

# Pneumatic Compression Devices (for Kentucky Only)

Policy Number: CS097KY.06  
Effective Date: June 1, 2023

[Instructions for Use](#)

Table of Contents	Page
<a href="#">Application</a> .....	1
<a href="#">Coverage Rationale</a> .....	1
<a href="#">Applicable Codes</a> .....	1
<a href="#">Description of Services</a> .....	2
<a href="#">Clinical Evidence</a> .....	2
<a href="#">U.S. Food and Drug Administration</a> .....	8
<a href="#">References</a> .....	8
<a href="#">Policy History/Revision Information</a> .....	9
<a href="#">Instructions for Use</a> .....	10

**Related Policy**

- [Durable Medical Equipment, Orthotics, Medical Supplies and Repairs/Replacements \(for Kentucky Only\)](#)

## Application

This Medical Policy only applies to the state of Kentucky.

## Coverage Rationale

Pneumatic compression devices are proven and medically necessary in certain circumstances for the treatment of lymphedema or chronic venous insufficiency with edema and non-healing lower extremity ulcers. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Durable Medical Equipment, Pneumatic and other Powered Compression Devices.

Click [here](#) to view the InterQual® criteria.

Intermittent limb compression devices are proven and medically necessary in an outpatient setting or upon discharge from an inpatient setting for the prevention of deep venous thrombosis (DVT). For medical necessity clinical coverage criteria, refer to the InterQual® CP: Durable Medical Equipment, Pneumatic and other Powered Compression Devices.

Click [here](#) to view the InterQual® criteria.

Advanced intermittent pneumatic compression devices (e.g., Flexitouch) for treating lymphedema of the head, face or neck are considered unproven and not medically necessary.

## Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS Code	Description
A4600	Sleeve for intermittent limb compression device, replacement only, each
E0650	Pneumatic compressor, nonsegmental home model
E0651	Pneumatic compressor, segmental home model without calibrated gradient pressure
E0652	Pneumatic compressor, segmental home model with calibrated gradient pressure
E0655	Nonsegmental pneumatic appliance for use with pneumatic compressor, half arm
E0660	Nonsegmental pneumatic appliance for use with pneumatic compressor, full leg
E0665	Nonsegmental pneumatic appliance for use with pneumatic compressor, full arm
E0666	Nonsegmental 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, two 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
E0675	Pneumatic compression device, high pressure, rapid inflation/deflation cycle, for arterial insufficiency (unilateral or bilateral system)
E0676	Intermittent limb compression device (includes all accessories), not otherwise specified

## Description of Services

Pneumatic compression devices (PCDs) use an air compressor unit that attaches to a garment or series of garments that sequentially inflate and deflate, applying pressure against the skin which results in a treatment effect. PCDs range from traditional single- or multichambered devices with limited adjustability to more complex advanced devices with more garment options and a wide range of treatment selections and programmability to address different clinical needs such as fibrosis, edema to the head, face, neck or trunk, chronic wounds, or localized swelling.

Intermittent pneumatic compression (IPC) includes inflatable sleeves that are wrapped around the legs and secured by Velcro. These sleeves can be applied to the calf or to both the calf and thigh. They are inflated, one side at a time to compress the legs at intervals. Some are inflated sequentially, first distally, then proximally to increase venous flow. IPC is thought to reduce the risk of venous thrombosis by reducing stasis and stimulating the release of intrinsic fibrinolytic factors.

## Clinical Evidence

### Lymphedema of the Head, Face or Neck

There is insufficient evidence in the peer-reviewed medical literature to establish the efficacy, clinical value, or safety of advanced pneumatic compression devices for treating lymphedema of the head, face or neck. Additional research is needed to define the role of advanced pneumatic compression devices in treating lymphedema of the head, face or neck.

Gutierrez et al.(2020), in an observational study, evaluated head and neck cancer (HNC) survivors experience with head and neck lymphedema (HNL) treatment. The authors explored the self-reported outcomes and satisfaction of patients with HNC receiving treatment for HNL with an advanced pneumatic compression device (APCD). The study population included 205 patients with HNC-related HNL. Patients were predominantly male (152, 74%) with a mean age of 60 (range 13-83), the majority having squamous cell carcinoma. Participants were prescribed with an at-home Flexitouch head and neck APCD completed pretreatment and posttreatment self-reported assessments addressing efficacy, function, and symptoms. Pre-post responses for  $\geq 25$  days of use were assessed via the non-parametric Wilcoxon Signed Rank test. Analysis revealed statistically significant improvement in all symptoms and all function items ( $p < 0.00001$ ). Compliance with prescribed therapy (at least 30 minutes daily) was high with 71% of participants reporting daily use and 87% reporting overall satisfaction. Despite the number of

participants included, study limitations included lack of a control group which does not allow for conclusions on efficacy. The authors note that the reported improvements in function and symptoms, and high compliance rate, provide a rationale for a subsequent randomized controlled trial.

Ridner et al.(2021) conducted an open-label, multi-site, stratified randomized, wait list control, pilot study to evaluate the feasibility and efficacy regarding the use of the Flexitouch (FT) or advanced compression device (APCD) in survivors of head and neck cancer (HNC) with lymphedema. Eligible patients had completed treatment for HNC, were disease free, and had lymphedema at enrollment. Participants were randomized to wait-list lymphedema self-management (standard of care) or lymphedema self-management plus the use of the Flexitouch bid. Safety and feasibility were primary endpoints; secondary endpoints included efficacy measure by objective examination and patient reported outcomes (symptoms, quality of life, function), adherence barriers, and satisfaction. Assessments were conducted at baseline and weeks 4 and 8. Forty-nine patients were enrolled (wait-list n = 25; intervention n = 24). In total, forty-three patients completed the study. No device-related serious adverse events were reported. Most patients used the APCD once per day, instead of the prescribed twice per day, mentioning time related factors as barriers to use. APCD use was associated with significant improvement in perceived ability to control lymphedema ( $p = 0.003$ ) and visible external swelling (front view  $p < 0.001$ , right view  $p = 0.004$ , left  $p = 0.005$ ), as well as less reported pain. Feasibility, adherence, and safety of the Flexitouch were the primary outcomes, with efficacy included to generate initial estimates of effect for larger future trials. Given the involvedness and clinical impact of head and neck lymphedema, the feasibility of a more aggressive, twice daily treatment regimen was tested. The adherence to the twice daily regimen was low. This result is expected as patients who were compliant with twice daily treatments had available time to spend up to 1.5 h daily using their device. Time limitations were mostly due to non-adherence. On the other hand, the data demonstrated that a once daily regimen was reasonable. Therefore, future studies should investigate a once daily treatment regimen. This study also noted a decrease in lymphedema symptoms, future studies should explore the underlying mechanism related to this improvement. The authors note that this trial supports the safety and feasibility of the APCD for the treatment of secondary lymphedema in head and neck cancer patients. In addition, initial data supports efficacy. Additional research with larger RCTs is needed to confirm these findings. In particular, the sample size may have been too small to detect important but infrequent adverse events.

Maryovitz et al. (2018) conducted a case series to assess the functional usage of an advanced pneumatic compression device (Flexitouch System) for the treatment of cancer-related head and neck lymphedema as well as identifying potential clinical benefits. The primary purposes of this prospective, functional feasibility study were to assess the ease of application, garment fit and comfort, and treatment comfort of an advanced pneumatic compression system specifically designed to treat patients with head and neck lymphedema. Secondary purposes were to assess safety and acute edema changes after a single treatment. Patient-reported comfort and other treatment aspects were evaluated, and multiple face and neck measurements were obtained on 44 patients with head and neck lymphedema before and after 1 treatment session to assess usability and treatment-related lymphedema changes. The majority of patients (82%) reported the treatment was comfortable; most patients (61%) reported feeling better after treatment, and 93% reported that they would be likely to use this therapy at home. One treatment produced overall small but highly statistically significant reductions in composite metrics (mean  $\pm$ SD) of the face ( $82.5 \pm 4.3$  cm vs  $80.9 \pm 4.1$  cm;  $p < .001$ ) and neck ( $120.4 \pm 12.2$  cm vs  $119.2 \pm 12.1$  cm;  $p < .001$ ) with no adverse events. The authors indicated that results found the treatment to be safe, easy to use, and well tolerated while demonstrating edema reduction after a single initial treatment. Larger more robust studies are needed to validate these preliminary findings, as his study was limited by short follow-up and lack of comparison group.

## Prevention of Deep Venous Thrombosis (DVT)

Arabi et al. (2019) conducted a multi-site randomized controlled trial that evaluated whether adjunctive intermittent pneumatic compression in critically ill patients receiving pharmacologic thromboprophylaxis with unfractionated heparin or low-molecular-weight heparin would result in a lower incidence of proximal lower-limb deep-vein thrombosis than pharmacologic thromboprophylaxis alone. Patients who were considered adults according to the local standards at the participating sites ( $\geq 14$ ,  $\geq 16$ , or  $\geq 18$  years of age), were randomly assigned within 48 hours after admission to an intensive care unit (ICU) to receive either intermittent pneumatic compression for at least 18 hours each day in addition to pharmacologic thromboprophylaxis with unfractionated or low-molecular-weight heparin (pneumatic compression group) or pharmacologic thromboprophylaxis alone (control group). The primary outcome was an episode of proximal lower-limb deep-vein thrombosis, as detected on twice-weekly lower-limb ultrasound after the third calendar day since randomization until ICU discharge, death, achievement of full mobility, or trial day 28, whichever occurred first. There was a total of 2003 patients underwent randomization, 991 were assigned to the pneumatic compression group and 1012 to the control group. Intermittent pneumatic compression was applied for a median of 22 hours daily for a median of 7 days. The primary outcome occurred in 37 of 957 patients (3.9%) in the

pneumatic compression group and in 41 of 985 patients (4.2%) in the control group (relative risk, 0.93; 95% confidence interval [CI], 0.60 to 1.44;  $p = 0.74$ ). Venous thromboembolism (pulmonary embolism or any lower-limb deep-vein thrombosis) occurred in 103 of 991 patients (10.4%) in the pneumatic compression group and in 95 of 1012 patients (9.4%) in the control group (relative risk, 1.11; 95% CI, 0.85 to 1.44), and death from any cause at 90 days occurred in 258 of 990 patients (26.1%) and 270 of 1011 patients (26.7%), respectively (relative risk, 0.98; 95% CI, 0.84 to 1.13). Authors found no benefit with the use of adjunctive pneumatic compression in the prevention of DVT in critically ill patients receiving pharmacologic prophylaxis.

Zhang et al. (2018) in a systematic review and meta-analysis examined the effect of intermittent pneumatic compression (IPC) on the risk of DVT's, PE and mortality compared with no IPC prophylaxis after a stroke. Databases were searched including Medline, EMBASE, Cochrane Library, Wanfang, CNKI, and CBM, from inception to June 2, 2017. Randomized controlled trials comparing IPC with no IPC in patients with stroke were included. The rates of PE, DVT, and mortality were compared. The results were pooled using a fixed effects model to evaluate the differences between the IPC and control groups. If there was significant heterogeneity in the pooled result, a random effect model was used. There were seven randomized controlled trials identified that included 3,551 participants. Overall, IPC significantly reduced the incidence of DVT (risk ratio [RR] = 0.50; 95% confidence interval [CI] 0.27, 0.94). These findings were similar among subgroup of participants for whom IPC was started more than 72 hours after the stroke and for those who did not receive pharmacological anticoagulation. However, IPC increased IPC-related adverse events (RR = 5.71; 95% CI [3.40, 9.58]). Though IPC was associated with a significant increase in survival by 4.5 days during 6 months of follow-up (148-152 days; 95% CI [-0.2, 9.1]), there was a mean gain of only 0.9 days (26.7-27.6 days; 95% CI [2.1, 3.9]) in quality-adjusted survival during the 6-month follow-up. Sensitivity analyses did not alter these findings. Limitations of the study included the small number of trials, moderate heterogeneity in the DVT prevention outcome and there were moderate quality studies included. The authors conclude that this study indicates that there is clear evidence that IPC significantly reduces the risk of DVT and significantly improves survival in a wide variety of patients who are immobile after stroke. However, IPC does not significantly improve quality-adjusted survival.

A 2018 Hayes health technology assessment, updated in 2021, on pneumatic compression (PC) for the prevention of DVT following knee arthroplasty, assessed 16 RCTs that compared PC with alternative methods of venous thromboembolism (VTE), or a combination of therapies including anticoagulants (including aspirin), low molecular weight heparin (LMWH) or graduated compression stockings (GCS). It was concluded that PC may be effective in reducing the incidence of DVT in patients who have undergone TKA, particularly when used in combination with LMWH but that PC alone is less effective than LMWH alone. The available studies concerning the efficacy of PC alone or combined with other methods of prophylaxis for DVT such as aspirin, GCS, and other anticoagulants provide limited and somewhat inconsistent evidence and additional RCTs are needed.

O'Connell et al. (2016) conducted a systematic review and meta-analysis as an up-to-date evaluation on the use of compression devices (with or without pharmacological anticoagulation) as deep vein thrombosis (DVT) prophylaxis methods in orthopedic and neurological patients, as compared to pharmacological anticoagulation alone. There were nine RCTs that were included in the review and meta-analysis for a total of 3,347 patients. The IPC group had a combined total of 1,667 patients and the pharmacological anticoagulation alone group 1,667 patients. The main outcome measures were the development of DVT and/or PE. In all nine studies, the rate of DVT significantly occurred in the pharmacological anticoagulation group (89/1667) than in the IPC group (38/1680) ( $p = 0.04$ ). Sensitivity testing did not change this finding. A sensitivity test that looked at IPC alone without additional chemoprophylaxis, showed no significant difference in the rate of DVT between IPC and the control group. A further test to assess if differences were related to the protocol differences and not necessarily related to IPC by using data from 7 studies using only low molecular weight heparin show the differences between the group to slightly favor the IPC group, although not significant. The main limitation was lack of binding in all studies and the heterogeneity of both the intervention and control group in the meta-analysis. Some intervention groups included IPC alone while others included IPC and pharmacological treatment. The authors concluded that the use of an intermittent pneumatic compression device alone is neither superior nor inferior to chemoprophylaxis.

Pavon et al. (2016) in a systematic review examined the results of 14 eligible randomized controlled trials and three eligible observational studies evaluating the effectiveness of intermittent pneumatic compression devices for venous thromboembolism prophylaxis in postoperative surgical patients. The authors looked at the comparative effectiveness of IPCDs for selected outcomes (mortality, venous thromboembolism [VTE], symptomatic or asymptomatic deep vein thrombosis, major bleeding, ease of use, and adherence) in postoperative surgical patients. Intermittent pneumatic compression devices were comparable to anticoagulation for major clinical outcomes (VTE: risk ratio, 1.39; 95% confidence interval, 0.73-2.64). Limited data suggest that concurrent use of anticoagulation with IPCD may lower VTE risk compared with anticoagulation alone, and that IPCD compared with anticoagulation may lower major bleeding risk. Subgroup analyses did not show significant differences by

device location, mode of inflation, or risk of bias elements. The authors concluded that intermittent pneumatic compression devices do not show clear differences in clinical outcomes although they may decrease the risk of VTE and should be used in accordance with current clinical guidelines. The current evidence base to guide selection of a specific device or type of device is limited and comparative studies are needed.

Dennis et al. (2015) in a health technology assessment based on the CLOTS 3 trial (2013) looked at whether or not the application of IPC to the legs of immobile patients after stroke reduced their risk of deep vein thrombosis (DVT). CLOTS 3 was a multicenter, parallel-group, randomized controlled trial which allocated patients via a central randomization system to IPC or no IPC. A technician blinded to treatment allocation performed compression duplex ultrasound (CDU) of both legs at 7-10 days and 25-30 days after enrolment. Participants were followed for 6 months to determine survival and later symptomatic VTE. There were 2,876 patients enrolled in 94 UK hospitals between 8 December 2008 and 6 September 2012. Inclusion criteria included patients admitted to hospital within 3 days of acute stroke and who were immobile (not able to get up from a chair / out of bed and walk to the toilet without the help of another person) on the day of admission (day 0) to day 3. Patients were excluded for any of the following: age < 16 years; subarachnoid hemorrhage; and contra-indications to IPC including dermatitis, leg ulcers, severe edema, severe peripheral vascular disease and congestive cardiac failure. Participants were allocated to routine care or routine care plus IPC for 30 days, until earlier discharge from the hospital or participating rehabilitation unit, or until walking independently, whichever happened first. Mean duration of ICP use was about 11 days with about one in four participants using ICP for three weeks or more. Most participants also received anti-platelet therapy and about half received pharmacological anticoagulation. The primary outcome occurred in 122 (8.5%) of 1438 patients allocated to IPC and 174 (12.1%) of 1438 patients allocated to no IPC, giving an absolute reduction in risk of 3.6% [95% confidence interval (CI) 1.4% to 5.8%] and a relative risk reduction of 0.69 (95% CI 0.55 to 0.86). After excluding 323 patients who died prior to any primary outcome and 41 who had no screening CDU, the primary outcome occurred in 122 of 1267 IPC participants compared with 174 of 1245 no-IPC participants, giving an adjusted odds ratio of 0.65 (95% CI 0.51 to 0.84;  $p = 0.001$ ). Secondary outcomes in IPC compared with no-IPC participants were death in the treatment period in 156 (10.8%) versus 189 (13.1%) ( $p = 0.058$ ); skin breaks in 44 (3.1%) versus 20 (1.4%) ( $p = 0.002$ ); and falls with injury in 33 (2.3%) versus 24 (1.7%) ( $p = 0.221$ ). Among patients treated with IPC, there was a statistically significant improvement in survival to 6 months (hazard ratio 0.86, 95% CI 0.73 to 0.99;  $p = 0.042$ ), but no improvement in disability. The authors determined that IPC is an effective method of reducing the risk of DVT and improving survival in immobile patients after a stroke.

Domeij-Arverud et al. (2015) in a randomized controlled trial investigated at the use of intermittent pneumatic compression therapy and the prevention of deep vein thrombosis in outpatients who had undergone surgical repair of acute ruptures of the Achilles tendon, were immobilized, and did not receive pharmacological anticoagulation. A total of 150 patients who had undergone surgical repair of the Achilles tendon were randomized to either treatment with IPC for six hours per day for two weeks ( $n = 74$ ) under an orthosis or treatment as usual ( $n = 74$ ) in a plaster cast without IPC. At two weeks post-operatively, the incidence of deep vein thrombosis was assessed using blinded, double-reported compression duplex ultrasound. At this point, IPC was discontinued and all patients were immobilized in an orthosis for a further four weeks. At six weeks post-operatively, a second compression duplex ultrasound scan was performed. At two weeks, the incidence of deep vein thrombosis was 21% in the treated group and 37% in the control group ( $p = 0.042$ ). Age over 39 years was found to be a strong risk factor for deep vein thrombosis (odds ratio (OR) = 4.84, 95% confidence interval (CI) 2.14 to 10.96). Treatment with IPC, corrected for age differences between groups, reduced the risk of deep vein thrombosis at the two-week point (OR = 2.60; 95% CI 1.15 to 5.91;  $p = 0.022$ ). At six weeks, that is four weeks after the end of the IPC intervention, the incidence of deep vein thrombosis was 52% in the treated group and 48% in the control group (OR 0.94, 95% CI 0.49 to 1.83). The authors concluded that IPC appears to be an effective method of reducing the risk of deep vein thrombosis in the early stages of post-operative immobile outpatients. Additional research is necessary to clarify whether it could result in similar benefits over longer periods of immobilization and in a more heterogeneous group of patients.

Arabi et al. (2013) in a single center observational study examined the association between the use of mechanical thromboprophylaxis with intermittent pneumatic compression (IPC) or graduated compression stockings (GCS) and the risk of VTE and hospital mortality among critically ill medical-surgical patients. They study was conducted in an adult medical surgical ICU between July 2006 and January 2008, they used multiple propensity scores adjustment to examine the association of IPC and GCS with VTE. The primary outcome was occurrence of VTE, including DVT and pulmonary embolism. The following information was collected: patient demographics, admission physiologic data, VTE risk factors, pharmacologic thromboprophylaxis, and mechanical thromboprophylaxis. Among 798 patients enrolled in the study, incident VTE occurred in 57 (7.1%). The use of IPC was associated with a significantly lower VTE incidence compared with no mechanical thromboprophylaxis (propensity scores adjusted hazard ratio, 0.45; 95% CI, 0.22-0.95;  $p = .04$ ). GCS were not associated with

decreased VTE incidence. No significant interaction was found between the mechanical thromboprophylaxis group, and the type of prophylactic heparin used ( $p = .99$ ), recent trauma ( $p = .66$ ), or recent surgery ( $p = .07$ ) on VTE risk. While this study had strengths, it had the limitation of not being an RCT. The use of IPC was associated with a significantly lower VTE risk irrespective of pharmacologic thromboprophylaxis but the use of GCS did not show the same result. This association was also consistent regardless of the type of prophylactic heparin used and was not modified by trauma or surgical admission.

## Clinical Practice Guidelines

### *American Society of Hematology (ASH)*

In the 2019 evidence-based guidelines for the prevention of venous thromboembolism in surgical hospitalized patients undergoing major surgery, ASH (Anderson et al.) makes the following conditional recommendations regarding mechanical prophylaxis based on very low certainty in the evidence:

- The use of pharmacological or mechanical prophylaxis:
  - For patients considered at high risk for bleeding, the balance of effects may favor mechanical methods over pharmacological prophylaxis
  - For patients who do not receive pharmacologic prophylaxis, the panel suggests using mechanical prophylaxis over no mechanical prophylaxis
  - For patients who receive mechanical prophylaxis, using intermittent compression devices over graduated compression stockings
- For patients who receive pharmacologic prophylaxis, using combined prophylaxis with mechanical and pharmacological methods over prophylaxis with pharmacological agents alone
  - For patients considered at high risk for VTE, combined prophylaxis is particularly favored over mechanical or pharmacological prophylaxis alone. (Further high-quality research studies using clinically important outcomes to identify patients with high baseline risk for VTE in whom combined pharmacological and mechanical prophylaxis would be of value, particularly outside the orthopedic setting, are needed)

In the 2018 ASH guidelines for management of venous thromboembolism: prophylaxis for hospitalized and nonhospitalized medical patients (Shunmehann et al.), the following statement is noted:

- In acutely or critically ill medical patients who do not receive pharmacological VTE prophylaxis, the ASH guideline panel suggests using mechanical VTE prophylaxis over no VTE prophylaxis (conditional recommendation, moderate certainty in the evidence of effects).

### *National Institute for Health and Care Excellence (NICE)*

A 2018 NICE guideline on reducing the risks of hospital acquired DVT or PE states that all patients should be assessed for risk upon admission and if their clinical condition changes. NICE states that the indications for anti-embolism stockings and pneumatic compression devices are both considered “mechanical prophylaxis” and states that mechanical prophylaxis should not be used in patients with the following:

- Suspected or proven peripheral arterial disease
- Peripheral arterial bypass grafting
- Peripheral neuropathy or other causes of sensory impairment
- Any local conditions in which mechanical prophylaxis may cause damage (e.g. fragile 'tissue paper' skin, dermatitis, gangrene or recent skin graft)
- Severe leg edema
- Major limb deformity or unusual leg size or shape that prevents a correct fit

### *European Guidelines Perioperative Venous Thromboembolism Prophylaxis*

Afshari et al. (2018, reaffirmed 2020) in a review of the European guidelines on perioperative venous thromboembolism prophylaxis. The authors note that the use of graduated compression stockings (GCS) and intermittent pneumatic compression (IPC) strongly differs between institutions. As a result, no robust recommendations can be made based on any current high-level evidence. Although different clinical practices can be supported, such approaches should be part of an institutional strategy to reduce the problem of venous thromboembolism (VTE). They made the following recommendations and suggestions in regard to mechanical prophylaxis:

- An institution-wide protocol for the prevention of VTE that integrates early ambulation, pharmacological thromboprophylaxis with anticoagulants and mechanical thromboprophylaxis (Grade IB).

- Against the routine use of graduated compression stockings (GCS) without pharmacological thromboprophylaxis to prevent VTE in patients at intermediate and high risk (Grade 1B)
- In patients with contra-indications to pharmacological thromboprophylaxis, we recommend the use of mechanical prophylaxis with IPC or GCS (Grade 1B) and suggest the use of IPC over GCS (Grade 2B).
- In patients with contra-indications for pharmacological thromboprophylaxis who are not at high risk for VTE, we suggest no prophylaxis over GCS alone (Grade 2C).
- In patients receiving pharmacological thromboprophylaxis who are not at very high risk for VTE, we recommend against the routine use of mechanical thromboprophylaxis with GCS or IPC (Grade 1B).
- Suggest combined mechanical and pharmacological prophylaxis in selected patients at very high risk for VTE (grade 2B).
- We suggest the use of IPC rather than GCS in selected high-risk patients in addition to pharmacological thromboprophylaxis (Grade 2B)

### ***American Association of Plastic Surgeons***

Pannucci et al. (2016) authored a clinical practice guideline based on a systematic review and meta-analysis sponsored by the American Association of Plastic Surgeons that examined both the benefits and risks of venous thromboembolism prophylaxis in plastic surgery patients. The authors found that meta-analyses of surgical patients (but not necessarily plastic surgery patients) have shown significant deep venous thrombosis risk reduction for intermittent pneumatic compression compared with placebo. Meta-analysis has also shown that intermittent pneumatic compression is superior to elastic compression stockings for deep venous thrombosis risk reduction (OR, 0.61; 95 percent CI, 0.39 to 0.93). The following statement were made:

- Recommend using intermittent pneumatic compression to prevent perioperative venous thromboembolism events in plastic surgery patients. In the absence of rigorous publications in plastic surgery, this recommendation was derived largely from meta-analyses in other specialties (Fig. 4) (GRADE 1B).
- Elastic compression stockings are associated with a decreased risk for perioperative venous thromboembolism in other surgical specialties. In the absence of rigorous publications in plastic surgery, this recommendation was derived largely from meta-analysis in other specialties (Fig. 5) (GRADE 1B).
- Intermittent pneumatic compression is superior to elastic compression stockings for venous thromboembolism prevention in other surgical specialties. In the absence of rigorous publications in plastic surgery, this recommendation was derived largely from meta-analysis in other specialties (Fig. 6) (GRADE 1B).

### ***American College of Chest Physicians Society***

Falck-Ytter Y et al. (2012, reaffirmed 2020) summarizes the recommendations from the American College of Chest Physicians Society on the optimal strategies for thromboprophylaxis after major orthopedic surgery include pharmacologic and mechanical approaches. The authors stated that mechanical approaches to perioperative thromboprophylaxis with pneumatic compression devices have the potential benefit of reducing the occurrence of VTE but without the risk for increased bleeding. An intermittent pneumatic device (IPCD) can also be used in the other leg even during surgery and the immediate postoperative period. Seven RCTs that included > 900 patients undergoing arthroplasty or HFS compared mechanical compression to no thromboprophylaxis. Six used an IPCD, and one a venous foot pump (VFP).<sup>77</sup> The risk of bias varied. It was unclear in most trials whether allocation was concealed. Blinding of patients and caregivers is not likely in such studies, and not all provided blinded VTE adjudication. Variation in design and performance of the devices as well as information about compliance, which was rarely reported in older trials, introduce uncertainty in how to apply the evidence. Although the study is somewhat of a low quality, a relative risk reduction of > 50% was observed for both DVT and PE in THA, TKA, and HFS (PE RR, 0.4; 95% CI, 0.17-0.92; DVT RR, 0.46; 95% CI, 0.35-30.61). The corresponding estimated absolute risk difference is 16 fewer symptomatic VTE per 1,000. The results failed to demonstrate or to exclude a beneficial effect on mortality. As a result, in patients undergoing major orthopedic surgery, the authors recommend, among other things, the use of one of the following rather than no antithrombotic prophylaxis: low-molecular-weight heparin; fondaparinux; dabigatran, apixaban, rivaroxaban (total hip arthroplasty or total knee arthroplasty but not hip fracture surgery); low-dose unfractionated heparin; adjusted-dose vitamin K antagonist; aspirin (all Grade 1B); or an intermittent pneumatic compression device (IPCD) (Grade 1C) for a minimum of 10 to 14 days; in patients undergoing major orthopedic surgery and increased risk of bleeding (Table 4), the authors suggested using an IPCD or no prophylaxis rather than pharmacologic treatment (Grade 2C); For patients undergoing major orthopedic surgery, they suggested extending thromboprophylaxis in the outpatient period for up to 35 days from the day of surgery rather than for only 10 to 14 days (Grade 2B). The recommendation regarding intermittent pneumatic compression devices can help clinicians make evidence-based treatment decisions related to prevention of venous thromboembolism in orthopedic surgery patients.

Lansberg et al. (2012, reaffirmed 2020) summarizes the recommendations from the American College of Chest Physicians Society on the use of antithrombotic therapy in patients with stroke or transient ischemic attack (TIA). They generated treatment recommendations (Grade 1) and suggestions (Grade 2) based on high (A), moderate (B), and low (C) quality evidence. In patients with acute stroke and restricted mobility, they suggest the use of prophylactic-dose heparin or intermittent pneumatic compression devices (Grade 2B) and suggest against the use of elastic compression stockings (Grade 2B). Among other suggestions and recommendation, the authors stated that pharmacologic and mechanical prophylaxis should be initiated as early as possible and should be continued throughout the hospital stay or until the patient has regained mobility. Mechanical devices should be temporarily removed as often as needed to allow for early mobilization and screening for skin complications. These recommendations were based on indirect but higher-quality evidence from other populations, such as postoperative patients. The trials that compared intermittent pneumatic compression devices to no treatment have shown an approximate 50% reduction in DVT detected by testing such as a venogram. The recommendations regarding intermittent pneumatic compression devices can help clinicians make evidence-based treatment decisions with their patients who have had strokes.

## U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

The Flexitouch Plus System (Tactile Systems Technology, Inc) received FDA clearance on December 20, 2020. The Flexitouch System and garments for the head and neck are intended for use by medical professionals and patients who are under medical supervision for the treatment of head and neck lymphedema. [https://www.accessdata.fda.gov/cdrh\\_docs/pdf20/K203178.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf20/K203178.pdf). (Accessed November 8, 2022)

Devices and systems to perform pneumatic compression are regulated by the FDA as Class II devices. Refer to the following website for more information (use product code JOW): <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>. (Accessed September 6, 2022)

## References

- Anderson DR, Morgano GP, Bennett C, et al. American Society of Hematology 2019 guidelines for management of venous thromboembolism: prevention of venous thromboembolism in surgical hospitalized patients. *Blood Adv*. 2019 Dec 10;3(23):3898-3944.
- Arabi YM, Al-Hameed F, Burns KEA, et al. Saudi Critical Care Trials Group. Adjunctive intermittent pneumatic compression for venous thromboprophylaxis. *N Engl J Med*. 2019 Apr 4;380(14):1305-1315.
- Arabi YM, Khedr M, Dara SI, et al. Use of intermittent pneumatic compression and not graduated compression stockings is associated with lower incident VTE in critically ill patients: a multiple propensity scores adjusted analysis. *Chest*. 2013 Jul;144(1):152-159.
- Afshari A, Ageno W, Ahmed A, et al. ESA VTE Guidelines Task Force. European Guidelines on perioperative venous thromboembolism prophylaxis: Executive summary. *Eur J Anaesthesiol*. 2018 Feb;35(2):77-83.
- CLOTS (Clots in Legs Or sTockings after Stroke) Trials Collaboration. Effectiveness of intermittent pneumatic compression in reduction of risk of deep vein thrombosis in patients who have had a stroke (CLOTS 3): a multicentre randomised controlled trial. *Lancet* 2013;382(9891):516-524.
- Dennis M, Sandercock P, Graham C, et al, CLOTS (Clots in Legs Or sTockings after Stroke) Trials Collaboration, Smith J. The Clots in Legs Or sTockings after Stroke (CLOTS) 3 trial: a randomised controlled trial to determine whether or not intermittent pneumatic compression reduces the risk of post-stroke deep vein thrombosis and to estimate its cost-effectiveness. *Health Technol Assess*. 2015 Sep;19(76):1-90.
- Domeij-Arverud E, Labruto F, Latifi A, et al. Intermittent pneumatic compression reduces the risk of deep vein thrombosis during post-operative lower limb immobilisation: a prospective randomised trial of acute ruptures of the Achilles tendon. *Bone Joint J*. 2015 May;97-B(5):675-80.
- 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-e325S. DOI: 10.1378/chest.11-2404. Reaffirmed 2020 May.



Gutiérrez C, Mayrovitz HN, Naqvi SHS, Karni RJ. Longitudinal effects of a novel advanced pneumatic compression device on patient-reported outcomes in the management of cancer-related head and neck lymphedema: A preliminary report. *Head Neck*. 2020 Aug;42(8):1791-1799.

Hayes, Inc., Health Technology Assessment. Pneumatic Compression For Prevention Of Deep Vein Thrombosis Following Knee Arthroplasty. Lansdale PA: Hayes, Inc., November 2018; Annual review December 2021.

Lansberg MG, O'Donnell MJ, Khatri, et al. Antithrombotic and thrombolytic therapy for ischemic stroke: antithrombotic therapy and prevention of thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. *Chest* 2012;141(2 Suppl):e601S-e636S.

Mayrovitz HN, Ryan S, Hartman JM. Usability of advanced pneumatic compression to treat cancer-related head and neck lymphedema: A feasibility study. *Head Neck*. 2018 Jan;40(1):137-143.

National Institute for Health and Care Excellence (NICE). NICE guidelines [(NG89)]. Venous thromboembolism in over 16s: reducing the risk of hospital-acquired deep vein thrombosis or pulmonary embolism. March 2018.

O'Connell S, Bashar K, Broderick BJ, et al. The Use of intermittent pneumatic compression in orthopedic and neurosurgical postoperative patients: A systematic review and meta-analysis. *Ann Surg*. 2016 May;263(5):888-9.

Pannucci CJ, MacDonald JK, Ariyan S, et al. Benefits and risks of prophylaxis for deep venous thrombosis and pulmonary embolus in plastic surgery: A systematic review and meta-analysis of controlled trials and consensus conference. *Plast Reconstr Surg*. 2016 Feb;137(2):709-730.

Pavon JM, Adam SS, Razouki ZA, et al. Effectiveness of intermittent pneumatic compression devices for venous thromboembolism prophylaxis in high-risk surgical patients: A systematic review. *J Arthroplasty*. 2016 Feb;31(2):524-32.

[Pneumatic Compression Devices \(L33829\)](#); DME MAC; CGS Administrators, LLC - 17013 (J-B) and 18003 (J-C); Noridian Healthcare Solutions, LLC - 16013 (J-A) and 19003 (J-D). Accessed September 6, 2022.

Ridner SH, Dietrich MS, Deng J, Ettema SL, Murphy B. Advanced pneumatic compression for treatment of lymphedema of the head and neck: a randomized wait-list controlled trial. *Support Care Cancer*. 2021 Feb;29(2):795-803.

Schünemann HJ, Cushman M, Burnett AE, et al. American Society of Hematology 2018 guidelines for management of venous thromboembolism: prophylaxis for hospitalized and nonhospitalized medical patients. *Blood Adv*. 2018 Nov 27;2(22):3198-3225.

Zhang D, Li F, Li X, et al. Effect of intermittent pneumatic compression on preventing deep vein thrombosis among stroke patients: A systematic review and meta-analysis. *Worldviews Evid Based Nurs*. 2018 Jun;15(3):189-196.

## Policy History/Revision Information

Date	Summary of Changes
06/01/2023	<p><b>Coverage Rationale</b></p> <ul style="list-style-type: none"> <li>• Added language to indicate advanced intermittent pneumatic compression devices (e.g., Flexitouch) for treating lymphedema of the head, face, or neck are considered unproven and not medically necessary</li> <li>• Revised language pertaining to medical necessity clinical coverage criteria: <ul style="list-style-type: none"> <li><i>Pneumatic Compression Devices</i></li> <li><b>Lymphedema or Chronic Venous Insufficiency with Edema and Non-Healing Lower Extremity Ulcers</b> <ul style="list-style-type: none"> <li>○ Added reference to the InterQual® CP: Durable Medical Equipment, Pneumatic and other Powered Compression Devices</li> <li>○ Removed reference to the InterQual® CP: Durable Medical Equipment, Pneumatic Compression Devices</li> </ul> </li> <li><b>Arterial Insufficiency (HCPCS code E0675)</b> <ul style="list-style-type: none"> <li>○ Removed reference to the InterQual® Medicare: Durable Medical Equipment, Pneumatic Compression Devices</li> </ul> </li> </ul> </li> </ul>

Date	Summary of Changes
	<p data-bbox="386 138 899 170"><i>Intermittent Limb Compression Devices</i></p> <ul data-bbox="386 176 1468 237" style="list-style-type: none"> <li data-bbox="386 176 1468 237">○ Replaced coverage criteria with reference to the InterQual® CP: Durable Medical Equipment, Pneumatic and other Powered Compression Devices</li> </ul> <p data-bbox="337 247 570 279"><b>Applicable Codes</b></p> <ul data-bbox="337 285 867 310" style="list-style-type: none"> <li data-bbox="337 285 867 310">● Removed HCPCS codes E0656 and E0657</li> </ul> <p data-bbox="337 321 639 352"><b>Supporting Information</b></p> <ul data-bbox="337 359 1455 449" style="list-style-type: none"> <li data-bbox="337 359 1455 417">● Updated <i>Description of Services, Clinical Evidence, FDA, and References</i> sections to reflect the most current information</li> <li data-bbox="337 424 899 449">● Archived previous policy version CS097KY.05</li> </ul>

## Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state, or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state, or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state, or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state, or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare uses InterQual® for the primary medical/surgical criteria, and the American Society of Addiction Medicine (ASAM) for substance use, in administering health benefits. If InterQual® does not have applicable criteria, UnitedHealthcare may also use UnitedHealthcare Medical Policies, Coverage Determination Guidelines, and/or Utilization Review Guidelines that have been approved by the Kentucky Department for Medicaid Services. The UnitedHealthcare Medical Policies, Coverage Determination Guidelines, and Utilization Review Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.