Pneumatic Compression Devices

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

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 forcing blood or lymph fluid away from the compressed area. 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 compression devices are not appropriate for all types of venous and lymphatic return impairments (e.g., diabetic neuropathy, cancer lesions, infections, etc.), 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. The different inflatable chambers are preset and cannot be manually changed in non-programmable devices.

"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 an advanced feature that allows adjustment of pressure for unicompartmental programmable or multicompartmental programmable devices.

"Advanced multicompartmental programmable pneumatic compression" are multi-chamber devices that inflate at different times; they work by first applying pressure to the proximal tissues 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 described above, except they apply significantly higher pressure and cycle more rapidly. These have been proposed for the treatment of arterial insufficiency, i.e., peripheral arterial disease.

"Immobile" or "bedridden" describes a clinical scenario when a member has limited mobility to leave the bed and/or limited ability to turn and position for self-care within the bed. This can be transient, such as recovery from a major orthopedic surgery or trauma, or it can be permanent, such as loss of motor function after spinal cord injury. A state of immobility can increase the risk of deep venous thrombosis and subsequent pulmonary emboli.

"Lymphedema" is a condition where the lymph channels are obstructed or damaged (from skin infections, surgery, radiation, etc.) causing inadequate lymph fluid return and resulting in swelling of the tissues in the affected region. The causes can be various in nature such as genetic, post-surgery, trauma, infection, or skin disorders.

"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. Using a PCD on a limb with known or suspected DVT could result in a pulmonary embolism as the movement of the PCD could dislodge the clot that can travel and lodge in the lung, which can be fatal.

"Chronic venous insufficiency" is a condition where the vein valves in the legs fail to properly close, resulting in progressive pooling of blood in the affected extremity. When the blood is not well circulated, the local tissues can be damaged resulting in edema and the formation of stasis ulcers.

Clinical Indications

General Criteria

The Plan considers medical necessity for a unicompartmental or multicompartmental pneumatic compressor without a calibrated gradient pressure when the member meets ALL of the following criteria:

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

The Plan considers medical necessity for a unicompartmental or multicompartmental pneumatic compressor without a calibrated gradient pressure (e.g., non-programmable) for initial requests for limbs when the General Criteria above is met 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*
        v. Underlying cause is treated, if possible.
    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 confirmed recent acute DVT (unless member is in therapeutic range on anticoagulation); *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 (e.g., dermal fibrosis, ulcers, scarring); *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 are 4 weeks of non-resolving lymphedema. Conservative therapy should include ALL the following treatments:
    1. Compression garment or bandage system; *and*
    2. Regular exercise if possible; *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.

The Plan considers medical necessity for a unicompartmental or multicompartmental pneumatic compressor with calibrated gradient pressure (e.g., programmable) for initial requests for limbs or two-phase or two-stage segmental home models with calibrated gradient pressure (e.g., Flexitouch System application for limbs only) when the General Criteria above are met and ONE 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 non-programmable PCD without calibrated gradient pressure that failed to resolve lymphedema. This requires previous conservative therapy to be tried first, as outlined above such as a 4-week trial of compression garment/bandage system. Therapy trial should include all of the following:
        i. Usage of a non-programmable PCD without calibrated gradient pressure for at least 4 weeks; *and*
        ii. Regular exercise if possible; *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; *or*
2. Chronic venous stasis ulcers that meet one of the following requirements:
    a. Member has not responded to 4 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 Care

Continued use of the pneumatic compression device (e.g., unicompartmental, multicompartmental, non-calibrated/non-programmable, calibrated gradient pressure/programmable, two-phase devices) is considered medically necessary for limbs (e.g., arms and/or legs) 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 treated; *and*
3. There is reasonable expectation that continued use of the device will continue to improve the member's condition or prevent further decompensation.

The medical necessity criteria for Continued Care applies to pneumatic compression devices that the member is currently using for the reauthorization for limbs only (e.g., arms and/or legs). This includes "two-phase" devices with initial external compression therapy applied (pneumomassage) and then form-fitting low-stretch elastic stockings or sleeves are used to maintain edema reduction for limbs. Also, this includes "two-stage" devices with initial programmed compression of the proximal areas, the "preparatory stage," followed by a second programmed compression of the distal areas of the affected limb(s), the "drainage" stage.

Experimental or Investigational / Not Medically Necessary

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

- Arterial insufficiency
- Critical limb ischemia
- Head or neck lymphedema
- Application of pneumatic compression devices to the abdomen, chest or trunk for edema or lymphedema are not medically necessary
- Distal radial fracture management
- Decompensated Heart failure (New York Health Association Class IV)
- Edema after lower extremity bypass surgery (e.g., femoropopliteal bypass surgery)
- Fractures and soft-tissue injuries
- Restless Leg Syndrome
- Sensory impairment in upper limb extremities in stroke patients
- Upper extremity vascular ulcers

Not all pneumatic compression devices have been shown to have significantly improved outcomes as compared to standard devices, thus not all devices are considered medically necessary by the Plan. 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., Cothera 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)
- Other advanced multi-compartment pneumatic compression devices, such as two-phase or two stage lymph preparation and drainage devices for use on the head, neck, chest, abdomen or trunk (e.g., FlexiTouch System, Flexitouch Plus System)

Evidence for Experimental, Investigational, or Unproven Services

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 self-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.

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 underwent post-op 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.

Decompensated Heart failure (NYHA Class IV)

According to a 2020 international consensus statement published in *Phlebology*, application of compression is not recommended in severe cases of cardiac insufficiency, (NYHA class IV) due to compression of both legs may lead to asymptomatic increase in cardiac preload and temporary strain on the heart.

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 of PCD in rehabilitation of distal radial fractures.

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 the treatment of critical limb ischemia. They found some suggestions 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.

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.

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 the 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.

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.

Arterial Insufficiency

A prospective randomized clinical trial was conducted by 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) for any other indication than limbs
Hayes's Evolving Evidence Review on Sept 29, 2021 concluded minimal support with full-text clinical studies and no clear support with systematic reviews or practice guidelines for *Flexitouch System (Tactile Medical) for Lymphedema of the Head and Neck*. In the 2019 Desai & Shao, all study participants in a 2 year prospective study had a primary diagnosis of secondary lymphedema. They include Bio Compression's model E0652-SC-3008-DL in their study, which is user-programmable and calibrated device that delivers individualized pressure to each of the 8 chambers; furthermore, it can be applied to legs, groin, buttock, abdomen, arms, and chest areas. They compared 8 chambers and 4 chambers, and the advanced device of 8 chambers showed a higher percent change of limb volume to be 31.2% reduction compared to the basic device of 21.8% reduction of limb volume. However, this study does not specifically use the Flexitouch model, which has up to 32 chambers. In 2011 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 clinical trial for Flexitouch 2016 FDA 510(k) K153311 approval has no comparison group for head/neck vs limbs. No control group with conservative measures (e.g., compression socks). Or no comparison of other devices to show that Flexitouch provides more benefit or equivalent on other brands for head/neck or limbs. 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.

Applicable Billing Codes (HCPCS/CPT Codes)

Pneumatic Compression Devices	
CPT/HCPCS Codes considered medically necessary if criteria are met:	
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	Non-segmental pneumatic appliance for use with pneumatic compressor, half arm
E0660	Non-segmental pneumatic appliance for use with pneumatic compressor, full leg
E0666	Non-segmental 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
E0671	Segmental gradient pressure pneumatic appliance, full leg
E0672	Segmental gradient pressure pneumatic appliance, full arm
E0673	Segmental gradient pressure pneumatic appliance, half leg
E0676	Intermittent limb compression device (includes all accessories) not otherwise specified
ICD-10 codes considered medically necessary if criteria are met:	
I83.001 - I83.029	Varicose veins of lower extremities with ulcer
I83.201 - I83.229	Varicose veins of unspecified lower extremity with both ulcer and inflammation
I87.2	Venous insufficiency (chronic) (peripheral)
I87.331 - I87.339	Chronic venous hypertension (idiopathic) with ulcer and inflammation
I89.0 - I89.9	Other noninfective disorders of lymphatic vessels and lymph nodes
I97.2	Postmastectomy lymphedema syndrome
L97.101 - L97.929	Non-pressure chronic ulcer of lower limb, not elsewhere classified

Q82.0	Hereditary lymphedema
Z74.01	Bed confinement status
ICD-10 codes considered experimental or investigational:	
G25.81	Restless legs syndrome
I50.22	Chronic systolic (congestive) heart failure
I50.32	Chronic diastolic (congestive) heart failure
I50.42	Chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.812	Chronic right heart failure
I50.84	End stage heart failure
I82.401 - I82.4Z9	Acute embolism and thrombosis of deep veins of lower extremity
I99.8	Other disorder of circulatory system
L03.011 - L03.91	Cellulitis and acute lymphangitis
M62.20 - M62.28	Nontraumatic ischemic infarction of muscle
S00.00xA - S09.90xS	Injuries to the head
S10.0xxA - S19.9xxS	Injuries to the neck
S20.00xA - S29.9xxS	Injuries to the thorax
S30.0xxA - S39.94xS	Injuries to the abdomen, lower back, lumbar spine, pelvis and external genitals
S40.011A - S49.92xS	Injuries to the shoulder and upper arm
S50.00xA - S59.919S	Injuries to the elbow and forearm

S60.011A - S69.92xS	Injuries to the wrist, hand and fingers
S70.00xA - S79.929S	Injuries to the hip and thigh
S80.00xA - S89.92xS	Injuries to the knee and lower leg
S90.00xA - S99.929S	Injuries to the ankle and foot

CPT/HCPCS codes *not* considered medically necessary:	
Code	*Description*
E0218	Water circulating cold pad with pump, any type
E0236	Pump for water circulating pad
E0652	Pneumatic compressor, segmental home model with calibrated gradient pressure ● Due to multiple products represented by this CPT/HCPCS code, specific exclusions are indicated: ● When this code is billed for Flexitouch for any other indication than limbs, it is considered not medically necessary.

CPT/HCPCS codes considered experimental or investigational:	
Code	*Description*
E0651	Pneumatic compressor, segmental home model without calibrated gradient pressure ● Due to multiple products represented by this CPT/HCPCS, specific exclusions are indicated: ● When this code is billed for cold/heat therapy or for the ActiTouch Adaptive Compression Therapy System, it is considered experimental/investigational

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 for arterial insufficiency (unilateral or bilateral system)
E0676	Intermittent limb compression device (includes all accessories) not otherwise specified • Due to multiple products represented by this CPT/HCPCS code, specific exclusions are indicated: • When this code is billed for the Cothera VPULSE or VenaPro, it is considered experimental/investigational

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