Anthem

Clinical UM Guideline

Subject: Pneumatic Compression Devices for Prevention of Deep Vein Thrombosis of the Extremities in the Home Setting
Guideline #: CG-DME-46 **Publish Date:** 06/28/2023
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Description

This document addresses the use of pneumatic compression devices for the prevention of deep vein thrombosis (DVT) of the extremities in the home setting. This therapy involves the use of an inflatable garment and an electrical pneumatic pump. The garment is intermittently inflated and deflated with cycle times and pressures that vary between devices. Pneumatic compression devices can be purchased or rented for home use for prevention and treatment of a number of conditions.

Note: This document addresses devices for the prevention of DVT only. Pneumatic devices used in the treatment or prevention of lymphedema, venous insufficiency, and therapy for musculoskeletal injuries are NOT addressed in this document. This document also does not address pneumatic compression devices with combined cooling or heating functions. For more information regarding such devices, please see the following related documents:

- CG-DME-06 Compression Devices for Lymphedema
- DME.00037 Cooling Devices and Combined Cooling/Heating Devices

Clinical Indications

Not Medically Necessary:

The use of pneumatic compression devices in the home setting for prevention of venous thromboembolism of the extremities is considered **not medically necessary** for all indications.

Coding

The following codes for treatments and procedures applicable to this guideline are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. 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.

When services are Not Medically Necessary:
For the following procedure codes when devices are used in the home for prophylaxis for DVT of the extremities

HCPCS	
A4600	Sleeve for intermittent limb compression device, replacement only, each
E0650	Pneumatic compressor, non-segmental home model
E0651	Pneumatic compressor, segmental home model without calibrated gradient pressure
E0652	Pneumatic compressor, segmental home model with calibrated gradient pressure
E0655	Non-segmental pneumatic appliance for use with pneumatic compressor, half arm
E0660	Non-segmental pneumatic appliance for use with pneumatic compressor, full leg
E0665	Non-segmental pneumatic appliance for use with pneumatic compressor, full arm
E0666	Non-segmental pneumatic appliance for use with pneumatic compressor, half leg
E0667	Segmental pneumatic appliance for use with pneumatic compressor, full leg
E0668	Segmental pneumatic appliance for use with pneumatic compressor, full arm
E0669	Segmental pneumatic appliance for use with pneumatic compressor, half leg
E0670	Segmental pneumatic appliance for use with pneumatic compressor, integrated, 2 full legs and trunk
E0671	Segmental gradient pressure pneumatic appliance, full leg
E0672	Segmental gradient pressure pneumatic appliance, full arm
E0673	Segmental gradient pressure pneumatic appliance, half leg
E0676	Intermittent limb compression device (includes all accessories), not otherwise specified

ICD-10 Diagnosis	
	All diagnoses

Discussion/General Information

The formation of blood clots in veins and arteries, also known as thrombosis, may be caused by injury to a blood vessel, abnormal blood flow or blood that clots more readily than normal as a result of a medical or genetic condition. The most common site of formation for a blood clot (thrombus, plural thrombi) is in the legs, but they may also form in the veins of the arms, the right side of the heart, at the tip of a catheter placed in a vein, or other locations. Blood clots that start in a vein (venous thrombi) pose a significant threat to an individual's health when they detach from their place of origin. This condition is referred to as venous thromboembolism (VTE). Thromboemboli can migrate through the blood vessels and block the flow of blood to vital organs such as the lungs, brain, and heart.

The large, deep veins of the thigh and calf are a major area of thrombus formation and thrombi that originate there are referred to as deep venous thrombosis (DVT); however, DVTs may occur in any of the deep veins of the body. DVTs most frequently form in individuals with limited mobility, those with abnormal blood flow in their legs, or those with abnormal blood clotting physiology. Other risk factors include childbirth within the last 6 months, the use of medications such as estrogen and birth control pills, a history of certain hematologic diseases, or the presence of a malignant tumor. There are numerous other risks, including genetic, environmental, lifestyle and chronic disease factors.

Prevention and treatment of DVT is achieved mainly through the use of drugs that affect clot formation or clot dissolution (e.g., aspirin,

heparin, warfarin, dabigatran, etc.). Mechanical devices also play an important role in the prevention of blood clots. Pneumatic compression devices are approved under the U.S. Food and Drug Administration's (FDA's) 510(k) process for the prevention of DVT. They are classified as Class II devices, cardiovascular therapeutic devices, and compressible limb sleeves. Pneumatic compression devices are used to simulate muscle action in the extremities of individuals with reduced mobility to encourage blood circulation with the goal of preventing formation of a thrombus. These devices involve the use of a sleeve or wrap that contains one or more inflatable air chambers. Attached to the garment is a control unit that controls the flow of compressed air into the air chamber. During use, the air chambers inflate in a distal to proximal fashion and squeeze the body to encourage blood to flow back to the heart. Some devices come with programmable control units. The control units allow variation in the duration and frequency of the inflation cycles as well as the degree of compression in individual air chambers in the garment.

While there is an established body of published evidence on the use of pneumatic compression devices to prevent DVT in the hospital-setting, their efficacy in the home setting has not been well studied. Findings from an observational study conducted by Martin-Ferrero (2014) suggests that this may, in part, be due to the low risk of DVT in the outpatient setting. In the study, 10,032 individuals who underwent outpatient orthopedic surgical procedures between June 1993 and June 2012 were enrolled and evaluated both pre- and post-operatively (48 hours, 7 days, and 28 days post-op) using a quality-of-life assessment (SF-36) and other quality indicators for orthopedic procedures. Participants' preoperative risk was evaluated according to the American Society of Anesthesiologists' (ASA) criteria (ASA, 2020). Individuals were considered eligible for enrollment if their ASA status was either a I or II or a well-controlled status of III or IV. The major complication rate was minimal and none of the individuals enrolled in the study reported complications of a DVT at 28 days post-procedure. This study was not designed to detect DVT, therefore asymptomatic DVTs would have remained undetected in this population and DVTs have reportedly occurred months following procedures. Therefore, the occurrence of a DVT in study enrollees post study-end cannot be ruled out. Nonetheless, in this very large, observational cohort of individuals following outpatient orthopedic surgery, none developed symptomatic DVT by 28 days post-procedure. There is also evidence from a systematic review and clinical trials evaluating pharmaceutical prophylaxis of DVT after outpatient orthopedic procedures showing that even in the control populations (no intervention), the incidence of DVT was so low that pharmaceutical prophylactic intervention was deemed unwarranted (Huang, 2018; Kaye, 2013; Mathews, 2018).

In 2013, Mauck and colleagues published results of a population-based, retrospective cohort study whose aim was to estimate the incidence of symptomatic VTE after arthroscopic knee surgery. A total of 4833 individuals were followed for up to 3 months post-procedure. Within 6 weeks, a total of 18 individuals (0.4%) developed VTE; no VTE was reported between 6 weeks to 3 months after knee arthroscopy. Of the 18 VTEs, 2 were in individuals taking oral contraceptives at the time of arthroscopy, 1 was pregnant (third trimester), 2 had known or suspected joint infections, and 3 had recently suffered a trauma. The type of VTEs that occurred were: 1 pulmonary embolism (PE); 1 PE and DVT; and 16 DVTs alone. At the time the VTEs were diagnosed, 3 of the 18 individuals were hospitalized (4, 8, and 38 days post-knee arthroscopy), 6 had been hospitalized in the 3 months prior to the VTE but were out-patients at the time the VTE was diagnosed, and the remaining 9 had no hospitalization in the preceding 3 months prior to VTE. Overall, the incidence of symptomatic VTE after knee arthroscopy at 6 weeks post-op in this large, population-based sample was 0.4%. While data on the proportion of study enrollees that had outpatient procedures versus inpatient procedures is not reported, arthroscopic knee surgery is most often performed in the outpatient setting. Authors concluded, "We believe our findings support the ACCP [American College of Chest Physicians] recommendations for no routine pharmacologic or mechanical VTE prophylaxis in this patient population."

A large, retrospective study was published with the primary aim of characterizing the incidence of symptomatic VTE after arthroscopic knee surgery (Maletis, 2012). In total, 20,770 eligible participants who had no documented history of a VTE and underwent elective knee arthroscopy, without prophylaxis for VTE, were enrolled in the study. Data was extracted from medical chart review up to 90-days post-op for evaluation of VTE occurrence. Overall, the incidence of symptomatic VTE after knee arthroscopy was 0.25% for DVT and 0.17% for PE.

A prospective study published by Mohtadi and colleagues in 2016 sought to determine the rate of DVT after outpatient arthroscopic hip surgery in low-risk individuals who did not receive prophylactic intervention for DVT. Of 120 consented participants, 115 were available for analysis at 10-22 days post-op and again at 3 months. Overall, 5 DVTs were detected (4 symptomatic and 1 asymptomatic) resulting in an incidence of 4.3% (the majority were distal). While arthroscopic hip surgery is widely accepted as a higher risk procedure than arthroscopic knee surgery, authors similarly conclude, "This study provides supportive evidence that routine prophylaxis and/or screening may not be necessary in low risk patients undergoing elective hip arthroscopy." A very similar trial evaluated the rate of VTE post arthroscopic hip surgery in low-risk individuals without prophylactic intervention (Alaia, 2014). Out of 139 enrolled participants only 2 events were reported (1 symptomatic DVT and 1 PE) for an overall VTE incidence of 1.4%. No cases of asymptomatic VTE were detected via bilateral venous duplex ultrasound at 2 weeks (study-end). This study's follow-up was relatively short, so incidence of VTE after the 2-week endpoint cannot be ruled out. Data regarding outpatient versus inpatient surgery was not reported. The existing body of literature shows that the incidence of VTE postoperative outpatient procedures is low, even following arthroscopic hip surgery which is generally considered higher risk for a thrombotic event amongst outpatient surgical procedures.

In 2008, a Cochrane Review evaluated interventions for prevention of VTE in adults undergoing knee arthroscopy (Ramos, 2008). The background of the systematic review stated,

> Surgeons generally agree that thromboprophylaxis should be used in moderate and high risk patients who undergo surgery. Graduated elastic stockings and intermittent pneumatic compression are mechanical devices used to prevent DVT, the latter often used in patients immobilized in bed. There are different opinions about whether or not prophylaxis should be used in knee arthroscopy, partly reflecting different perceptions of the underlying risk of DVT.

Selection criteria included randomized clinical trials (RCTs) and controlled clinical trials. Interventions included mechanical or pharmacological approaches, alone or in combination, used to prevent DVT in adults undergoing knee arthroscopy. In total, only four trials involving 527 predominantly male participants were included in the final analysis. The review concluded the following:

> Although this review suggests that some benefit may be obtained from prophylaxis, we considered only two studies to be of adequate methodological quality with small sample size, and poorly defined or stratified in their arthroscopic intervention. No studies on mechanical devices alone were found, other than the ongoing combined protocol. No strong evidence was found to conclude thromboprophylaxis is effective in preventing thromboembolic events in people undergoing knee arthroscopy with unknown risk factors for DVT.

A 2016 Cochrane Review assessed studies on combined intermittent pneumatic leg compression and pharmacological prophylaxis for the prevention of VTE (Kakkos et al, 2016). The results of the review demonstrated agreement with current guideline recommendations, which support the use of combined modalities in hospitalized individuals (limited to those with trauma or undergoing surgery) at risk of developing VTE. Neither the Cochrane Review nor the published guidelines it references address uses of pneumatic compression devices in the outpatient setting or following ambulatory surgical procedures.

An ACCP Evidence-Based Clinical Practice Guidelines entitled Prevention of VTE in Orthopedic Surgery Patients: Antithrombotic

Therapy and Prevention of Thrombosis (2012), gives the following recommendations for use of pneumatic compression devices after major orthopedic surgery:

> In summary, use of an IPCD [intermittent pneumatic compression device] for thromboprophylaxis is attractive because of its possible effectiveness and likelihood of no increase in bleeding events. However, suboptimal compliance with the use of an IPCD while in the hospital and the inability to continue this treatment at home for most patients may limit their use. Newer battery-powered IPCDs that monitor compliance might be successfully used after discharge.

The ACCP's recommendations regarding knee arthroscopy state the following: "For patients undergoing knee arthroscopy without a history of VTE, we suggest no thromboprophylaxis" (neither pharmaceutical nor mechanical). The ACCP proposes this as a Grade 2B 'Weak' recommendation with 'moderate-quality' evidence. The guidelines offer the following recommendations for future clinical trial research:

> Large, practical, RCTs are needed to further study thromboprophylaxis after orthopedic surgeries. Those trials should avoid screening for asymptomatic VTE and ensure that symptomatic VTE is recorded up to 3 months after surgery, regardless of duration of intervention…At a minimum, trials that use mechanical devices for thromboprophylaxis should be able to accurately record and report proper use and daily and cumulative wear time to document compliance.

Evidence-based guidelines published in 2011 from the American Academy of Orthopedic Surgeons (AAOS) entitled,'Preventing venous thromboembolic disease in patients undergoing elective hip and knee arthroplasty,' state the following:

> Current evidence is unclear about which prophylactic strategy (or strategies) is/are optimal or suboptimal. Therefore, we are unable to recommend for or against specific prophylactics in these patients.
>
> There is moderate evidence to suggest that pharmacological agents and/or mechanical compression devices reduce DVT rates in patients undergoing elective knee or hip arthroplasty. This is why we are suggesting prophylaxis. Readers of this guideline should recognize, however, that the available, published evidence does not establish whether these prophylactic strategies affect rates of all-cause mortality, fatal PE, symptomatic PE, or symptomatic DVT in patients undergoing elective hip or knee arthroplasty.
>
> Grade of Recommendation: Inconclusive Description: Evidence from a single low quality study or conflicting findings that do not allow a recommendation for or against the intervention. An Inconclusive recommendation means that there is a lack of compelling evidence resulting in an unclear balance between benefits and potential harm.

In a systematic review published in 2012 Craigie and colleagues evaluated compliance with the use of compression devices. MEDLINE was searched from January 1, 2000 through May 21, 2015 for English-language observational studies that assessed adherence to mechanical prevention of VTE following surgical procedures. Amongst inpatient hospitals stays, the study concluded that up to one-fourth of individuals were non-adherent. While no studies were identified that followed individuals post-discharge, it is unlikely adherence levels would be improved in the outpatient setting as the ACCP guidelines suggest.

In a large retrospective analysis of Medicare claims, 2,509,530 lower extremity and 130,258 upper extremity arthroplasty procedures performed in the hospital setting were analyzed for occurrence of VTE. VTE complications occurred in 30,227 (1.2%) lower extremity arthroplasties and 695 (0.53%) upper extremity arthroplasties. Individuals with a primary diagnosis of fracture, history of VTE and comorbidities, were significantly more likely to report occurrence of VTE. This data demonstrates that even amongst aged, hospital-admitted (2-5 day average stay) individuals with significant risk-factors for VTE, the incidence of VTE in upper and lower extremities is rare (Day, 2015). To date, there is no published evidence demonstrating the efficacy of pneumatic compression devices in reducing the incidence of VTE of the upper extremities.

In another large retrospective analysis, 16,120 individuals who had undergone colorectal surgery were surveyed for thromboprophylaxis use and incidence of VTE. Although, perioperative and in-hospital VTE prophylaxis increased significantly during the study period from 31.6% to 86.4% and from 59.6% to 91.4%, respectively, the incidence of VTE over the study period remained largely unchanged. Although the study only included investigation of chemoprophylaxis, authors note, "…it becomes difficult to argue for more prophylaxis in the discharge setting with the currently available data given similar VTE rates despite increased use of preoperative and in-hospital prophylaxis." Post colorectal surgery, the incidence of VTE is low (Colorectal Writing Group for the Surgical Care and Outcomes Assessment Program [SCOAP], 2015)

In 2019, the American Society of Hematology (ASH) published guideline recommendations on the 'Prevention and Management of Venous Thromboembolism' in "hospitalized and nonhospitalized medical patients, pregnant women, and children." A major recommendation from the guideline states, "In all acutely ill medical patients, venous thromboembolism (VTE) prophylaxis is recommended during hospitalization but not after discharge (strong recommendation; moderate certainty)." The authors state that the recommendation against extending prophylaxis after discharge is, in part, due to the lack of reduction in mortality or symptomatic DVT and only a very small reduction in PE. Although authors are referring to extended use of pharmacoprohylaxis, it is widely known to be more effective than mechanicoprophylaxis (PCD) (Paul, 2019).

In a cross-sectional, descriptive study, 388 individuals post major orthopedic surgery were enrolled and surveyed regarding thromboprophylaxis use post-hospital discharge. A total of 94% of the surveyed population reported being prescribed a pharmacologic agent for thromboprophylaxis at discharge, whereas 56% (n=217) reported mechanical compression therapy for thromboprophylaxis. Of the 217 prescribed mechanical compression, 86.6% were prescribed graded compression stockings (GCS) and 13.4% were prescribed IPC (intermittent pneumatic compression). Of the 14 survey respondents who reported mechanical compression as monotherapy, just 2 individuals were prescribed IPC alone. Of the 122 respondents who reported their compliance to mechanical compression therapy, 18% reported wearing their mechanical compression therapy less than 50% of the time and 63% reported wearing their mechanical compression therapy at least 75% of the time. Authors conclude:

> Because the number of respondents who were using IPC at home was so small, more research on this important aspect of patient safety after orthopedic surgery with a larger sample of respondents using IPC therapy is needed… The results of this study suggest that duration of thromboprophylaxis and rates of IPC therapy use after hospitalization for major orthopedic surgery are suboptimal. (Giuliano, 2019).

A prospective cohort study enrolled and followed 102 individuals post total joint arthroplasty (50 hips and 65 knees) who were prescribed a daily aspirin in conjunction with mobile IPC devices to be worn for 2 weeks postoperatively. Postoperative day 1 recorded the highest compliance at 34.7% (40/102) and by day 14 compliance fell to 14.8% (17/102). Difficulty using the pumps and discomfort related to heat from the pumps were significantly associated with noncompliance, 1 individual developed blistering from the device. During the 90-day follow-up period, 1 DVT and 1 nonfatal PE were confirmed via imaging in 2 separate subjects during

the study period. Authors note that even with poor IPC compliance, the incidence of VTE was low post-total joint arthroplasty (Dietz, 2020).

A very large, retrospective study enrolled 30,824 medically ill individuals in critical care. Authors sought to establish if use of ICDs reduced the incidence of VTE because the vast majority of literature on ICDs focuses only on the post-operative population. Authors found that during the hospital stay of this critically ill population, 67 (0.22%) developed a VTE (55 DVTs and 12 PEs). Risk-adjusted analysis revealed no significant difference in the incidence of VTE in the ICD group (n=20,018) compared to those who wore no ICDs (n=10,819 [p=0.74]. This large cohort study of medically ill individuals, casts further doubt on the efficacy of ICDs for the prevention of a thrombotic event in this population.

In summary, studies have not conclusively shown that home use of pneumatic compression devices reduces the incidence of thromboembolism. The paucity of literature investigating ICD efficacy for indications other than orthopedic procedures, both in and out of the hospital setting, is particularly concerning. A small clinical study sought to measure peak venous flow using four commercially available ICPs compared to manual mechanical compression and found wide variations in the devices' impact on venous flow; this finding warrants further investigation into the variability in efficacy between device-types (Amanatullah, 2020).

Definitions

American Society of Anesthesiology (ASA) Physical Status Classifications:

ASA I A normal healthy patient

ASA II A patient with mild systemic disease

ASA III A patient with severe systemic disease

ASA IV A patient with severe systemic disease that is a constant threat to life

ASA V A moribund patient who is not expected to survive without the operation

ASA VI A declared brain-dead patient whose organs are being removed for donor purposes

Deep vein thrombosis (DVT): A condition where blood clots in the veins located deep in the extremities. The term "DVT" is usually understood to refer to blood clots in the legs unless otherwise specified.

Embolus: Any free mass; either solid, liquid, or gas; carried in the blood circulation, which is capable of clogging arterial capillary beds at a site distant from its point of origin.

Pulmonary embolism (PE): A condition where an embolus lodges in the lungs, preventing blood flow to the pulmonary circulation.

Thrombus: Another name for a blood clot.

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Peer Reviewed Publications:

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Government Agency, Medical Society, and Other Authoritative Publications:

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Websites for Additional Information

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History

Status	Date	Action
Reviewed	05/11/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated References section.
Reviewed	05/12/2022	MPTAC review. Updated References section.
Reviewed	05/13/2021	MPTAC review. Updated Discussion/General Information and References sections. Reformatted Coding section.
Revised	05/14/2020	MPTAC review. Expanded Scope and revised MN statement to include prevention of DVT for all indications in the home setting. Updated Title, Description, Discussion/General Information and References sections.
Revised	08/22/2019	MPTAC review. Updated Title, expanded Scope and revised MN statement to include upper extremities. Updated Discussion/General Information and Reference sections. Updated Coding section; added HCPCS E0655, E0665, E0668, E0672.
New	09/13/2018	MPTAC review. Initial document development.