Pneumatic Compression Devices (for Ohio Only)

Policy Number: CS097OH.B
Effective Date: June 1, 2024

➲ Instructions for Use

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Related Policy

- Durable Medical Equipment, Orthotics, Medical Supplies, and Repairs/Replacements (for Ohio Only)

Application

This Medical Policy only applies to the state of Ohio. Any requests for services that are stated as unproven or services for which there is a coverage or quantity limit will be evaluated for medical necessity using Ohio Administrative Code 5160-1-01.

Coverage Rationale

Note: For general coverage and payment policies for durable medical equipment (DME), prosthesis, orthotic devices, medical/surgical supplies, and supplier services, refer to the Ohio Administrative Code, Rule 5160-10-01, Durable medical equipment, prostheses, orthoses, and supplies (DMEPOS): general provisions.

For medical necessity clinical coverage criteria for pneumatic compression devices for the extremities, chest, or trunk, refer to the Ohio Administrative Code, Rule 5160-10-17, DMEPOS: pneumatic compression devices and accessories.

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

For medical necessity clinical coverage criteria for intermittent limb compression devices, 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).

Coverage Limitations and Exclusions

For coverage limitations and exclusions, refer to the Ohio Administrative Code, Rule 5160-10-01, Durable medical equipment, prostheses, orthoses, and supplies (DMEPOS): general provisions and the Ohio Administrative Code, Rule 5160-10-02, DMEPOS: repair.

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 federal, state, or contractual requirements 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

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 (APCDs) for treating lymphedema of the head, face or neck. Additional research is needed to define the role of APCDs in treating lymphedema of the head, face, or neck.

Cheng et al. (2023) conducted a systematic review on the rehabilitation interventions for head and neck cancer-associated lymphedema (HNCaL). Twenty-three studies (n = 2147 patients) were eligible for inclusion (six randomized controlled trials [RCTs] and seventeen observational studies). The studies were categorized by intervention type, including standard lymphedema therapy and adjunct therapy. Adjunct therapy interventions included APCDs (one RCT, five observational studies), kineso taping, photobiomodulation, acupuncture/moxibustion and sodium selenite. The one RCT for APCD therapy (Rider, et al, 2021, described in detail below) compared a two-month intervention with a waitlist control condition and found improvement in the APCD group in clinician-rated external lymphedema but no improvement in endoscopic assessment of internal lymphedema. Of the observational studies for APCD, early studies showed that one treatment session improved objective tape measurements in forty-four participants and lymphatic flow in ten participants. Adverse events were either not found or not reported. The authors concluded standard lymphedema therapy with kinesio taping and APCDs appear to be safe and beneficial, and that low-quality evidence also suggested that APCDs may be beneficial. However, more prospective, controlled and adequately powered studies are needed to establish treatment guidelines. Limitations of the studies include the sample size, study type, possible conflict of interest and limited geography.

In 2021 (updated 2023) Hayes conducted an Evolving Evidence Review on the Flexitouch Plus System for head and neck lymphedema (HNL). The evidence base was limited to four clinical studies (one controlled study; three uncontrolled studies) no relevant systematic reviews were identified. The data showed no severe device-related adverse events with short-term improvement in lymphedema symptoms, patient-reported soft tissue symptoms and suggestive benefits in pain control. The report concluded minimal support for the use of Flexitouch Plus System for treating lymphedema of the head and neck. The summary of findings showed no clinical practice guidelines specifically addressing the use of the Flexitouch

Plus System for the treatment of HNL Limitations of the studies included non-validated assessment tools, small sample sizes, short term follow-up and poor statistical analyses.

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 HNL, 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 HNC 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.

Gutierrez et al. (2020), in an observational study, evaluated HNC survivors experience with HNL treatment. The authors explored the self-reported outcomes and satisfaction of patients with HNC receiving treatment for HNL with an advanced 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 ≥ 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.

Maryovitz et al. (2018) conducted a case series to assess the functional usage of an APCD (Flexitouch System) for the treatment of cancer-related HNL 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 HNL. 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 ±SD) of the face (82.5 ±4.3 cm vs. 80.9 ±4.1 cm; $p < .001$) and neck (120.4 ±12.2 cm vs. 119.2 ±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)

In 2022 a Cochrane review (Kakkos, et al. 2022) assessed the efficacy of combined IPC and pharmacological prophylaxis compared to single modalities in preventing venous thromboembolism (VTE). Thirty-four studies (n = 14,931) including twenty-five RCTs mainly undergoing surgery or admitted trauma were evaluated for pulmonary embolism (PE), DVT, bleeding and major bleeding outcomes. The use of combined IPC and pharmacological prophylaxis modalities compared with pharmacological prophylaxis alone reduced the incidence of PE from 1.84% (61/3318) in the pharmacological

prophylaxis group to 0.91% (31/3419) in the combined group (OR 0.46, 95% CI 0.30 to 0.71; 15 studies, 6737 participants, low-certainty evidence). The authors concluded combining IPC with pharmacological prophylaxis, compared to pharmacological prophylaxis alone reduces the incidence of both PE (low-certainty of evidence and DVT (high-certainty of evidence). The limitations of the study include publication bias, patient demographic, intervention and modality restriction.

Arabi et al. (2019) included in the 2022 Cochrane review above, conducted a multi-site randomized controlled trial that evaluated whether adjunctive IPC 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 (≥ 14, ≥ 16, or ≥ 18 years of age), were randomly assigned within 48 hours after admission to an intensive care unit (ICU) to receive either IPC 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. IPC 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). VTE (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 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 2023, on pneumatic compression (PC) for the prevention of DVT following knee arthroplasty, assessed 16 RCTs that compared PC with alternative methods of 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 (IPCD) 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 (IPCDs) for VTE prophylaxis in postoperative surgical patients. The authors looked at the comparative effectiveness of IPCDs for selected outcomes (mortality, VTE, symptomatic or asymptomatic deep vein thrombosis, major bleeding, ease of use, and adherence) in postoperative surgical patients. IPCDs 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 IPCDs 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 IPC 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.

Clinical Practice Guidelines

American Society of Hematology (ASH)

In the 2019 evidence-based guidelines for the prevention of VTE 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 (updated 2022) ASH guidelines for management of VTE: prophylaxis for hospitalized and nonhospitalized medical patients (Shunmemann 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 (updated 2019) 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 PCDs 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 VTE prophylaxis, the authors note that the use of graduated compression stockings (GCS) and 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 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 IB).
- In patients with contra-indications to pharmacological thromboprophylaxis, we recommend the use of mechanical prophylaxis with IPC or GCS (Grade IB) 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 VTE prophylaxis in plastic surgery patients. The authors found that meta-analyses of surgical patients (but not necessarily plastic surgery patients) have shown significant DVT risk reduction for IPC compared with placebo. Meta-analysis has also shown that IPC is superior to elastic compression stockings for DVT risk reduction (OR, 0.61; 95 percent CI, 0.39 to 0.93). The following statement were made:

- Recommend using IPC to prevent perioperative VTE 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 VTE 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).
- IPC is superior to elastic compression stockings for VTE 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).

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. (Accessed October 18. 2023)

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 October 18, 2023)

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Policy History/Revision Information

Date	Summary of Changes
06/01/2024	**Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information • Archived previous policy version CS097OH.A

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state (Ohio Administrative Code [OAC]), or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state (OAC), or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state (OAC), or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state (OAC), 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 Ohio 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.