APPENDIX to Postsurgical Outpatient Use of Limb Compression Devices for Venous Thromboembolism Prophylaxis Policy

Prior Authorization Requirements

This service (or procedure) is considered **medically necessary** in certain instances and **investigational** in others (refer to policy for details).

For instances when the indication is **medically necessary**, clinical evidence is required to determine **medical necessity**.

For instances when the indication is **investigational**, you may submit additional information to the Prior Authorization Department.

Within five days before the actual date of service, the Provider MUST confirm with Blue Shield of California / Blue Shield of California Life & Health Insurance Company (Blue Shield) that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal www.blueshieldca.com/provider.

Evidence Basis for the Policy

Rationale

Patients undergoing major surgery are at increased risk of developing 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 deep vein thrombosis (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. Though frequently asymptomatic and generally resolve when mobility is restored, some episodes of acute DVT can be associated with substantial morbidity and mortality. The most serious adverse consequence of an acute DVT is a pulmonary embolism (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 PE is approximately 1-

28% (Fisher, 2011). Other surgical patients may also be at increased risk of VTE during and after hospitalization. For example, it is estimated that rates of VTE without prophylaxis after gynecologic surgery is about 15-40% (American College of Obstetricians and Gynecologists [ACOG], 2007).

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 (Falck-Ytter et al., 2012). The guidelines further recommend the use of pharmacologic prophylaxis during hospitalization, whether or not patients are using a pneumatic compression device.

A minimum of 10 to 14 days of prophylaxis is recommended, a portion of which can be postdischarge outpatient use.

The ACCP guidelines noted that compliance is a major issue with limb 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 published by Froimson et al. 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.

The ACCP also issued guidelines on VTE prophylaxis in non-orthopedic surgery patients (Gould et al., 2012). 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 recommend 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 limb compression devices in the outpatient setting. However, especially with the availability of portable, battery-operated devices, there is interest in use of outpatient limb compression devices for DVT following discharge from the hospital for major orthopedic and non-orthopedic surgery.

Limb Compression Devices

Multiple pneumatic and peristaltic limb 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 devices that have been cleared by the FDA include:

- Venowave™ VW5 (Saringer Life Science Technologies Inc., Stouffville, Ontario, Canada): The device is a peristaltic pump 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. It is powered using a single NiMH AA battery.

- ActiveCare®+S.F.T. (Synchronized Flow Technology) 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 (Stryker® Sustainability Solutions, Tempe, AZ): This is a lightweight device that utilizes single chamber pressure cuffs attached to the patient's lower legs.
- Kendall SCD™ 700 Sequential Compression System (Covidien, Mansfield, MA): This pneumatic compression device can be used in the clinic or at home. It has a 2-pronged plug and is not battery-operated.

Venous Thromboembolism Prophylaxis in Major Orthopedic Surgery Patients

Patients Without a Contraindication to Prophylaxis With Pharmaceutical Agents

Anticoagulation is the mainstay of DVT prophylaxis after major surgery and is sometimes continued into the outpatient setting. Treatment with limb compression devices may offer additional 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 limb compression device. Key health outcomes include incidence of DVT and PE, as well as measures of functional status and/or quality of life associated with these outcomes.

Randomized Controlled Trials

No RCT with the above design was identified. In 2012, Kakkos et al. 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. The authors identified 4 trials that compared anticoagulation alone to anticoagulation plus use of limb compression devices. Three of the 4 studies used limb compression devices only until discharge from the hospital. In the fourth study, the article did not clearly state that the 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).

A 2013 systematic review and meta-analysis by Sobieraj et al. was similar to the Kakkos et al. (2012) study, described above. It reviewed studies comparing combined pharmacologic and mechanical prophylaxis to either method alone in patients undergoing major orthopedic surgery.

Six RCTs were identified and these studies all focused on inpatient treatment. Most studies evaluated outcomes in the postoperative period. In one study that followed patients for 90 days, intermittent limb compression continued only until hospital discharge.

There are several reasons why the benefit of limb 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 limb 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 et al. in Italy included both inpatient and outpatient DVT prophylaxis with limb compression devices and anticoagulants. The study included 34 patients who underwent total knee replacement (4 patients had bilateral replacements). All patients used a 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 low-molecular-weight-heparin (LMWH), beginning after surgery and continuing until the operated leg was completely weight bearing (15 to 30 days). Ultrasonography detected DVTs in 3 of 34 (8.8%) patients; all were distal DVTs. One symptomatic DVT developed on post-operative day 4, 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 limb 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 a RCT comparing prophylaxis with limb 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 limb compression devices are beneficial in the absence of outpatient anticoagulant use. The study, reported on in 2 publications, one in 2010 by Colwell et al. and the other in 2011 by Hardwick et al., was conducted at multiple centers in the United States and included 395 patients undergoing total hip replacement. 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 LMWH or a mobile limb compression device (ActiveCare+S.F.T.). 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 of hospital stay ranged from 2 days to 10 days; thus, patients had between 0-8 days of outpatient use of their assigned method of prophylaxis. According to ultrasound findings, 8 of 196 (4.1%) in the limb compression group and 8 of 190 (4.2%) in the LMWH group had a DVT. In addition, 2 PEs 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%) patients in the LMWH group had a major bleeding event compared to no patients in the limb 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 limb 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.

Section Summary

There is very little published evidence on the efficacy of outpatient use of limb compression devices for DVT prophylaxis after major orthopedic surgery. There are no RCTs that evaluate outpatient use of limb compression as an adjunct to pharmacologic prophylaxis in patients without a contraindication to anticoagulants. Some RCTs have evaluated the inpatient use of limb 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 compression devices in the outpatient setting. National clinical guidelines support the use of limb compression devices for 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 limb compression devices or LMWH provides some evidence in support of limb 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.

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 limb 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 (Kakkos et al., 2008)

and the other on VTE prevention after gynecologic surgery (Rahn et al., 2011); neither meta-analysis included RCTs relevant to the research question being considered.

However, a RCT by Sobieraj-Teague et al. (2012) may contribute some relevant data. 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 heparin or LMWH) 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. In the Venowave group, 3 patients (4%) developed VTE and 14 (19%) in the control group developed VTE. 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.

Section Summary

There is very little published evidence on the efficacy of outpatient use of limb compression devices for DVT prophylaxis after major non-orthopedic surgery. There are no RCTs that evaluate outpatient use of limb 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 compression devices in the outpatient setting. National clinical guidelines support the use of limb compression devices for DVT prophylaxis after major non-orthopedic surgery in individuals at moderate and high risk of DVT. Moreover, one RCT found significantly fewer VTEs in patients undergoing 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 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 other high-risk surgeries, limb 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 limb compression devices offer additional benefit. There is a lack of studies that evaluate the incremental benefit of limb compression devices in addition to anticoagulants and a lack of evidence on outpatient compliance. Therefore, outpatient use of limb 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.

The ACCP recommendations on use of limb compression devices in orthopedic surgical patients (Falck-Ytter et al., 2012):

- 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).
- 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 limb compression devices.

The 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 (Gould et al., 2012):

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 VTE in patients undergoing elective hip and knee arthroplasty. The guideline included the following recommendations relevant to this policy:

- We suggest 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 and Gynecologists (ACOG) published a practice bulletin on prevention of DVT and PE after gynecologic surgery. 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 hypercoagulable 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.

Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program (FEP)) prohibit Plans from denying Food and Drug Administration (FDA) - approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the

terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

Type	Number	Description
CPT	None	
HCPC	E0676	Intermittent limb compression device (includes all accessories), not otherwise specified
ICD9 Procedure	None	
ICD9 Diagnosis	All Diagnoses	
Place of Service	All Places of Service	

Tables

N/A

Definitions

American College of Chest Physicians (ACCP) Grading Recommendations: Retrieved from http://journal.publications.chestnet.org/article.aspx?articleid=1084215.

(Guyatt et al., 2006)

Grade of Recommendations	Benefit vs Risk and Burdens	Methodological Quality of Supporting Evidence	Implications
1A: Strong recommendation, high-quality evidence	Benefits clearly outweigh risk and burdens, or vice versa	RCTs without important limitations or overwhelming evidence from observational studies	Strong recommendation, can apply to most patients in most circumstances without reservation
1B: Strong recommendation, moderate quality evidence	Benefits clearly outweigh risk and burdens, or vice versa	RCTs with important limitations (inconsistent results, methodological flaws, indirect, or	Strong recommendation, can apply to most patients in most circumstances

		imprecise) or exceptionally strong evidence from observational studies	without reservation
1C: Strong recommendation, low-quality or very low-quality evidence	Benefits clearly outweigh risk and burdens, or vice versa	Observational studies or case series	Strong recommendation but may change when higher quality evidence becomes available
2A: Weak recommendation, high-quality evidence	Benefits closely balanced with risks and burden	RCTs without important limitations or overwhelming evidence from observational studies	Weak recommendation, best action may differ depending on circumstances or patients' or societal values
2B: Weak recommendation, moderate-quality evidence	Benefits closely balanced with risks and burden	RCTs with important limitations (inconsistent results, methodological flaws, indirect, or imprecise) or exceptionally strong evidence from observational studies	Weak recommendation, best action may differ depending on circumstances or patients' or societal values
2C: Weak recommendation, low-quality or very low-quality evidence	Uncertainty in the estimates of benefits, risks, and burden; benefits, risk, and burden may be closely balanced	Observational studies or case series	Very weak recommendations; other alternatives may be equally reasonable

American Academy of Orthopaedic Surgeons (AAOS) Recommendations:

- **Consensus -** Expert opinion supports the guideline recommendation even though there is no available empirical evidence that meets the inclusion criteria of the guideline's systematic review.
  - Implications: Practitioners should be flexible in deciding whether to follow a recommendation classified as Consensus, although they may give it preference over alternatives. Patient preference should have a substantial influencing role.
- **Inconclusive -** There is a lack of compelling evidence that has resulted in an unclear balance between benefits and potential harm.
  - Implications: Practitioners should feel little constraint in following a recommendation labeled as Inconclusive; exercise clinical judgment, and be alert for emerging evidence that clarifies or helps to determine the balance between benefits and potential harm. Patient preference should have a substantial influencing role.
- **Moderate -** The benefits exceed the potential harm (or that the potential harm exceeds the benefits in the case of a negative recommendation), but the quality/applicability of the supporting evidence is not as strong.
  - Implications: Practitioners should generally follow a Moderate recommendation but remain alert to new information and be sensitive to patient preferences.

Index / Cross Reference of Related BSC Medical Policies

The following Medical Policies share diagnoses and/or are equivalent BSC Medical Policies:

- Compression Therapy for Lymphedema and Venous Stasis Ulcers

Key / Related Searchable Words

- ActiveCare+SFT
- Compression pumps
- Deep vein thrombosis
- DVT
- PE
- Pneumatic compression devices
- Pneumatic compression pumps
- Pulmonary embolism
- Restep DVT System
- Venous thromboembolism
- Venowave VW5
- VTE
- VTE prophylaxis

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Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action	Reason
9/27/2013	BCBSA Medical Policy adoption	Medical Policy Committee
7/14/2014	Policy title change from Outpatient Use of Limb Pneumatic Compression Devices for Venous Thromboembolism Prophylaxis Policy revision with position change	Medical Policy Committee

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.

Click here to view the policy statement for this policy

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