# Pneumatic Compression Devices (for Nebraska Only)

**Policy Number**: CS097NE.S
**Effective Date**: December 1, 2025

➲ Instructions for Use

**Table of Contents** **Page**



**Related Policy**

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

## Application

This Medical Policy only applies to the State of Nebraska.

## Coverage Rationale

### State-Specific Criteria

For coverage information of pneumatic compressors and appliances, refer to the Nebraska Department of Health and Human Services, Code 471-7-004.02(VV): Pneumatic Compressors and Appliances.

### Additional Non State-Specific 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.**

**Pneumatic compression devices (high pressure, rapid inflation/deflation cycle) for treating peripheral arterial disease (PAD) are considered unproven and not medically necessary.**

**Pneumatic compression devices are proven and medically necessary in certain circumstances for the treatment of lymphedema.** 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 certain circumstances 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.

## 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 |
| E0658 | Segmental pneumatic appliance for use with pneumatic compressor, integrated, 2 full arms and chest |
| E0659 | Segmental pneumatic appliance for use with pneumatic compressor, integrated, head, neck and chest |
| 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 multi-chambered 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 (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 = 2,147 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), kinesio taping, photo biomodulation, 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 HNL 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.

## Treatment of Peripheral Arterial Disease

The evidence on the relative benefits of PCDs for the treatment of PAD is inconsistent; evidence for the benefit of treatment on patient-centered outcomes are lacking. The evidence is insufficient to determine the safety and efficacy of treatment for high-pressure compression devices on arterial insufficiency.

In 2021 ECRI conducted a Clinical Evidence Assessment on IPC for treating PAD. The assessment included evidence from two systematic reviews (SRs), one RCT, 1 before-and-after study and one case series. The assessment indicates IPC improves walking distance, intermittent claudication, and resting pain in patients with critical limb ischemia (CLI). Evidence from one SR that did not synthesize data in meta-analysis, one RCT, and one case series also suggest that IPC may improve wound healing and reduce amputation risks in patients with CLI. However, these studies are at high risk of bias and additional controlled studies are needed to enable conclusions. Studies varied in IPC treatment regimens and duration, and additional RCTs are needed to determine appropriate IPC use. Guidance from US and International medical societies recommend considering IPC in patients with intractable, severe PAD.

Oresanya et al. (2018) conducted a systematic review and meta-analysis to evaluate the efficacy of high-pressure intermittent limb compression (HPILC) as an alternative treatment modality for disabling intermittent claudication. Eight RCTs (n = 290) measured the primary outcome of absolute claudication distance (ACD). The study data demonstrated an increase in walking distance for subjects receiving compression therapy. The mean difference of ACD from baseline to follow-up among subjects receiving compression compared with controls was 125 m (95% confidence interval, 58.38-191.63 m; $p < .01$). This increase in ACD seen for patients is comparable to the benefit seen for other modalities used to treat intermittent claudication. Yet, it is not yet clearly identified what regimen is most effective in terms of device, session, and total treatment length. The authors concluded the results suggest that intermittent limb compression (ILC) could be beneficial in improving ACD along with supervised exercise and surgical intervention. Broader studies comparing limb compression with alternative treatment strategies would help better define its role in the multimodal management of PAD. The study limitations include small sample size, low-quality studies, risk of bias, significant heterogeneity between studies, and limited generalizability of results. (This study is included in the ECRI 2021 Clinical Evidence Assessment.)

Williams et al. (2017) conducted a systematic review to identify and analyze non-invasive hemodynamic devices in the management of PAD. The devices identified and included in the study (n = 22) were IPC, electronic nerve (NMES) or muscle stimulators (EMS), and galvanic electrical dressings. The results showed in patients with intermittent claudication, IPCDs increase popliteal artery velocity (49-70%) and flow (49-84%). Over 4.5-6 months IPC increased intermittent claudication distance (ICD) (97-150%) and absolute walking distance (AWD) (84-112%). In patients with CLI, IPC reduced rest pain in 40-100% and was associated with ulcer healing rates of 26%. IPC had an early limb salvage rate of 58-83% and 58-94% at 1.5-3.5 years. The authors concluded there is evidence to support the use of IPC in the management of claudication and CLI, however there is a need for more robust research in the form of RCTs. Also, there is limited evidence to support the use of electrical stimulators to date for PAD. These devices may be of benefit to those with limited exercise capacity and in non-reconstructable CLI. Limitations of the study include small sample size, low-quality of studies and heterogeneity. (This study is included in the ECRI 2021 Clinical Evidence Assessment.)

Alvarez et al. (2015) conducted an RCT on the effects of HPILC for the treatment of PAD and CLI in patients without a surgical option. Thirty-four subjects with symptomatic PAD or CLI who were experiencing claudication pain, chronic rest pain, numbness, and ischemic lower leg/foot ulceration were randomized into two treatment groups. Eighteen patients received treatment with HPIPC sixty minutes twice daily for sixteen weeks, and sixteen subjects received standard care consisting of an exercise regimen of walking for twenty minutes twice daily for sixteen weeks. The patient-centered outcomes measured peak walking time (PWT), defined as time to maximally tolerated claudication pain, change in resting ankle brachial index (ABI), ulcer healing, relief of resting/wound pain and quality of life index. The study showed no significant change in PWT treatment groups at week four or eight. At week sixteen the percent change in treatment groups was more significant (35.5% for standard care group and 54.7% for the HPIPC group). In addition, the HPIPC group reported an increased reduction of wound surface area, greater pain relief and physical function at sixteen weeks.

The authors concluded therapy consisting of HPIPC for two hours daily for a period of sixteen weeks significantly improved PWT, reduced resting pain and improved healing rates, physical function, and bodily pain. The authors conclude that HPIPC is safe and effective and should be considered for patients who are not candidates for endovascular or surgical procedures. The study limitations include small sample size, single-center focus, and lack of blinding. (This study is included in the ECRI 2021 Clinical Evidence Assessment.)

In 2013 (updated 2017) Hayes published a Health Technology Assessment on IPCs for peripheral arterial disease. The assessment concluded that IPCs appear to be safe with many of the studies reporting no complications, only minor complications such as calf pain or discomfort. The evidence for IPC for PAD was moderate in size and in quality, with five small sample size RCTs included. The studies provided low-quality evidence, small sample sizes, lack of blinding, lack of randomization, lack of control group, incomplete reporting of the study population characteristics, lack of statistical analysis results, and brief or no posttreatment follow-up period. The report concluded there is some potential benefit for PIC for patients with PAD however, there is substantial uncertainty about the safety and impact on health outcomes because of poor-quality, sparse data and conflicting study results. Published evidence shows no proven benefit for IPC for decreasing edema compared with compression stockings in patients with PAD following peripheral bypass surgery. In addition, there is insufficient evidence for IPC for patients with CLI who are not candidates for revascularization. Future studies should investigate at what point in the PAD disease continuum PIC provides the most benefit.

## *Clinical Practice Guidelines*

### European Society for Vascular Surgery (ESVS)

In 2019 (Conte et al.) the World Federation of Vascular Societies and ESVS provided guidelines on the management of chronic limb-threatening ischemia. The published studies supporting the guidelines did not show robust evidence from high quality trials. The guideline states:

- Consider IPC therapy in carefully selected patients (e.g., rest pain, minor tissue loss) in whom revascularization is not possible (Grade 2B).

### American Heart Association (AHA)/American College of Cardiology (ACC)

In a 2024 update (Gornick et al.) AHA/ACC provided guidelines on the management of patients with lower extremity peripheral artery disease. The guideline for IPC states:

- In patients with chronic limb-threatening ischemia (CLTI) for whom revascularization is not an option, arterial IPC devices may be considered to augment wound healing or ameliorate ischemic rest pain (Grade 2B).

## Treatment of Lymphedema or Chronic Venous Insufficiency (CVI) With Edema and Non-Healing Lower Extremity Ulcers

Alvarez et al. (2020) conducted a prospective, randomized-controlled, parallel-group, comparative trial to investigate whether IPC assisted the healing of venous ulcers in patients with lymphedema who were already receiving standard compression with short stretch or multilayered compression therapy. The study included 52 subjects with CVI and hard-to-heal lower leg ulceration (> 1-year-old and > 20-$cm^2$ surface area) were treated with either intermittent, gradient, pneumatic compression (n = 27) plus standard compression therapy or compression therapy alone (control). The median time to wound closure by nine months was 141 days for the IPC-treated group and 211 days for the control group ($p = 0.031$). The rate of healing was 0.8 ±0.4 mm/d for the control group and 2.1 ±0.8 mm/d for the group treated with IPC ($p < 0.05$). When compared with subjects treated with standard care, the group treated with IPC reported less pain at each evaluation point for the first six weeks of the trial. At weeks one, two and three, the visual analog pain scores were significantly lower for the IPC-treated group ($p < 0.05$) The authors concluded that the results suggest that IPC is a valuable adjunct to compression therapy in the management of large or painful venous ulcers. Limitations of the study include small sample size and short-term follow-up, and lack of masking using a sham device.

Lurie et al. (2017) conducted a multi-center RCT focusing on patient-outcomes of dual action therapy PCDs in comparison to compression stockings (CS) for patients with chronic venous disease (CVD). Eighty-nine patients (136 limbs) received either dual action therapy (AT group) with compression or CS. The results of the study showed compliance with compression was not significantly different between the groups (100% vs. 88%, AT and CS groups, respectively, at 15 days; 87% vs. 85% at the end of the study; $p = 0.97$). Daily use was not different either (10.7 hours in the AT group, 11.7 ±6 2.7 hours in the CS group). At the 30-day visit nearly one-third of all limbs decreased in volume ≥ 10% compared to baseline volume. The AT group demonstrated a significant volume reduction advantage compared with the standard compression garment use in obese patients (body mass index > 30). The authors concluded use of dual action therapy PCDs is comparable to CS in patient-centered outcomes. Limitations of the study include limited techniques, patient variability, pilot investigation, and small-sample size.

## *Clinical Practice Guidelines*

### European Society for Vascular Surgery (ESVS)

In 2022 (De Maeseneer et al.) the ESVS provided clinical practice guidelines on the management of CVD of the lower limbs. The guideline addressed the use of different compression modalities which included elastic compression stockings (ECS), inelastic bandages (IB), adjustable compression garments (ACG) and IPC. The recommendations for venous leg ulceration (VLU) and CVD with compression therapy states:

- For patients with active VLU, compression therapy is recommended (Grade 1A).
- For patients with active VLU, multilayer or IB or ACG, exerting a target pressure of at least 40 mmHg at the ankle, are recommended to improve ulcer healing (Grade 1A).
- For patients with active VLU, IPC should be considered when other compression options are not available, cannot be used, or have failed to promote ulcer healing. Grade 2a (weight of evidence/opinion is in favor of the usefulness/efficacy), Level B.
- For patients with mixed ulcer due to coexisting arterial and venous disease, modified compression therapy under close clinical supervision, with a compression pressure less than 40 mmHg may be considered, provided the ankle pressure is high than 60 mmHg. Grade 2b (usefulness/efficacy is less well established by evidence/opinion) Level C.
- For patients with healed VLU, long term compression therapy should be considered to reduce the risk of ulcer recurrence. Grade 2a (weight of evidence/opinion is in favor of the usefulness/efficacy), Level B.
- For patients with symptomatic CVD, ECS, exerting a pressure of at least 15 mmHg at the ankle, are recommended to reduce venous symptoms (Grade 1B).
- For patients with CVD and edema (CEAP clinical class C3), compression treatment, using below knee ECS, IB, or ACG, exerting a pressure of 20-40 mmHg at the ankle, is recommended to reduce edema (Grade 1B).

In 2022 (De Maeseneer et al.) the ESVS provided clinical guidelines on compression after treatment interventions for venous incompetence. ESVS further declares postprocedural compression is controversial, even if the vast majority of practitioners still use it in their daily practice.

In addition, several RCTs on postinterventional compression shows conflicting evidence and the duration of compression is equally controversial. In order to effectively compress the above knee GSV, eccentric compression is needed with a compression pad on top of the GSV. The recommendation states:

- For patients with superficial venous incompetence undergoing intervention, the duration of post-intervention compression, used to minimize postoperative local complications, should be decided on an individual basis (Grade 1A).

### American Vein and Lymphatic Society (AVLS)

In 2016 the American College of Phlebology and AVLS provided clinical practice guidelines for the treatment of venous disease. The recommendations state:

- Compression therapy is an effective method for the management of symptoms related to superficial disease but it does not correct the source of reflux. When patients have a correctable source of reflux definitive treatment should also be offered unless it is contraindicated or unwanted (Grade 1A).
- AVLS recommends against compression therapy as a prerequisite therapy for symptomatic venous reflux disease when other definitive treatments such as endovenous ablation are appropriate (Grade 1A).
- After interventional treatment, the use of a compression garment is recommended in the postoperative period. There is extra benefit to the patient in the form of reduced pain after use of compression. The compression dosage and duration are at the discretion and clinical judgment of the treating physician (Grade 2B).
- Superficial venous insufficiency is a chronic disease and as such recommendations for the patients with this disease should be counseled to wear a compression garment even after definite treatment has been provided. The compression dosage is at the discretion and clinical judgment of the treating physician (Grade 2C).
- Suggestive treatment of some CEAP C2 patients with isolated varices, by medical compression hose alone may be an acceptable form of treatment. A short 1-2 week trial of compression hose may be appropriate where an alternative etiology of symptoms is considered, e.g., musculoskeletal pain or neuropathy (spinal stenosis, sciatica, hip or knee arthritis, diabetic neuropathy etc.) (Grade 2C).

## Prevention of Deep Venous Thrombosis (DVT)

Kim et al. (2024) conducted a systematic review and meta-analysis to determine the effects of IPC intervention to prevent DVT in surgical patients. Sixteen RCTs met the inclusion criteria with 2,828 participants (1,389 in the intervention group and 1,436 in the control group). The results showed the overall effect size of IPC for DVT prevention was OR 0.81 (95% CI: 0.59-1.11), which was not statistically significant ($Z = 1.31$, $p = .190$). Heterogeneity was $I^2 = 68\%$ ($\chi^2 = 50.52$, df = 16, $p < .001$). The sixteen studies showed no difference in DVT incidence between the experimental and control groups. The authors concluded that IPC did not differ from pharmacotherapy in preventing DVT but was able to reduce the incidence of DVT compared with patients who did not receive any management of DVT prevention. Further studies should continue to confirm the effect of IPC on DVT incidence in surgical patients through well-designed RCTs. The limitations of the study include high heterogeneity of the surgery-related variables, clinical heterogeneity of IPC duration and methodology, and multiple methods of DVT diagnosis.

Herring et al. (2023) conducted a systematic review comparing the safety and efficacy of IPC and graduated compression stockings (GCS) used singularly and in combination for surgical patients . The review included 14 studies articles (12 RCTs and 2 retrospective studies), seven studies compared IPC and GCS directly, and the remaining seven compared a combination of IPC and GCS versus GCS alone. No studies were found comparing a combination against IPC alone. The results suggested that combination mechanical prophylaxis may be superior to GCS alone in high-risk patients. IPC appeared to have a superior safety profile, although it had a worse compliance rate, and the quality of evidence was poor. The addition of pharmacological prophylaxis may make mechanical prophylaxis unnecessary in the post-operative setting. The authors concluded IPC may be superior to GCS when used as a single prophylactic device. A combination of IPC and GCS may be more efficacious than GCS alone for high-risk patients. Further high-quality research is needed focusing on clinical relevance, safety and comparing combination prophylaxis. The limitations of the study include small sample size, heterogeneity of the literature and risk of bias.

In 2023 Zhang et al. conducted a systematic review on the incidence of venous thromboembolism (VTE) in neurosurgical interventions to establish an optimum prevention strategy since these patients usually have longer immobilization time after surgery and possible neurological deficits which can negativity influence mobility. This is an update to a 2012 review of thromboembolic events in patients undergoing spinal or intracranial neurosurgical procedures. In 2012 it was concluded that intracranial surgical patients were more at risk to develop a VTE compared to spinal surgery patients. Also, the use of antithrombotic prophylaxis in neurosurgical interventions lowers the VTE incidence from 30 to about 1.5 to 6%, that a twofold higher VTE rate was demonstrated in patients systematically screened for DVT in comparison to those clinically screened, and that subclinical DVT was described to be associated with the incidence of PE. However, large heterogeneity with respect to diagnostic methods for VTE events and variable antithrombotic prophylaxis prevented the authors from drawing firm conclusions on optimal treatment strategy. The current study now 10 years later utilized the Newcastle-Ottawa Quality Assessment Scale and Cochrane risk of bias to select twenty-five studies (21 case series, 3 comparative studies and 1 RCT) within the inclusion criteria. The results demonstrated VTE was substantially higher if the evaluation was done by duplex ultrasound (DUS), or another systematic screening method, in comparison to clinical evaluation (clin). Without prophylaxis DVT, incidence varied from 4 (clin) to 10% (DUS), studies providing low molecular weight heparin (LMWH) reported an incidence of 2 (clin) to 31% (DUS), providing LMWH and compression stockings (CS) reported an incidence of 6.4% (clin) to 29.8% (DUS), and providing LMWH and intermittent pneumatic compression devices (IPC) reported an incidence of 3 (clin) to 22.3% (DUS). Due to a lack of data, VTE incidence could not meaningfully be compared between patients with intracranial and spine surgery. The authors concluded low molecular weight heparin, compression stockings, and intermittent pneumatic compression devices were all evaluated to give reduction in VTE, but with the currently available data, no conclusion can be drawn on generalizing the optimum treatment strategy to lower the incidence of thromboembolic complications. Limitations of the study include selection bias and heterogeneity of the surgical intervention types.

In 2022 a Cochrane review (Kakkos, et al. 2022) assessed the efficacy of combined IPC and pharmacological prophylaxis compared to single modalities in preventing 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% (61/3,318) in the pharmacological prophylaxis group to 0.91% (31/3,419) in the combined group (OR 0.46, 95% CI 0.30 to 0.71; 15 studies, 6,737 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 DVT 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 DVT, 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 2,003 patients underwent randomization, 991 were assigned to the pneumatic compression group and 1,012 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 1,012 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 1,011 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 2024, 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 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 (89/1,667) than in the IPC group (38/1,680) (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 DVT, 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 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 1,438 patients allocated to IPC and 174 (12.1%) of 1,438 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 1,267 IPC participants compared with 174 of 1,245 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 DVT 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 DVT 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 DVT 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 DVT [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 DVT 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 DVT 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 DVT 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

In 2024 (Fenger-Eriksen et al.) updated the 2018 (Afshari et al.) European guidelines on perioperative VTE prophylaxis, the authors note that the use of graduated compression stockings (GCS) and IPC strongly differs between institutions. Most evidence does not support the use of mechanical prophylaxis alone. In patients at very high-risk of VTE, a combination of mechanical and pharmacological prophylaxis may further reduce DVT, and IPC appears to be more effective than GCS. 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).
- For each patient before surgery, an assessment of the risk of postoperative VTE and the bleeding related to both the surgical procedure and the patient’s characteristics (Grade 1B).
- In patients with a low thrombosis risk, such as day surgery and/or immediate mobilization: we recommend general measures of thromboprophylaxis (including early ambulation and optimal hydration) over mechanical or pharmacological prophylaxis (Grade 1B).
- In patients with low thrombosis risk such as hospitalized patients and/or postoperative immobilization, pharmacological prophylaxis is recommended over no prophylaxis (Grade 1C). Additional IPC is optional (Grade 2C).
- In hospitalized patients with a high thrombosis risk, we suggest prophylaxis with IPC if there is a high bleeding risk or contra-indication to pharmacological prophylaxis (Grade 2C).
- In patients with high thrombosis risk and a low bleeding risk, we suggest pharmacological prophylaxis plus optional IPC or GCS (Grade 2B).
- In patients with high thrombosis risk and high bleeding risk, we recommend IPC over no prophylaxis (Grade 1C).
- In patients with very high thrombosis risk, we suggest IPC plus pharmacological prophylaxis (Grade 1C).

## 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 statements 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 January 18, 2025)

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 January 18, 2025)

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# Policy History/Revision Information

| Date | Summary of Changes |
|---|---|
| 12/01/2025 | **Applicable Codes**<br>• Updated list of applicable HCPCS codes to reflect quarterly edits; added E0658 and E0659<br>**Supporting Information**<br>• Archived previous policy version CS097NE.R |

# 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 may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. The UnitedHealthcare Medical Policies 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.