MEDICAL POLICY

univera HEALTHCARE

Medical Policy Title	Powered Compression Devices/Lymphedema Pumps
Policy Number	1.01.17
Current Effective Date	November 20, 2025
Next Review Date	November 2026

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Standard pneumatic compression devices without calibrated gradient pressure (HCPCS codes E0650, E0651) and associated appliances are considered **medically appropriate** for home use when **ALL** of the following are met:

   A. When used for the treatment of proven intractable lymphedema, regardless of body part;

   B. Documented failure of a 4-week trial of conservative therapy which consists of **ALL** of the following:

      1. Regular and compliant use of an appropriate compression bandage system or compression garment to provide adequate graduated compression;

      2. Regular exercise; **and**

      3. Elevation of the affected body part; **and**

   C. The patient has undergone a supervised training program and is able to show proficiency in using the device.

II. Advanced pneumatic compression devices with calibrated gradient pressure (HCPCS codes E0652) and associated appliances are considered **medically appropriate** for home use when **ALL** of the following are met:

   A. The individual is otherwise eligible for a standard pneumatic compression pump, meeting the criteria in Policy Statement I; **and**

   B. The individual meets **EITHER** of the following:

      1. Documented failure of a standard pneumatic compression device without calibrated gradient pressure; **or**

      2. Documentation of unique characteristics (e.g., significant scarring) that prevent satisfactory pneumatic compression with a standard compression device without calibrated gradient pressure.

III. Compression devices are considered **investigational** for **ALL** other indications, including but not limited to:

   A. Venous statis ulcers;

   B. Peripheral artery disease (e.g., intermittent claudication, ischemia, arterial insufficiency)

(HCPCS code E0675);

C. Non-pneumatic compression pump or non-pneumatic sequential compression garment for **any** indication (e.g., Koya Dayspring, VenoWave) (HCPCS codes E0680, E0681, E0682, E0677, E0678, E0679, E0683).

Repair and Replacement

IV. Repair and/or replacement of a **medically necessary** powered compression device and/or components not under warranty will be considered **medically appropriate** when the following criteria are met:

A. Physician documentation includes **ALL** of the following:

1. date of device implantation/initiation,
2. manufacturer warranty information, **and**
3. attestation that the patient has been compliant with the use of device and will continue to benefit from the use of device; **AND ONE OF THE FOLLOWING APPLY**:

B. Repair of the currently used device when **ALL** of the following are met:

1. it is no longer functioning adequately,
2. inadequate function interferes with activities of daily living, **and**
3. repair is expected to make the equipment fully functional (as defined by manufacturer); **or**

C. Replacement of the currently used device when the following are met:

1. it is no longer functioning adequately, **AND EITHER**
2. has been determined to be non-repairable, **or**
3. the cost of the repair is in excess of the replacement cost; **or**

D. Replacement of the currently used device when **BOTH** of the following are met:

1. there is documentation that a change in the patient's condition makes the present unit non-functional, **and**
2. improvement is expected with a replacement unit.

V. Repair or replacement of equipment damaged due to patient neglect, theft, abuse, or when another available coverage source is an option (e.g., homeowners, rental, auto, liability insurance, etc.) is **ineligible for coverage**.

VI. The replacement of properly functioning powered device and/or external components is considered **not medically necessary**. This includes, but is not limited to, replacement desired due to advanced technology or in order to make the device more aesthetically pleasing.

RELATED POLICIES

Corporate Medical Policy

1.01.51 Limb Pneumatic Compression Devices for Venous Thromboembolism Prophylaxis

10.01.01 Breast Reconstruction Surgery and Prophylactic Breast Cancer Risk-Reducing Mastectomy

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

I. The Federal Women's Health and Cancer Right Act (WHRCA) of 1998, as well as the New York Insurance Law, mandates coverage of all stages of reconstructive surgery (including surgery and reconstruction of other breast to produce symmetrical appearance, chest wall reconstruction, prosthesis and treatment of physical complication following mastectomy such as lymphedema) for all group health plans, whether insured or self-funded, that provide medical and surgical benefits including mastectomies. Federal laws do not require a diagnosis of breast cancer (preventive mastectomies are also covered).

II. According to the New York State Insurance Laws for prostheses and physical complications of all stages of the mastectomy, including lymphedemas, while an issuer may perform a medical necessity review of these items or services, the issuer should use appropriate written clinical criteria and the most recent medical literature to determine medical necessity.

III. Medical documentation of **ALL** of the following criteria is required for consideration of a powered compression device/ lymphedema pump:

   A. The lymphedema is intractable (has been difficult to manage and nonresponsive to decongestive treatment). Documentation should include etiology, symptoms and objective findings, measurements establishing the severity of the condition, and the extent to which the lymphedema impairs function of the extremity causing pain and gross distention.

   B. Conservative treatments have been tried and found inadequate (e.g., leg/arm elevation, custom fabricated gradient pressure stockings or sleeves, and exercise).

   C. Appropriate oversight (e.g., instruction in the operation of the machine, amount of pressure to be used, frequency and duration of use, and ongoing monitoring of use and response to treatment) has been provided.

IV. Per the manufacturer's user guide (Tactile Medical, Minneapolis, MN), the Flexitouch and Flexitouch plus pneumatic compression devices have a two-year warranty for the controller and a five-year warranty for the garments and garment accessories. The average expected controller lifetime is five (5) years.

DESCRIPTION

Lymphedema is the abnormal accumulation of lymph fluid in the subcutaneous tissues, most commonly affecting the limbs, but it may also involve the chest, head and neck, or genitals. It is classified as either primary, due to a genetic malformation of the lymphatic system, or secondary, resulting from damage caused by surgery, radiation, or trauma. Although lymphedema is considered

incurable, early-stage cases may be reversible. Without appropriate treatment, the condition typically progresses.

Management focuses on nonsurgical therapies to reduce limb volume and maintain size, including compression garments, exercise, and pharmacologic support. The standard of care for stage II lymphedema is Complete Decongestive Therapy (CDT), which consists of skin care, manual lymphatic drainage (MLD) or self-administered MLD (SMLD), and compression bandaging. MLD, performed by trained therapists, is a key component of CDT but is not recommended as a standalone treatment for volume reduction.

Compression therapy devices, commonly referred to as lymphedema pumps, are used to promote lymphatic and venous fluid movement from the extremities toward central drainage areas. These devices help prevent complications associated with unmanaged lymphedema and are being investigated as adjunctive therapy for chronic venous insufficiency and venous stasis ulcers. By mimicking the natural pumping action of the calf muscles, they enhance circulation, reduce swelling, and support ulcer healing.

Compression devices are generally categorized into four types:

- Standard non-segmental compression pumps are single-chamber, non-programmable devices that apply uniform pressure across the entire limb during inflation. These basic pumps do not allow for pressure variation between limb regions. Examples include the KCI Extremity Pump 7000 and Huntleigh Flowpress.
- Standard segmental compression pumps feature multiple chambers that inflate sequentially, delivering fixed pressure either equally or following a preset gradient. These non-programmable devices offer more targeted compression than non-segmental models. Examples include the Flowtron Hydroven FPR, KCI Extremity Pump 7500, Lympha Press, Petite Basic 701A, and BioCompression Pump Model 2004.
- Advanced pneumatic compression devices (APCDs) are programmable segmental pumps that deliver calibrated gradient pressure, higher distally and lower proximally, to promote central lymphatic and venous flow. Each chamber's pressure can be individually adjusted, allowing for customized therapy, especially beneficial for patients with localized sensitivity, scarring, or pain. Examples include the Flexitouch System, which features a two-phase treatment cycle, and the ACTitouch System, a wearable device offering both intermittent and sustained compression for venous ulcer management.
- Non-pneumatic compression devices utilize mechanisms other than air pressure to promote lymphatic drainage and improve circulation. These portable devices are designed for mobility during treatment, making them suitable for daily activities. Examples include the Koya Dayspring and Dayspring Lite, which use shape-memory flex frames embedded in wearable garments to provide sequential calibrated gradient pressure. Another example is the Venowave VW5, a battery-operated device worn below the knee that uses peristaltic motion to promote upward fluid displacement in the lower limbs.

SUPPORTIVE LITERATURE

Lymphedema- Pneumatic Compression Applied to Extremities

Multiple moderate-to-high quality randomized controlled trials (RCTs) and systematic reviews have demonstrated significant improvements in lymphedema outcomes with the use of pneumatic compression pumps compared to conservative care alone.

Hou et al (2024) conducted a systematic review and meta-analysis of 12 studies (identified through March 2024) to assess the efficacy of intermittent pneumatic compression (IPC) as an adjunct to complete decongestive therapy (CDT) for treatment of breast cancer-related upper limb lymphedema. The results indicated that adding IPC to CDT enhanced lymphedema reduction during the initial 4 weeks of treatment. However, this benefit diminished over time, with reduced effectiveness observed approximately 9.4 ± 2.6 weeks after discontinuation of physical therapy. To sustain the synergistic effects of CDT and IPC in promoting lymphatic drainage and symptom relief, the authors recommend periodic and ongoing treatment. Treatment durations across the included studies ranged from 4 to 12 weeks, which may introduce potential bias.

Yao et al (2024) performed a systematic review and meta-analysis of nine RCTs comparing decongestive lymphatic therapy (DLT) with and without IPC in managing upper limb lymphedema following breast cancer surgery. The pooled standardized mean difference for percentage volume reduction was 0.63, indicating no statistically significant difference between the two groups ($p = .15$). Pain and heaviness scores were also similar. However, a significant improvement in external rotation joint mobility was observed in the DLT plus IPC group. These findings suggest that while DLT with IPC is as effective as DLT alone in reducing lymphedema volume and symptoms, it may offer additional benefits in improving joint mobility.

Zaleska and Krzesniak (2025) investigated the effects of a single 45-minute IPC session on fluid movement in patients with stage II and III breast cancer-related lymphedema (BCRL). The study included 25 patients and utilized indocyanine green imaging to assess lymphatic flow before and after treatment. Post-treatment, 92% of patients showed fluid movement in the upper arm, with newly identified drainage pathways directed toward the ipsilateral supraclavicular lymph node (30%), ipsilateral axilla (22%), and axilla, chest, and scapula (26%). Fluorescent intensity changes revealed decreased signal in the hand and forearm, increased signal in the arm (64%), and overall reduction along some or all limb segments (36%). Additionally, skin, and subcutaneous tissue stiffness decreased at all limb levels, with statistically significant reductions in the middle forearm (36.4%) and elbow (33.4%). The authors concluded that IPC effectively promotes proximal fluid movement, facilitates compensatory lymphatic drainage pathways, and reduces tissue stiffness. Early application of IPC was recommended to prevent limb enlargement and secondary tissue changes.

Lymphedema - Pneumatic Compression Applied to Chest or Trunk

There is limited evidence in the peer-reviewed literature that pneumatic compression pumps applied to the chest and/or trunk provides incremental improvement beyond that provided by pumps treating the affected limb only.

Ridner et al (2012) conducted a RCT to evaluate the effectiveness of advanced pneumatic

compression therapy applied to the trunk, chest, and arm (experimental group; n=21) versus treatment of the arm alone (control group; n=21) in patients with stage II breast cancer-related lymphedema. The Flexitouch System was used for both groups at home for 30 days. Statistically significant reductions in bioelectrical impedance and arm circumference were observed within each group; however, no statistically significant difference was found between the two groups. These findings suggest that while both treatments are effective in reducing lymphedema symptoms, there may be no added benefit to pneumatic treatment of the trunk and/ or chest for arm lymphedema. The authors recommend further research with a larger sample size to confirm these findings.

Fife et al (2012) conducted a randomized trial comparing the Flexitouch advanced pneumatic compression device (APCD) with a standard pneumatic compression device (SPCD), the Bio Compression Systems Sequential Circulator, in 36 women across three centers. All participants had at least 5% upper extremity edema volume and were randomized to use either device for one hour daily over 12 weeks (n=18 per group). The SPCD treated only the arm, while the APCD used three garments to treat the arm, chest, and truncal quadrant. Outcome assessments were performed by experienced lymphedema therapists, although blinding procedures were not reported. Edema outcomes were available for all participants, while local tissue water data were available for 28 (78%). At 12 weeks, two of the four primary outcomes showed statistically significant improvements favoring the APCD: percent edema volume reduction ($p = .047$) and tissue water content ($p = .049$). No significant differences were observed in absolute arm volume ($p = .141$) or edema volume in milliliters ($p = .050$). Study limitations include the small sample size, missing data, and lack of clarity regarding assessor blinding. The authors concluded that the observed improvements with APCD use warrant further, more comprehensive research.

<u>Lymphedema - Pneumatic Compression Applied to the Head and Neck</u>

The current literature on the use of the Flexitouch system for head and neck lymphedema (HNL) is limited and primarily consists of a few industry-sponsored randomized controlled trials (RCTs). These studies suggest that the device may offer modest reductions in HNL.

Mayrovitz et al (2017) conducted a functional usability study involving 44 patients with HNL. Participants reported the devices was comfortable and subjective improvement after a single treatment. However, the study was limited by its single-arm, single-treatment design and did not assess long-term home use. A secondary objective assessed safety and acute changes in edema using facial and neck measurements. Statistically significant reductions were observed in composite facial (82.5 ± 4.3 cm to 80.9 ± 4.1 cm; $p < .001$) and neck (120.4 ± 12.2 cm to 119.2 ± 12.1 cm; $p < .001$) measurements, with no adverse events reported. Despite its limitations, the study suggests potential short-term benefits of the device.

Gutierrez et al (2019) evaluated the effects of advanced pneumatic compression device APCD treatment in ten head and neck cancer (HNC) survivors who underwent facial composite measurements and near-infrared fluorescence lymphatic imaging (NIRFLI) before and after (APCD) treatments. After a single pneumatic compression treatment, NIRFLI showed enhanced lymphatic uptake and drainage in all subjects. After two weeks of daily use, dermal backflow was reduced or resolved in six of the eight participants with baseline backflow. The authors noted that reductions in facial measurements generally aligned with imaging improvements and patient-reported outcomes.

However, they emphasized the need for longer-term studies to determine sustained efficacy and the potential of APCD to reverse dermal backflow in HNL.

Gutierrez et al (2020) conducted an observational study to assess self-reported outcomes and satisfaction among 205 HNC survivors using the Flexitouch APCD for HNL. After at least 25 days of home use, participants completed pre- and post-treatment assessments evaluating efficacy, function, and symptom relief. Statistically significant improvements were observed across all symptom and function domains ($p < 0.00001$), based on the Wilcoxon Signed Rank test. Compliant use for a minimum of 30 minutes per day was high, with 71% reporting daily use and 87% expressing overall satisfaction. These findings support the device's potential for improving quality of life in HNL patients, though the study relied on self-reported data and lacked a control group.

Ridner et al (2021) conducted a randomized, wait-list controlled trial involving 49 patients (control group, n=24; intervention group, n=19). A total of 43 patients completed the study. All participants were assessed at 1, 4, and 8 weeks. The intervention group reported 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 $p = 0.005$). However, there was no statistically significant differences were found in functional outcomes ($p=0.312$ - $p=0.615$) or in inflammatory biomarker levels ($p>0.10$) between groups from baseline to 8 weeks. Compliance was low, with only one participant using the device the prescribed. The authors concluded that the device appears safe and feasible for HNL management, but acknowledge the need for larger, more diverse RCTs.

Shires et al (2022) conducted a non-industry-sponsored retrospective cohort study evaluating patient-reported outcomes following prolonged home use of the Flexitouch APCD for HNL. Of the 35 patients approved for home-based therapy, the average time from cancer treatment completion to therapy initiation was 9 months. Common symptoms included stiffness (n=31), pain (n=29), dysphagia (n=20), and swelling (n=9). Compliance was high: 33 patients used the device daily, one used it twice daily, and one was non-compliant. The average duration of use was 4.4 months. Patients reported improvements in fibrosis, daily functioning, and overall satisfaction, supporting the potential value of home-based APCD therapy.

Tritter et al (2022) conducted a small pilot study to investigate anecdotal reports of improved dysphagia and dysphonia following pneumatic compression garment therapy (PCGT) in patients with cervical lymphedema post-radiation for head and neck cancer (HNC). Seven patients who had used PCGT for at least six months were surveyed. While 85% reported subjective improvement, objective laryngoscopic assessments showed no significant change in laryngeal edema scores ($p = .975$). The authors noted that low inter-rater reliability may have affected the results. Despite the lack of objective findings, the authors concluded that the strong patient-reported benefits suggest the need for further formal investigation.

Cheng et al (2023) performed a systematic review and meta-analysis of 23 studies (n=2147 participants) published through January 2023 evaluating rehabilitation interventions for HNL. Interventions were categorized as standard lymphedema therapy (e.g., standard or modified CDT, early manual lymphatic drainage, focused exercise) and adjunct therapies (e.g., APCDs, kinesio taping, photobiomodulation, acupuncture Six studies (n=399) specifically assessed the Flexitouch APCD, including one RCT and five observational studies. Intervention durations ranged from a single

session to six months. Most studies involved participants who had completed or were undergoing CDT, though one study noted no CDT use among its participants. Four studies (80%) were industry-funded or had author affiliations with the manufacture. While reported outcomes were generally positive, the studies were rated as low quality due to high risk of bias. The authors concluded that APCDs may be beneficial and appear safe, but higher-quality research is needed to inform treatment guidelines.

Gregor et al (2025) conducted a proof-of-concept study to evaluate the immediate effects of external advanced pneumatic compression (APC) on pharyngeal and laryngeal head and neck cancer-related lymphedema (HNCRL) using fluoroscopic imaging. Thirty patients underwent imaging before and after a single APC session. All participants demonstrated significant reductions in both external and internal lymphedema. The authors concluded that fluoroscopy is a clinically valuable tool for detecting and quantifying internal HNL and may complement clinical assessment for detecting, monitoring, and quantifying internal HNCRL.

Pneumatic Compression for Venous Insufficiency with Venous Statis Ulcer(s)

There is insufficient evidence in the peer-reviewed literature to establish that intermittent pneumatic compression (IPC) improves outcomes in patients with chronic venous insufficiency (CVI) or venous stasis ulcers.

A Cochrane review updated by Nelson et al (2014) examined whether IPC improves the healing outcomes in patients with of venous leg ulcers. In a meta-analysis of three of the five trials the added benefit of IPC over continuous compression therapy alone, combined treatment was associated with a significantly higher healing rate. However, two of the three trials included in the meta-analysis were judged to have a high risk of bias due to issues such as lack of blinding and unclear allocation or concealment methods. Additionally, there was substantial heterogeneity among the studies, and results from other randomized controlled trials (RCTs) were not pooled. Notably, two trials comparing IPC with continuous compression (stockings or bandages) did not find statistically significant differences in healing rates between groups.

A RCT by Dolibog et al (2014), published after the Cochrane review's literature search cutoff, compared five types of compression therapy for venous leg ulcers. The study evaluated changes in ulcer surface area, volume, linear dimensions, and healing rates. The treatment modalities included: intermittent pneumatic compression (IPC) using a 12-chamber Flowtron device, compression stockings, multilayer bandages, two-layer bandages, and Unna boots. A total of 147 patients with unilateral venous leg ulcers were randomized into one of the five treatment groups. After two months, the highest healing rates were observed in the IPC group (57%; 16/28 patients), the ulcer stocking system group (56%; 17/30), and the multilayer bandage group (58%; 17/29). In contrast, significantly lower healing rates were reported in the two-layer bandage group (16%; 5/30) and the Unna boot group (20%; 6/30).

Alvarez et al (2020) conducted a small RCT involving patients (n= 52) with large chronic venous leg ulcers (>20 cm^2). The study compared intermittent pneumatic compression (IPC) plus standard compression therapy (n=27) to standard compression therapy alone (n=25), which consisted of multilayer compression bandages. IPC was administered for one hour, twice daily. At nine months,

the median time to complete wound closure was significantly shorter in the IPC group compared to the control group (141 days vs. 211 days; p=.03). Additionally, greater pain relief was reported in the IPC group during the first three weeks of treatment, although pain levels were similar between groups at later time points.

A meta-analysis by Xu and Li (2023) was retracted in August 2024 due to findings that the peer review and publishing process for the article were found to be manipulated.

Pneumatic Compression for Arterial Insufficiency

There is insufficient evidence in the peer-reviewed literature to establish that intermittent pneumatic compression (IPC) improves outcomes in patients with chronic arterial insufficiency. Preliminary studies have proposed that IPC improves exercise tolerance in a model of peripheral arterial insufficiency, in part, by enhancing blood flow to collateral-dependent tissues but further research is needed to validate use for these indications.

Moran et al (2015) conducted a systematic review on the use of intermittent pneumatic compression (IPC) for patients with critical limb ischemia (CLI) who were not candidates for revascularization. The review included two controlled before-and-after (CBA) studies and six case series; no randomized controlled trials were identified. One retrospective CBA study using calf compression reported improved limb salvage and wound healing ($p < .01$). Another prospective CBA study using sequential compression of the foot and calf showed statistically significant improvements in claudication distance and quality of life. All included studies had a high risk of bias. The authors concluded that while IPC may be associated with improvements in limb salvage, wound healing, and pain management, the treatment remains unproven due to the lack of well-designed analytical studies.

Zaki et al (2016) performed a retrospective analysis involving 187 patients with critical limb ischemia, comparing outcomes between those who used a specific sequential pneumatic compression device and those who did not receive IPC therapy. The primary endpoint was limb salvage, with secondary endpoints including amputation-free survival and improvements in toe pressure. Among device users, amputation-free survival rates were 98% at 6 months and 96% at 12 months, compared to 90% and 84%, respectively, in the non-user group. Although the difference in limb salvage was not statistically significant ($p = .714$), significant improvements were observed in rest pain ($p < .0001$), reduction in minor amputations ($p = .023$), and overall amputation-free survival (p-value not fully reported).

Non-Pneumatic Compression

There are a few manufacturer-sponsored trials published in 2022. Rockson et al (2022a) conducted an open-label pilot study to the safety, efficacy, and impact on quality of life (QoL) of a novel wearable compression device, Dayspring, for the treatment of upper extremity lymphedema secondary to breast cancer. The study enrolled 40 participants, who used the device for 28 days. Participants in the intervention group received intermittent pneumatic compression therapy for approximately 44 minutes per day, with an adherence rate of 98%. At the end of the study period, participants experienced a statistically significant 18% improvement in overall QoL, as measured by the Lymphedema Quality-of-Life Questionnaire ($p < 0.001$). Additionally, there was a statistically significant reduction in limb volume (mean decrease of 2%; range: 1–12%; $p = 0.042$). The contralateral (non-study) arm showed a negligible, non-significant volume increase of 0.4% (p =

0.042). The authors concluded that the Dayspring device appears to be safe, well-tolerated, and effective in improving both limb volume and quality of life in patients with breast cancer-related lymphedema. They recommended further research to validate these findings in larger, controlled trials.

Rockson et al (2022b) conducted a non-randomized, open-label study to evaluate the safety and effectiveness of the Koya Dayspring device for lower limb lymphedema. The study enrolled 24 participants who used the Dayspring lower leg garment for one hour daily over a 12-week period. Participants were encouraged to remain active while wearing the device. The primary outcomes included changes in quality of life (QoL) and lower limb volume. Only 18 participants completed the study. Results showed an 8% improvement in QoL and a 39.4% reduction in lower limb edema compared to baseline, during which no compression pump had been used. Despite these promising findings, the study was limited by its small sample size and lack of a control group. The authors concluded that while the results are encouraging, larger, well-designed, and long-term studies are needed to establish the role of nonpneumatic compression therapy in standard lymphedema treatment protocols.

Rockson et al (2022c) reported findings from the NILE study, a multicenter randomized crossover head-to-head trial comparing the novel nonpneumatic Koya Dayspring to the APCD, the Flexitouch, in 50 adult women with unilateral breast cancer-related upper extremity lymphedema. Participants were randomized to use either the nonpneumatic compression device (NPCD) or the APCD for 28 days, followed by a 4-week washout period, and then crossed over to the alternate device for another 28 days. Compared to the APCD, NPCD resulted in a significantly greater mean reduction in limb edema volume (64.6% vs. 27.7%; $p < .001$), greater improvements in QoL scores, higher adherence (95.6% vs. 49.8%; $p < .001$), and greater patient satisfaction (90% vs. 14%; $p < .001$). Participants also reported that the NPCD facilitated exercise and was more convenient for travel. No adverse events were reported. No adverse events were reported. There was a significant difference in reported compliance between groups, with 95.6% of Dayspring subjects complying with the 60-minute per day therapy and only 49.8% of the control group subjects complying. The authors concluded that the NPCD was noninferior to the APCD in reducing edema volume and offered superior outcomes in symptom relief, adherence, and patient satisfaction.

Barfield et al (2025) conducted the TEAYS study, a randomized, prospective, multicenter, crossover head-to-head trial designed to evaluate the safety and efficacy of a novel NPCD compared to an APCD for treating lower extremity lymphedema. Following a 30-day washout period without pneumatic therapy, 71 patients (108 affected limbs) were randomized to receive either NPCD or APCD treatment for 90 consecutive days. After this initial phase, participants underwent another 30-day washout period before crossing over to the alternate device for an additional 90 days. Outcome measurements were assessed at baseline and at the end of each 90-day treatment period, with patient-reported outcomes collected at the conclusion of the study. The NPCD group demonstrated a significantly greater mean reduction in limb edema volume compared to the APCD group (369.9 mL vs. 83.1 mL; $p < .05$). Quality of life improvements were also significantly greater with NPCD (mean change of 1.01; $p < .05$) compared to APCD (0.17; $p > .05$). Additionally, patients reported higher adherence with the NPCD (81% vs. 56%; $p < .001$) and greater satisfaction (78% vs. 22%). No device-related adverse events were reported. While the study was industry-funded and subject to

potential biases common in crossover designs, the authors concluded that the TEAYS findings, in conjunction with prior research, support the NPCD as a differentiated and potentially superior treatment option for managing lower extremity lymphedema.

PROFESSIONAL GUIDELINE(S)

Pneumatic Compression for Lymphedema

In 2022, the American Venous Forum (AVF), American Vein and Lymphatic Society (AVLS), and the Society for Vascular Medicine (SVM) published an expert opinion consensus statement on lymphedema diagnosis and treatment (Lurie 2022). The following statements were issued regarding use of pneumatic compression:

- "Sequential pneumatic compression should be recommended for lymphedema patients." (92% panel agreement; 32% strongly agree)
- "Sequential pneumatic compression should be used for treatment of early stages of lymphedema." (62% panel agreement - consensus not reached; 38% panel disagreement; 2% strongly disagreed)

Pneumatic Compression for Venous Insufficiency with Venous Ulcer(s)

According to the 2014 joint guidelines from the Society for Vascular Surgery and the American Venous Forum on the management of venous ulcers, when IPC is used, rapid compression cycling appears to improve ulcer healing rates compared to slow cycling (86% vs 61% at 6 months; p=.003) (O'Donnell 2014). The guidelines state:

- "We suggest use of intermittent pneumatic compression when other compression options are not available, cannot be used, or have failed to aid in venous leg ulcer healing after prolonged compression therapy." (Grade – 2, Level of Evidence – C).

The 2025 NCCN clinical practice guidelines on cancer survivorship, version 2.2025, recommend education to identify signs and symptoms of lymphedema, as well as self-care management, skin care, and self-bandaging. The guidelines also recommend consideration of compression garments, manual lymphatic drainage, and pneumatic compression for ongoing home management.

The Wound Healing Society updated guidelines for venous ulcers in 2015 (Marston 2016). The guidelines recommend that for patients with venous ulcers, intermittent pneumatic pressure can be used with or without compression dressings and can provide another option in patients who cannot or will not use an adequate compression dressing system. Venous ulcers of the lower extremity are a chronic, long-term problem. Recurrence rates are as high as 70%; therefore, long-term maintenance must be addressed even for healed ulcers.

In 2019, the American Academy of Family Physicians published recommendations for diagnosis and treatment of venous ulcers (Bonkemeyer 2019). The following statements were issued regarding use of intermittent pneumatic compression.

- "Intermittent pneumatic compression may be considered when there is generalized, refractory edema from venous insufficiency; lymphatic obstruction; and significant ulceration of the lower

> extremity. Although intermittent pneumatic compression is more effective than no compression, its effectiveness compared with other forms of compression is unclear. Intermittent pneumatic compression may improve ulcer healing when added to layered compression."

In 2022, the AFF/AFLS/SVM expert opinion consensus on lymphedema diagnosis and treatment reached consensus that all patients with chronic venous insufficiency (C3–C6) should be considered for treatment similar to lymphedema patients (Lurie 2022). Studies have demonstrated that sequential pneumatic compression (SPC) results in more rapid healing of chronic venous stasis ulcerations compared to traditional compression bandages.

The 2022 European Society for Vascular Surgery (ESVS) issued clinical practice guidelines on the management of chronic venous disease of the lower limbs (De Maeseneer 2022).

- IPC has a limited role in the conservative treatment of CVD. There are no consistent data available on the use of IPC in CEAP clinical class C0s - C4.
- For patients with active venous leg ulceration, intermittent pneumatic compression should be considered when other compression options are not available, cannot be used, or have failed to promote ulcer healing. (Class IIb recommendation; Level of evidence B)

<u>Pneumatic Compression for Arterial Insufficiency</u>

The Wound Healing Society updated its guidelines in 2023 for the treatment of arterial insufficiency ulcers, reaffirming its 2014 recommendation. The guidelines state that intermittent pneumatic compression (IPC) can increase blood flow and may be beneficial for limbs with impaired distal perfusion, either as a pre- or post-revascularization intervention (Level II evidence) (Federman 2014, 2024).

In 2024, the American College of Cardiology (ACC) and the American Heart Association (AHA), in collaboration with other organizations, issued a joint clinical practice guideline for the management of lower extremity peripheral artery disease (PAD) (Gornik 2024). For patients with chronic limb-threatening ischemia (CLTI) who are not candidates for revascularization, the use of arterial IPC devices may be considered to support wound healing and alleviate ischemic rest pain. This recommendation carries a Class 2b strength (weak recommendation) and is based on moderate-quality evidence from non-randomized studies.

REGULATORY STATUS

The Federal Women's Health and Cancer Right Act (WHRCA) of 1998, as well as the New York Insurance Law, mandates coverage of all stages of reconstructive surgery (including surgery and reconstruction of other breast to produce symmetrical appearance, chest wall reconstruction, prosthesis and treatment of physical complication following mastectomy such as lymphedema) for all group health plans, whether insured or self-funded, that provide medical and surgical benefits including mastectomies. Federal laws do not require a diagnosis of breast cancer (preventive mastectomies are also covered).

According to the New York State Insurance Laws for prostheses and physical complications of all

stages of the mastectomy, including lymphedemas, while an issuer may perform a medical necessity review of these items or services, the issuer should use appropriate written clinical criteria and the most recent medical literature to determine medical necessity.

The United States Food and Drug Administration (FDA) regulates compression pumps as medical devices. All devices require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2025 Oct 21]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. on our website by the date that the FDA posts the information on our website. Available from: https://www.fda.gov/medical-devices/medical-device-safety/medical-device-recalls [accessed 2025 Oct 21]

Pneumatic Compression

Several pneumatic compression pumps, indicated for the primary or adjunctive treatment of primary or secondary (e.g., postmastectomy) lymphedema, have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. Examples of devices with these indications intended for home or clinic/hospital use include the Sequential Circulator (Bio Compression Systems); the Lympha-Press and Lympha-Press Optimal (Mego Afek); the Flexitouch and Flexitouch Plus systems (Tactile Medical, formerly Tactile Systems Technology); the Powerpress Unit Sequential Circulator (Neomedic); and the EzLymph and EzLymph M (EEZCare Medical).

Several pneumatic compression devices have been cleared by the FDA for treatment of venous stasis ulcers. Examples include the Lympha-Press, Flexitouch, Flexitouch Plus, and Recovery+ (Pulsar Scientific).

Non-Pneumatic Compression

In 2021, the FDA granted Class II 510(k) clearance for marketing two non-pneumatic, battery-operated, wearable compressible limb devices: the Koya Dayspring System and Dayspring Lite.

- Koya Dayspring system is a prescription-only wearable compression device designed to enhance lymphatic flow. It is indicated for a wide range of conditions, including lymphedema (primary and secondary), post-mastectomy edema, edema following trauma or sports injuries, post-immobilization edema, venous insufficiency, delayed wound healing, stasis dermatitis, venous stasis ulcers, arterial and diabetic leg ulcers, lipedema, and phlebolymphedema.
- Dayspring Lite is also a prescription-only wearable compression system, indicated for the treatment of chronic edema, lymphedema, venous insufficiency, and to support wound healing.

In 2008, the Venowave VW5 initially received FDA clearance in 2008 and was granted an updated 510(k) approval in 2024. This nonpneumatic, battery-operated device is intended for use in adults (18 years and older) to manage symptoms associated with post-thrombotic syndrome (PTS), reduce postoperative pain and swelling, and improve blood circulation. It is also indicated for the prevention

of deep vein thrombosis (DVT), primary thrombosis, lymphedema, leg swelling due to vascular insufficiency, varicose veins, chronic venous insufficiency, and intermittent claudication.

The 2024 updated contraindications for the Venowave VW5 specify that the device "should not be used to treat patients who have open or freshly healed ulcers, other wounds, or otherwise fragile skin between the knee and ankle of the leg to be treated."

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
Not Applicable	

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HCPCS Codes

Code	Description
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
E0656	Segmental pneumatic appliance for use with pneumatic compressor, trunk
E0657	Segmental pneumatic appliance for use with pneumatic compressor, chest
E0658	Segmental pneumatic appliance for use with pneumatic compressor, integrated, 2 full arms and chest (effective 10/01/25)
E0659	Segmental pneumatic appliance for use with pneumatic compressor, integrated, head, neck, and chest (effective 10/01/25)
E0660	Nonsegmental pneumatic appliance for use with pneumatic compressor, full leg

Code	Description
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 (E/I)	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
E0677 (E/I)	Nonpneumatic sequential compression garment, trunk
E0678 (E/I)	Nonpneumatic sequential compression garment, full leg
E0679 (E/I)	Nonpneumatic sequential compression garment, half leg
E0680 (E/I)	Nonpneumatic compression controller with sequential calibrated gradient pressure
E0681 (E/I)	Nonpneumatic compression controller without calibrated gradient pressure
E0682 (E/I)	Nonpneumatic sequential compression garment, full arm
E0683 (E/I)	Nonpneumatic, nonsequential, peristaltic wave compression pump

ICD10 Codes

Code	Description
Multiple Codes	

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SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Pneumatic Compression Devices (NCD 280.6) [accessed 2025 Oct 25]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.
- If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

POLICY HISTORY/REVISION

Committee Approval Dates

09/26/02, 10/23/03, 09/23/04, 10/27/05, 12/07/06, 02/28/08, 04/23/09, 08/27/09, 08/26/10, 02/27/12, 02/28/13, 02/27/14, 02/26/15, 02/25/16, 06/22/16, 06/22/17, 04/26/18, 04/25/19, 04/23/20, 04/21/22, 06/22/23, 05/16/24, 12/19/24, 11/20/25

Date	Summary of Changes
11/20/25	• Annual review. Clarifying and updating edits to terminology. Policy statement revised to change compression therapy for the treatment of chest/trunk and head/neck lymphedema from investigational to medically necessary.
01/01/25	• Summary of changes tracking implemented.
09/26/02	• Original effective date