

Pneumatic Compression Devices

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Summary

Pneumatic Compression Devices, or PCDs, are a type of durable medical equipment that are used to improve venous blood return and lymphatic fluid movement. The device involves an inflatable garment and a pump; the pump inflates the garment with air to compress a specific body part with the goal of assisting with the circulation of blood or lymph fluid. This can be therapeutic in patients who may require additional care over static compression therapy (in which bandages or hosiery are used to apply a constant pressure gradient along an affected limb). There are many variations including unicompartmental devices with or without manual control, multicompartmental devices with or without manual control, high pressure rapid inflation pumps, two-stage multichamber programmable PCDs, and combination cold/compression pumps. Certain devices are not appropriate for all types of venous and lymphatic return impairments, and consultation with your healthcare provider can help determine the best initial therapy.

Definitions

“Pneumatic Compression” refers to the use of air to inflate and deflate a cuff to mimic a rhythmic squeezing motion.

“Unicompartmental devices,” or **non-segmented devices**, are a type of appliance that has only one inflatable chamber. These are typically used with a compressor that has a single outflow tube, and allows for an equal amount of pressure to be applied across the entire device.

“Multicompartmental devices,” or segmented devices, are a type of appliance where there are multiple inflatable chambers. These can be used with a compressor that has a single outflow tube, similar to unicompartmental devices, but certain designs of the chambers can allow for a gradient of pressure to be applied, meaning that one compartment can have less pressure than the adjacent compartment. This is a predetermined pressure gradient inherent to the design of the device, and cannot be manually controlled (e.g. non-programmable)

“Calibrated gradient pressure” (e.g., programmable) is a feature of certain devices where the compressor has multiple outflow tubes that allow for the individual to manually control the pressure in three or more inflatable chambers. This is different than the predetermined pressure gradient that can be set up by the design of the chambers, as seen in the non-programmable appliance. In unicompartmental programmable devices, there is only one inflatable chamber, but it can be programmed to different pressures. In multicompartmental programmable devices, there are multiple chambers which can be individually programmed to different pressures.

“Advanced multicompartmental programmable pneumatic compression” are multi-stage devices that work by priming the proximal tissues first with compression followed by compression of the distal extremity, similar to manual lymph drainage. The initial compression is usually proximal to the affected extremity, (e.g., the "preparatory stage") followed by a second programmed compression of the affected extremity, (e.g., the "drainage" stage)

“High pressure rapid inflation” devices are similar to traditional PCDs, except they apply significantly higher pressure and cycle more rapidly. These have been proposed for the treatment of arterial insufficiency or peripheral arterial disease.

“Immobile” or “bedridden” describes a clinical scenario where a patient has limited ability to leave bed or who has limited mobility. This can be transient, such as during recovery from a major orthopedic surgery or trauma, or it can be more long-standing such as loss of function after spinal cord paralysis. A state of immobility can increase risk for deep venous thrombosis and subsequent pulmonary emboli.

“Lymphedema” is a condition where the lymph fluid is not effectively circulated back to the bloodstream, resulting in swelling of the affected region.

“Deep vein thrombosis (DVT)” is a condition where a blood clot forms in one of the deep veins, which can be associated with acquired syndrome, genetic factors, or prolonged immobilization (venous stasis). Using a PCD on a limb with known or suspected DVT could result in a pulmonary embolism as the movement of the PCD could break the clot loose and move it further towards the central circulatory system.

“Chronic venous insufficiency” is a condition where the blood in the veins of distal extremities is not effectively circulated back to the heart. When the blood is not well circulated, the local tissues can be damaged resulting in edema and the formation of stasis ulcers.

Covered Services and Clinical Indications

General Coverage Criteria

Oscar covers a unicompartmental or multicompartmental pneumatic compressor without a calibrated gradient pressure when the condition specific criteria below and **ALL** of the following is present:

1. Expected duration of injury, disease, and/or immobility must be provided; **and**
2. The member's medical history including any contraindication and/or trial and failure of conservative therapy has been documented in the medical record; **and**
3. The PCD will not be used on a limb with a suspected or known DVT.

Condition Specific Criteria

Oscar covers a unicompartmental or multicompartmental pneumatic compressor without a calibrated gradient pressure when the general coverage criteria above and **ONE** of the following is present:

1. Deep venous thrombosis (DVT) prevention for members who meet **all** of the following:
 - a. Immobile or bedridden, as defined above; **and**
 - b. Member is unable to use other compression interventions such as compression stockings due to specific medical comorbidities or contraindications; **and**
 - c. Member has no absolute contraindications, including, but not limited to:
 - i. Arterial occlusive disease with an ankle-brachial pressure index <0.5; **or**
 - ii. NYHA Class III or IV heart failure; **or**
 - iii. Suspected or known DVT; **or**
 - iv. Acute cellulitis, infection, or necrotic tissue
2. Chronic venous insufficiency with venous stasis ulcers in member who meet **ALL** of the following:
 - a. Failure to show decrease in size and/or symptoms after at least 6 months of conservative therapy, which includes ALL of the following (or contraindications to the following):
 - i. Compression garment or bandage system; **and**
 - ii. Appropriate dressing for wound; **and**
 - iii. Exercise; **and**
 - iv. Elevation of the limb; **and**
 - b. Member has no absolute contraindications, including, but not limited to:
 - i. Arterial occlusive disease with an ankle-brachial pressure index <0.5; **or**
 - ii. NYHA Class III or IV heart failure; **or**
 - iii. Suspected or known DVT; **or**
 - iv. Acute cellulitis, infection, or necrotic tissue
3. Symptomatic lymphedema that meets **ALL** the following:
 - a. Documentation of ONE of the following:
 - i. Lymphedema with skin involvement; **or**
 - ii. Medical records confirming persistent lymphedema; **and**
 - b. The member meets ONE of the following:
 - i. A 4 week trial of conservative therapy fails to resolve the condition. If there is initial improvement of lymphedema, therapy should continue until there is 4 weeks of non-resolving lymphedema. Conservative therapy should include **ALL** the following treatments:

1. Compression garment or bandage system; **and**
 2. Regular exercise; **and**
 3. Elevation of the limb; **or**
- ii. The member is unable to use other compression interventions such as compression bandages or garments due to specific medical comorbidities or contraindications.

Oscar covers a unicompartmental or multicompartmental pneumatic compressor with calibrated gradient pressure (e.g., programmable) when **ALL** of the following are present:

1. Lymphedema that extends onto chest, trunk or abdomen that meets one of the following requirements:
 - a. Prior 4 week trial of therapy with a PCD that failed to resolve lymphedema. This requires previous conservative therapy to be tried first, as outlined above. Therapy trial with a PCD should include all of the following:
 - i. Usage of a PCD without calibrated gradient pressure for at least 4 weeks; **and**
 - ii. Regular exercise; **and**
 - iii. Elevation; **and**
 - iv. Manual lymphatic drainage where appropriate; **and**
 - v. Diet changes if necessary; **and**
 - vi. Medications if appropriate; **and**
 - vii. Anemia or hypoproteinemia correction; **or**
 - b. Documentation of unique characteristics (e.g., contracture, skin sensitivity, and/or significant scarring) that prevents treatment using a PCD without calibrated gradient pressure
2. Chronic venous stasis ulcers that meets one of the following requirements:
 - a. Member has not responded to 3 weeks of appropriate treatment with a unicompartmental or multicompartmental pneumatic compressor without a calibrated gradient pressure and continues to meet criteria above; **or**
 - b. Documentation of unique characteristics prevents treatment using a PCD without calibrated gradient pressure (e.g. ulcer pain limits use)

Continued use of the pneumatic compression device is considered medically necessary when ALL of the following criteria are met:

1. There is documented adherence with the use of the device as prescribed by the treating healthcare professional; **and**
2. Medical records document clinical improvement in the condition being treating; **and**
3. There is reasonable expectation that continued use of the device will continue to improve the member's condition or prevent further decompensation

Coverage Exclusions

Pneumatic compression devices are not covered by Oscar for any other indication, as it is considered experimental, investigational, or unproven. Non-covered indications include, but are not limited to, the following:

- Fractures and soft-tissue injuries
- Edema after femoropopliteal bypass surgery

- Distal radial fracture management
- Critical limb ischemia
- Restless Leg Syndrome
- Sensory impairment in upper limb extremities in stroke patients
- Upper extremity vascular ulcers
- Chest or trunk edema
- Arterial insufficiency
- Other advanced multicompartiment pneumatic compression devices and two-phase lymph preparation and drainage devices (e.g., Flexitouch)

Not all pneumatic compression devices have been shown to have significantly improved outcomes as compared to standard devices, thus not all devices are covered by Oscar. A list of devices that are considered experimental, investigational, or unproven include, but are not limited to, the following:

- Intermittent pneumatic compression devices with **sustained gradient pressure** (e.g., ACTitouch Adaptive Compression Therapy System)
- Intermittent pneumatic compression devices with **combination cold or heat therapy** (e.g., Cotherra VPULSE, NanoTherm, VascuTherm, Kinex ThermoComp)
- Pneumatic compression pumps with **high pressure rapid inflation** (e.g., FlowMedic FM220, AirCast VenaFlow Elite System)
- Intermittent pneumatic compression devices for **single patient use** (e.g., VenaPro)
- Pneumatic compression devices for use on the **chest or trunk** (e.g., FlexiTouch)

Evidence for non-coverage

Fractures and soft-tissue injuries

Khanna et al. performed a database search to investigate the use of pneumatic compression devices in fractures and soft-tissue injuries. Their review included sixteen studies between 1989 and 2007, nine of which were human studies, and seven which were animal studies. They concluded that PCDs are safe and effective for fracture and soft-tissue injuries, but that the limited numbers of patients in the human studies made the evidence unreliable. With larger randomized control trials to confirm these results, there may one day be a role for PCDs in fracture and soft-tissue injuries, but that has not yet been proven.¹

Edema after femoropopliteal bypass surgery

Te Slaa et al. performed a prospective randomized trial to observe the effect of using pneumatic compression devices in patients who were post-op of femoropopliteal bypass surgery. They compared groups using either compression stockings or using a PCD, and found that compression stockings were more effective at prevention and treatment of edema.²

Distal radial fracture management

Handoll and Elliott performed an updated Cochrane Database Review of management of distal radial fractures, including 26 trials of 1269 patients. Regarding PCD, there were only 31 patients who had received that as a

treatment option leading to very low quality evidence. The authors concluded that the evidence is insufficient to support any role for PCD in rehabilitation of distal radial fractures.³

Critical limb ischemia

Moran et al. reviewed a systematic literature review to evaluate the efficacy of PCD in critical limb ischemia. Previously, there had been a thought that PCD could assist in wound healing and help prevent limb amputation. The authors found 8 total studies that addressed PCD in limb ischemia, but found that all of the studies had a high risk of bias. They ultimately concluded that the current research has not proven the efficacy of the treatment for limb ischemia.⁴ Abu Dabrh et al independently conducted a systematic review to compare medical therapy to PCD management in treatment of critical limb ischemia. They found some suggestion that PCD could reduce the risk of amputation, but similarly found the evidence to be low-quality and thus the results were poorly supported.⁵ The American Heart Association and American College of Cardiology recently reviewed the role of PCD in critical limb ischemia and concluded that the evidence was weak that PCD usage would help pain or wound healing.⁶

Restless Leg Syndrome

Lettieri and Eliasson conducted a randomized trial with 35 patients to look at the efficacy of utilizing pneumatic compression devices in patients with Restless Leg Syndrome (RLS). They found that devices improved the severity of RLS symptoms for many of the patients. Their results were statistically significant, but further work needs to be done to confirm the role of PCD in RLS. At this time, PCD is considered experimental in treating RLS.⁷

Sensory impairment in upper extremities in stroke patients

Sensory loss of upper extremities can be common in patients who have a stroke, and medical research has tried to identify what interventions may be helpful in regaining sensation. Doyle et al. reviewed 13 studies looking at interventions and found that there were no clear conclusions on effectiveness of many of the currently used therapies. They found preliminary evidence for the use of PCDs in helping to regain sensation, but there were limited numbers of studies that included PCD as an intervention. Thus, at this time, PCD is considered experimental in the treatment of sensory impairment for stroke patients.⁸

Upper extremity vascular ulcers

As the utility of PCD in lower extremity ulcers has been shown, there is a similar thought as to whether this therapy would be equally helpful in upper extremity ulcers. A pilot study was conducted including 26 patients, and was associated with a rate of healing. There was no comparison group in this study, and thus there are no conclusions as to whether PCD actually provides therapeutic benefit to the healing of upper extremity ulcers. This may be in part due to the fact that upper extremity ulcers are less common than lower extremity ulcers, and thus less studied. At this time, PCD in upper extremity ulcer treatment is considered experimental.⁹

Arterial Insufficiency

A prospective randomized clinical trial was conducted by te Slaa et al (2011) comparing standard of care compression stocking with intermittent pneumatic compression for 57 patients undergoing femoral-popliteal bypass surgery for arterial insufficiency. They concluded that, "For the prevention and treatment of that edema the use of a class I [compression stocking] proved superior to treatment with IPC. The use of CS remains the

recommended practice following femoropopliteal bypass surgery.” Further studies are needed to determine any potential benefit of PCD in this population of patients.

Advanced multicompartment pneumatic compression devices and two-phase lymph preparation and drainage devices (e.g., Flexitouch Device)

A 2017 study by Karaca-Mandic et al retrospectively compared 1013 patients treated with non-programmable PCDs with 718 patients treated with programmable PCDs (Flexitouch) and found that the “NP-PCD group had a 53% reduction in episodes of cellulitis (from 17·9% to 8·5%), compared with a greater 79% reduction in the P-PCD group (from 23·7% to 5·0%) ($P < 0·001$)” in patients with cancer, and in the non-cancer cohort, the “P-PCD group also experienced a larger 76% decline (from 31·0% to 7·4%) vs. 54% decline (from 22·9% to 10·6%) in cellulitis rates ($P = 0·003$).” The authors concluded that Flexitouch was superior to non-programmable devices. However, this study is limited by its retrospective population from an insurer claim database, limiting the generalizability. Another study by Fife et al (2012) randomizing patients with breast cancer to non-programmable PCDs vs. Flexitouch concluded that for “the home maintenance phase of treatment of arm lymphedema secondary to breast cancer therapy, the adjuvant treatment with an APCD provides better outcomes than with a SPCD”. However, the results of this study show that there are no significant differences in any of the measured parameters. Ridner et al performed a randomized clinical trial comparing advanced pneumatic truncal, chest, and arm treatment to arm treatment only in self-care of arm lymphedema. 42 patients were enrolled. The study found “a statistically significant reduction in both the number of symptoms and overall symptom burden within each group; however, there were no statistically significant differences in these outcomes between the groups. There was no statistically significant overall change or differential pattern of change between the groups in function.” All other measured parameters showed no statistical difference. The authors concluded that “both configurations are effective, but that there may be no added benefit to advanced pneumatic treatment of the truncal lymphatics prior to arm massage when the trunk is not also affected.” The available evidence appears to be conflicting and there is a lack of large, randomized data showing a benefit in these advanced, programmable, multi-compartmental devices such as the Flexitouch. ²¹⁻²³

Applicable Billing Codes (HCPCS/CPT Codes)

<i>Pneumatic Compression Devices</i>	
CPT/HCPCS Codes covered if criteria are met:	
<i>Code</i>	<i>Description</i>
A4600	Sleeve for intermittent limb compression device, replacement only, each
E0650	Pneumatic compressor, nonsegmental home model [not covered if used to report cold/heat therapy]
E0651	Pneumatic compressor, segmental home model without calibrated gradient pressure [not covered if used to report cold/heat therapy]

E0652	Pneumatic compressor, segmental home model with calibrated gradient pressure
E0655, E0660, E0666 - E0669, E0671 - E0673	Nonsegmental or segmental pneumatic appliances for use with pneumatic compressors
E0676	Intermittent limb compression device (includes all accessories) not otherwise specified
ICD-10 codes covered if criteria are met:	
I87.2	Venous insufficiency (chronic)
I89.0 - I89.9	Other noninfective disorders of lymphatic vessels and lymph nodes
I97.2	Postmastectomy lymphedema syndrome
Q82	Hereditary lymphedema
ICD-10 codes <i>not</i> covered:	
G25.81	Restless leg syndrome
I82.401 - I82.429	Acute embolism and thrombosis of deep veins of lower extremity
I99.8	Other disorder of circulatory system [critical limb ischemia]
L03.01 - L03.91	Cellulitis and lymphangitis [Acute]
M62.20 - M62.28	Other disorder of circulatory system [critical limb ischemia]
S00.00xA - S99.929S	Fractures and soft-tissue injuries, including unspecified [closed] fracture of the lower end of radius [Dupuytren's fracture]

CPT/HCPCS codes <i>not</i> covered:	
<i>Code</i>	<i>Description</i>
E0218	Water circulating cold pad with pump
E0236	Pump for water circulating pad

E0651	Pneumatic compressor, segmental home model without calibrated gradient pressure [not covered if used to report cold/heat therapy or for the ActiTouch Adaptive Compression Therapy System]
E0652	Pneumatic compressor, segmental home model with calibrated gradient pressure [not covered for Flexitouch]
E0656	Segmental pneumatic appliance for use with pneumatic compressor, trunk
E0657	Segmental pneumatic appliance for use with pneumatic compressor, chest
E0670	Segmental pneumatic appliance for use with pneumatic compressor; integrated, 2 full legs and trunk
E0675	Pneumatic compression device, high pressure, rapid inflation/deflation cycle [e.g., FlowMedic FM220]
E0676	Intermittent limb compression device (includes all accessories) not otherwise specified [not covered for the Cotherra VPULSE or VenaPro]

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