DVT and PE after gynecologic surgery. (2) As with the ACCP recommendations, described above, prophylaxis recommendations varied according to patient risk level. For patients at moderate and high risk of DVT, intermittent pneumatic compression was one of the recommended options for DVT prophylaxis. For patients at highest risk i.e., older than 60 years plus prior VTE, cancer or molecular hypercoaguable state, IPC or graduated compression stockings plus LDUH or LMWH was recommended as a prophylaxis option. 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 document stated that continuing prophylaxis for 2-4 weeks after discharge should be considered.

V. DEFINITIONS

NA

POLICY TITLE	OUTPATIENT USE OF LIMB PNEUMATIC COMPRESSION DEVICES FOR VENOUS THROMBOEMBOLISM PROPHYLAXIS
POLICY NUMBER	MP- 6.053

VI. BENEFIT VARIATIONS

The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital for benefit information.

VII. DISCLAIMER

Capital's 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. Capital considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. REFERENCES

1. Fisher WD. *Impact of venous thromboembolism on clinical management and therapy after hip and knee arthroplasty. Can J Surg* 2011; 54(5):344-51.
2. *Committee on Practice Bulletins--Gynecology ACoO, Gynecologists. ACOG Practice Bulletin No. 84: Prevention of deep vein thrombosis and pulmonary embolism. Obstet Gynecol* 2007; 110(2 Pt 1):429-40.
3. 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* 2012; 141(2 Suppl):e278S-325S.
4. Froimson MI, Murray TG, Fazekas AF. *Venous thromboembolic disease reduction with a portable pneumatic compression device. J Arthroplasty* 2009; 24(2):310-6.

POLICY TITLE	OUTPATIENT USE OF LIMB PNEUMATIC COMPRESSION DEVICES FOR VENOUS THROMBOEMBOLISM PROPHYLAXIS
POLICY NUMBER	MP- 6.053

5. 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* 2012; 141(2 Suppl):e227S-77S.
6. American Academy of Orthopaedic Surgeons (AAOS). Preventing venous thromboembolic disease in patients undergoing elective hip and knee arthroplasty. [Website]: <http://www.guideline.gov/>. Accessed July 3, 2013.
7. Kakkos SK, Warwick D, Nicolaidis AN et al. Combined (mechanical and pharmacological) modalities for the prevention of venous thromboembolism in joint replacement surgery. *J Bone Joint Surg Br* 2012; 94(6):729-34.
8. Giannoni MF, Ciatti R, Capoccia L et al. Total knee replacement: prevention of deep-vein thrombosis using pharmacological (low-molecular-weight heparin) and mechanical (intermittent foot sole pump system) combined prophylaxis. Preliminary results. *Int Angiol* 2006; 25(3):316-21.
9. Colwell CW, Jr., Froimson MI, Mont MA et al. Thrombosis prevention after total hip arthroplasty: a prospective, randomized trial comparing a mobile compression device with low-molecular-weight heparin. *J Bone Joint Surg Am* 2010; 92(3):527-35.
10. Hardwick ME, Pulido PA, Colwell CW, Jr. A mobile compression device compared with low-molecular-weight heparin for prevention of venous thromboembolism in total hip arthroplasty. *Orthop Nurs* 2011; 30(5):312-6.
11. Kakkos SK, Caprini JA, Geroulakos G et al. Combined intermittent pneumatic leg compression and pharmacological prophylaxis for prevention of venous thromboembolism in high-risk patients. *Cochrane Database Syst Rev* 2008; (4):CD005258.
12. Rahn DD, Mamik MM, Sanses TV et al. Venous thromboembolism prophylaxis in gynecologic surgery: a systematic review. *Obstet Gynecol* 2011; 118(5):1111-25.
13. 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* 2012; 10(2):229-35.
14. Other sources Durable Medical Equipment Regional Carrier (DME MAC A) Region A Local Coverage Determination (LCD) (L11503) Pneumatic Compression Devices. Effective 01/01/2013 [Website]: http://www.medicarenhic.com/dme/medical_review/mr_lcds/mr_lcd_current/L11503_2013-01-01_PA_2013-04.pdf
Accessed December 19, 2013.

POLICY TITLE	OUTPATIENT USE OF LIMB PNEUMATIC COMPRESSION DEVICES FOR VENOUS THROMBOEMBOLISM PROPHYLAXIS
POLICY NUMBER	MP- 6.053

IX. CODING INFORMATION

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:

CPT Codes®								

Current Procedural Terminology (CPT) copyrighted by American Medical Association. All Rights Reserved.

Investigational, therefore not covered:

CPT Codes®								

Current Procedural Terminology (CPT) copyrighted by American Medical Association. All Rights Reserved

Covered when medically necessary:

HCPCS Code	Description
E0650- E0673	Pneumatic compression device code range
E0676	Intermittent limb compression device (includes all accessories), not otherwise specified

ICD-9-CM Diagnosis Code*	Description
714.0- 714.9	Rheumatoid arthritis and other inflammatory polyarthropathies code range
715.00- 715.98	Osteoarthritis code range (fifth digit 5 would be used for hip and fifth digit 6 would be used for knee)
716.15	Traumatic arthropathy hip
716.16	Traumatic arthropathy knee
733.14	Pathologic fracture of neck of femur
820.00- 820.9	Fracture of neck of femur code range

MEDICAL POLICY

POLICY TITLE	OUTPATIENT USE OF LIMB PNEUMATIC COMPRESSION DEVICES FOR VENOUS THROMBOEMBOLISM PROPHYLAXIS
POLICY NUMBER	MP- 6.053

ICD-9-CM Diagnosis Code*	Description
821.00-821.11	Fracture of shaft of femur code range
V43.64-V43.65	Organ or tissue replaced by other means, joint (hip and knee codes respectively)
V54.81	Aftercare following joint replacement

*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.

The following ICD-10 diagnosis codes will be effective October 1, 2014:

ICD-10-CM Diagnosis Code*	Description
M05.051-M05.059; M05.061-M05.069	Felty's syndrome, hip and knee code ranges
M05.151-M05.159; M05.161-M05.169	Rheumatoid lung disease with rheumatoid arthritis, hip and knee code ranges
M05.251-M05.259; M05.261-M05.269	Rheumatoid vasculitis with rheumatoid arthritis, hip and knee code ranges
M05.351-M05.359; M05.361-M05.369	Rheumatoid heart disease with rheumatoid arthritis, hip and knee code ranges
M05.451-M05.459; M05.461-M05.469	Rheumatoid arthritis with involvement of other organs and systems, hip and knee code ranges
M05.751-M05.759; M05.761-M05.769	Rheumatoid arthritis with rheumatoid factor without organ or systems involvement, hip and knee code ranges

MEDICAL POLICY

POLICY TITLE	OUTPATIENT USE OF LIMB PNEUMATIC COMPRESSION DEVICES FOR VENOUS THROMBOEMBOLISM PROPHYLAXIS
POLICY NUMBER	MP- 6.053

ICD-10-CM Diagnosis Code*	Description
M05.851- M05.859; M05.861- M05.869	Other rheumatoid arthritis with rheumatoid factor, hip and knee code ranges
M06.051- M06.059; M06.061- M06.069	Rheumatoid arthritis without rheumatoid factor, hip and knee code ranges
M06.851- M06.859; M06.861- M06.869	Other specified rheumatoid arthritis, hip and knee code ranges
M08.051- M08.059; M08.061- M08.069	Unspecified juvenile rheumatoid arthritis, hip and knee code ranges
M08.251- M08.259; M08.261- M08.269	Juvenile rheumatoid arthritis with systemic onset, hip and knee code ranges
M08.451- M08.459; M08.461- M08.469	Pauciarticular juvenile rheumatoid arthritis, hip and knee code ranges
M08.851- M08.859; M08.861- M08.869	Other juvenile arthritis, hip and knee code ranges
M08.951- M08.959; M08.961- M08.969	Juvenile arthritis, unspecified, hip and knee code ranges
M12.551- M12.559; M12.561- M12.569	Traumatic arthropathy, hip and knee code ranges
M15.0- M15.9	Polyosteoarthritis code range

MEDICAL POLICY

POLICY TITLE	OUTPATIENT USE OF LIMB PNEUMATIC COMPRESSION DEVICES FOR VENOUS THROMBOEMBOLISM PROPHYLAXIS
POLICY NUMBER	MP- 6.053

ICD-10-CM Diagnosis Code*	Description
M16.0- M16.9	Osteoarthritis of hip code range
M17.0- M17.9	Osteoarthritis of knee code range
M80.051- M80.059	Age-related osteoporosis with current pathological fracture, femur code range
M80.851- M80.859	Other osteoporosis with current pathological fracture, femur code range
M84.451- M84.453; M84.459	Pathological fracture, femur and hip unspecified code range
M84.550- M84.553; M84.559	Pathological fracture in neoplastic disease, femur and hip unspecified code range
M84.650- M84.653; M84.659	Pathological fracture in other disease, femur and hip unspecified code range
S72.001A- S72.399S	Fracture of head and neck of femur code range

*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.

X. POLICY HISTORY

MP 6.053	CAC 9/24/13 New policy partially adopting BCBSA with addition of coverage criteria for after non-major orthopedic surgery of the lower extremity. Previously silent regarding use of compression pumps for thromboembolism prophylaxis. Now considered medically necessary with criteria.
-----------------	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

Health care benefit programs issued or administered by Capital BlueCross and/or its subsidiaries, Capital Advantage Insurance Company®, Capital Advantage Assurance Company® and Keystone Health Plan® Central. Independent licensees of the BlueCross BlueShield Association. Communications issued by Capital BlueCross in its capacity as administrator of programs and provider relations for all companies.