



Cigna Medical Coverage Policy

**Subject Pneumatic Compression
Devices in the Home Setting**

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INSTRUCTIONS FOR USE

*The following Coverage Policy applies to health benefit plans administered by Cigna companies including plans formerly administered by Great-West Healthcare, which is now a part of Cigna. Coverage Policies are intended to provide guidance in interpreting certain **standard** Cigna benefit plans. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations. Proprietary information of Cigna. Copyright ©2013 Cigna*

Coverage Policy

Coverage for a pneumatic compression device provided in the home is subject to the terms, conditions and limitations of the applicable benefit plan's Durable Medical Equipment (DME) benefit and schedule of copayments. Please refer to the applicable benefit plan document to determine benefit availability and the terms, conditions and limitations of coverage. Under many benefit plans, coverage for DME is limited to the lowest-cost alternative.

If coverage for a pneumatic compression device is available, the following conditions of coverage apply.

Cigna covers a pneumatic compression device in the home setting (HCPCS code E0650–E0652, E0660, E0666–E0667, E0669–E0671, E0673, E0675, E0676) as medically necessary for the treatment of refractory edema of the lower extremities from chronic venous insufficiency (CVI) with venous stasis ulcer(s), when BOTH of the following criteria are met:

- The individual has received medically-supervised treatment of the ulcer(s) for at least 24 weeks using standard wound care treatment, including compression, wound dressings, exercise, and elevation of the limb.
- Failure of the ulcer(s) to decrease in size or demonstrate improvement despite conventional therapy.

When the above medical necessity criteria are met, Cigna covers the following pneumatic compression devices as medically necessary:

- non-segmental/segmental (HCPCS code E0650, E0651)
- segmental with calibrated gradient pressure (HCPCS code E0652), when there is evidence of failure of relief with the non-segmental device **OR** requirement of specified pressure to a localized area

Cigna does not cover a pneumatic compression device in the home setting* for the treatment of ANY other indication because it is considered experimental, investigational or unproven.

***Please refer to Cigna Coverage Policy Lymphedema Pumps and Compression Garments which addresses coverage for the treatment of lymphedema.**

General Background

There are several types of pneumatic compression devices. Standard pneumatic compression devices consist of an inflatable garment for the extremity and an electrical pump that fills the garment with compressed air. The garment is intermittently inflated and deflated with cycle times that vary between devices. The use of a pneumatic compression device in the home environment may be an alternative to other compression therapies (e.g., stockings, bandages, Unna boots) for patients who are unable or refuse to comply with other methods of treatment or are refractory to standard wound care treatment. Compression therapy counteracts venous hypertension by facilitating venous return toward the heart, improving venous pump function and lymphatic drainage. It reduces edema by increasing local hydrostatic pressure and lowering superficial venous pressure, preventing the leakage of fluids and macromolecules, improving cutaneous blood flow, and aiding fibronolysis (Etufugh, et al., 2007; Berliner, et al., 2003; Montori, et al., 2002).

One type of pneumatic compression device combines intermittent pneumatic compression with cold therapy. This pneumatic compression device has been proposed for elimination of knee, shoulder and ankle swelling as a result of traumas or surgery. These devices are also proposed for use on soft tissue injuries such as pulled hamstrings, tendinitis, sprains and inflamed joints. For information on the coverage of pneumatic compression with cold therapy, please refer to the Cigna Coverage Policy, Cryorounits/Cooling Devices.

A non-segmented pneumatic compressor (E0650) is a device which has a single outflow port on the compressor. The air from the single tube may be transmitted to the device with multiple compartments or segments (E0660, E0666). A segmented pneumatic compressor (E0651, E0652) is a device which has multiple outflow ports on the compressor which lead to distinct segments on the appliance that inflate sequentially. In a segmented device without calibrated gradient pressure (E0651), the pressure is usually set by a single control on the distal segment (E0667, E0669). A segmented device with calibrated gradient pressure (E0652) is a device with a manual control on at least three outflow ports which can deliver an individually determined pressure on each segmental unit (E0671, E0673). A non-segmented (E0650) or segmented device without manual control in each chamber (E0651) is generally sufficient to meet the clinical needs of a patient (Centers for Medicare and Medicaid Services [CMS], 2011; CMS, 2002).

There are other types of pneumatic compression devices (E0676) that are often referred to as deep vein thrombosis (DVT) pumps, massage therapy pumps, post surgical DVT preventative pumps (list not all inclusive) (CMS, 2011).

Established uses for pneumatic compression devices in the home setting are for the treatment of chronic venous insufficiency (CVI) and lymphedema. For information on the coverage of pneumatic compression devices for lymphedema, please refer to the Cigna Coverage Policy, Lymphedema Pumps and Compression Garments.

Pneumatic compression devices have been proposed for use in the home setting for other indications, including but not limited to, prevention of venous thromboembolism (VTE) including deep vein thrombosis (DVT) and pulmonary embolism (PE), treatment of arterial ischemic ulcers or diabetic neuropathic ulcers, fracture and soft-tissue healing, and restless leg syndrome.

Chronic Venous Insufficiency (CVI)

Treatment of CVI is best initiated before the occurrence of venous ulceration. Knee-length heavyweight elastic stockings are recommended. Mild diuretic therapy (e.g., hydrochlorothiazide) may be of some help in persistent edema. The recommended treatment when ulceration occurs is an extended period of bed rest with elevation of the involved extremity well above heart level at all times, combined with wet-to-dry saline dressings to the ulceration, applied three times daily. The patient is encouraged to exercise the calf muscles repeatedly while in bed, ideally against a footboard, to minimize the occurrence of acute DVT (Freischlag, et al., 2012; Cantelmo and Brewster, 2009).

Pressure dressings are an alternative for patients with venous ulcers who are unable to spend extended periods with their legs elevated. The Unna paste venous boot is the standard approach to pressure dressings. Properly applied, this zinc-impregnated gauze pressure bandage can supply good compression and allows the patient to remain ambulatory. The boot is typically changed every 7–10 days and continued for 3–6 months. It is reported that up to 60% of ulcers will heal if continued for one year, with healing occurring in nearly 80% of cases. Once the ulcer is healed, chronic use of a heavyweight elastic stocking is resumed. Surgical referral may be recommended for recurrent or nonhealing ulcerations (Freischlag, et al., 2012; Cantelmo and Brewster, 2009).

U.S. Food and Drug Administration (FDA)

There are numerous manufacturers and models of pneumatic compression devices. Pneumatic compression devices are cleared for marketing under the FDA 510(k) process as Class II devices intended for use in prevention of blood pooling in a limb by periodically inflating a sleeve around the limb. No clinical data was needed for FDA approval since they existed prior to the passage of the Medical Device Amendments of 1976.

Literature Review

Although there is limited evidence in the peer-reviewed published medical literature to support the use of pneumatic compression devices for the treatment of patients with refractory edema from chronic venous insufficiency with significant ulceration of the lower extremities who have failed standard therapy (i.e., a compression bandage system or garment, dressings for the wounds, exercise, and elevation of the limb), the treatment has become the standard of care for this subset of patients.

Margolis et al. (1999) studied factors that predict which venous ulcers will not heal with limb compression bandages alone. They found that most ulcers that were < 6 months old and were < 5 cm² healed within 24 weeks with compression bandages alone. They chose a 24-week period, because it is a reasonable length of time to receive limb compression therapy, and it is the time frame frequently used for randomized clinical trials evaluating therapy for venous leg ulcers.

The effectiveness of intermittent pneumatic compression (IPC) as a treatment for venous leg ulcers was reviewed by Mani et al. (2001) and updated by Nelson et al. (2011). The results of the review stated that “seven randomized controlled trials (n=367) were identified. Only one trial reported both allocation concealment and blinded outcome assessment. In one trial (80 people) more ulcers healed with IPC than with dressings (62% versus 28%; p=0.002). Four trials compared IPC with compression against compression alone. The first of these trials (45 people) found increased ulcer healing with IPC plus compression than with compression alone (relative risk for healing 11.4, 95% Confidence Interval 1.6–82). The remaining three trials (122 people) found no evidence of a benefit for IPC plus compression compared with compression alone. One small trial (16 people) found no difference between IPC (without additional compression) and compression bandages alone. One trial compared different ways of delivering IPC (104 people) and found that rapid IPC healed more ulcers than slow IPC (86% versus 61%; log rank p=0.003). The authors reported that IPC may increase healing compared with no compression, but it is not clear whether it increases healing when added to treatment with bandages, or if it can be used instead of compression bandages. Rapid IPC was better than slow IPC in one trial. Further trials are required to determine whether IPC increases the healing of venous leg ulcers when used in modern practice where compression therapy is widely used.”

The Agency for Healthcare Research and Quality (AHRQ) conducted a systematic review of the literature to evaluate evidence on the use of pneumatic compression devices in the home environment for treatment of CVI and venous ulcers. Eight trials met the inclusion criteria, including several randomized controlled trials. With the use of pneumatic compression devices, several studies showed significant improvement of longstanding chronic ulcers that had not healed with other methods. No studies compared the effectiveness of single-chamber

devices with that of gradient multi-chamber devices. The authors noted that relative contraindications to pneumatic compression are significant arterial insufficiency, edema from congestive heart failure, active phlebitis, deep vein thrombosis, and the presence of localized wound infection or cellulitis (Berliner, et al., 2003).

Other Indications

There is a paucity of randomized controlled or comparative trials in the peer-reviewed medical literature supporting the efficacy of pneumatic compression devices for the treatment of other indications, including but not limited to, arterial ischemic ulcers or diabetic neuropathic ulcers of the lower extremities, prevention of venous thromboembolism (VTE) including deep vein thrombosis (DVT) and pulmonary embolism, fracture and soft-tissue healing and restless leg syndrome. No standardization of devices exists with the mode of compression, the flow rate, or the type of sleeve. Many of the studies of compression devices are on small groups of patients using more than a single modality (Hardwick, et al., 2011; Morris and Fedullo, 2010; Eliasson and Lettieri, 2009; Khanna, et al., 2008; Handoll, et al., 2006; Labropoulos, et al., 2002).

Peripheral Artery Disease (PAD): PAD is a circulatory problem that develops when the arteries that supply blood to the extremities (usually the legs) become narrowed or blocked, resulting in an insufficient blood supply. Treatment for PAD focuses on reduction of symptoms and prevention of further progression of the disease. Most individuals with claudication benefit from a comprehensive medical approach that includes risk factor modification, exercise rehabilitation, and use of standard pharmacotherapy for claudication. Critical limb ischemia is considered to be present in patients with lower extremity ischemic rest pain, ulceration, or gangrene. If left untreated, severe PAD could lead to major limb amputation within six months. For a minority of patients, the above recommendations and treatments are not sufficient, and minimally invasive treatment or surgery may be needed. Arterial ulcers, however, should not be compressed for fear of further arterial compromise (Brewster, 2009; American Heart Association [AHA], 2009; Hirsch, et al., 2006).

A proposed alternative for individuals with PAD who are ineligible or who fail medical or surgical therapies is the application of high pressures by compression cuffs placed on the thigh, the calf, and/or the foot. These devices intermittently inflate and deflate with cycle times and pressures that vary between devices. These devices offer higher pressures than offered in the typical pneumatic compression device. An example is the ArtAssist[®] Device, a mechanical pneumatic pump consisting of an impulse generator and two plastic inflatable cuffs, applies high pressure in a synchronized manner to the foot and calf. This outpatient treatment is usually performed for three hours per day while the patient is sitting upright. The ArtAssist may restore pulsatility to the affected limb by several proposed mechanisms (ECRI, 2005; ACI Medical, Inc.).

U.S. Food and Drug Administration (FDA)

Some examples of devices include The FlowMedic[™] FM220 System (Flowmedic, Inc., (Orangeburg, NY) which received 510(k) approval on January 12, 2005. The FDA indications for use state intended for the improvement of blood circulation in the lower extremities to help prevent and reduce complications of poor circulation. The predicate devices are ArtAssist[®] The Arterial Assist Device [™] (ACI Medical, Inc; San Marcos, CA); Arterialflow System, Model 32A (Aircast, Inc, Summit, NJ); and the WizAir[™] DVT (Medical Compression Systems, Ltd, Israel) (FDA, 2005).

Labropoulos et al. (2002) conducted a systematic review of the literature to identify the most effective program of IPC in patients with lower limb arterial disease. Twenty-six studies met the inclusion criteria. The diverse patient criteria and methods used in the studies made it difficult to compare the studies. Since patients varied on how long their symptoms persisted, the overall treatment periods varied drastically, even within a single study, and thus were not reported. Of all the studies, three were prospective-randomized with low sample sizes (n=12–34). Two studies measured the healing of nine of 12 ulcers in patients with non-healing ulcers. Another study reported the healing of partial to full ulceration in refractory ulcer or combined venous and arterial disease. Limb salvage was reported in 94% of 38 legs with ischemia, necrosis, and failure of conservative treatment. In another study, nine of 14 limbs were salvaged in patients with critically ischemic legs. The authors concluded that IPC may be beneficial for PAD patients who cannot undergo invasive surgeries, but large-scale, randomized, double-blind trials are needed to clarify the most beneficial regimen for increasing lower limb blood flow and improving the quality of life of PAD patients.

Prevention of Venous Thromboembolisms (VTE): DVT is usually treated with the anticoagulants warfarin or heparin or a combination of the two drugs. Heparin acts quickly and is often stopped once warfarin starts working, usually two to three days after it is initiated. Other treatments include vena cava filters, which catch

existing blood clots before they travel to the lung, and graduated compression stockings. Stockings fit over the foot up to the knee and are tight at the ankle and looser at the knee, creating a gentle pressure up the leg to prevent blood pooling and clotting. With pneumatic compression devices, the application and release of pressure promotes venous blood flow and may prevent DVT in patients who are at risk of developing this condition. Compression devices may be designed to fit over the patient's leg, calf, or foot (foot pumps) (ECRI, 2012).

The use of pneumatic compression devices in the hospital setting for the prevention of VTE in high risk patients is considered standard of care. In a Cochrane review, Kakkos et al. (2006) assessed the efficacy of intermittent pneumatic leg compression combined with pharmacological prophylaxis versus single modalities in preventing VTE in high-risk patients. Eleven studies, six of them randomized controlled trials, were identified. The trials included 7431 patients, in total. Compared with compression alone, the use of combined modalities reduced significantly the incidence of both symptomatic pulmonary embolism (PE) (from about 3% to 1%) and deep vein thrombosis (DVT) (from about 4% to 1%). Compared with pharmacological prophylaxis alone, the use of combined modalities significantly reduced the incidence of DVT (from 4.21% to 0.65) but the included studies were underpowered with regard to PE. The comparison of compression plus pharmacological prophylaxis versus compression plus aspirin showed a non-significant reduction in PE and DVT in favor of the former group. The authors reported that "compared with compression alone, combined prophylactic modalities decrease significantly the incidence of venous thromboembolism. Compared with pharmacological prophylaxis alone, combined modalities reduce significantly the incidence of DVT but the effect on PE is unknown. The results of the current review support, especially in high-risk patients, the use of combined modalities. More studies on their role in PE prevention, compared with pharmacological prophylaxis alone, are urgently needed." This review did not discuss intermittent pneumatic leg compression in the home setting.

Pneumatic compression therapy in the home setting for the prevention of VTE including DVT and PE is not considered standard of care in the practicing medical community. The scientific evidence supporting the use of pneumatic compression therapy as a treatment modality in the home setting for the prevention of VTE including DVT and PE is extremely limited.

Recent textbook literature discusses the prevention of VTE stating that, "the trend toward earlier hospital discharge has been accompanied by an increased incidence of postdischarge VTE. Thromboembolic risk does not necessarily end at the time of hospital discharge or transfer to a lower level of care. In patients with an ongoing predisposition to thrombosis at the time of discharge from an acute inpatient setting, prophylaxis should be continued until the risk for VTE has resolved. The objective of the prophylactic strategy is to identify the degree of thromboembolic risk in the individual patient and to match the intensity of prophylaxis to that degree of risk. Although a variety of prophylactic approaches have been investigated and utilized, four approaches have proved effective: low-dose unfractionated heparin, low-molecular-weight heparin (LMWH), intermittent pneumatic compression devices, and warfarin. Furthermore the authors state that "A variety of questions remain unanswered about pneumatic compression devices. For example, it is not known whether the various compressive devices differ in efficacy. It is also unknown whether efficacy depends on strict (24/7) compliance with this intervention during the period of increased thromboembolic risk. In addition, it is unclear whether pneumatic compression devices are as effective as unfractionated heparin in general medical, surgical, gynecologic, and urologic patients, and their use is indicated in patients in whom pharmacologic methods of prophylaxis are contraindicated" (Morris and Fedullo, 2010).

Restless Leg Syndrome (RLS): In a prospective, randomized, double-blinded, sham-controlled trial (n=35), Eliasson and Lettieri (2009) evaluated the effectiveness of pneumatic compression devices (PCDs) as a non-pharmacologic treatment for restless legs syndrome (RLS). Devices were provided to subjects who were enrolled for home use. Subjects wore a therapeutic or sham device prior to the usual onset of symptoms for a minimum of one hour daily. Measures of severity of illness, quality of life, daytime sleepiness, and fatigue were compared at baseline and after one month of therapy. Groups were similar at baseline. Therapeutic PCDs significantly improved all measured variables more than shams. Restless legs severity score improved from 14.1 +/- 3.9 to 8.4 +/- 3.4 (p=0.006) and Johns Hopkins restless legs scale improved from 2.2 +/- 0.5 to 1.2 +/- 0.7 (p=0.01). All quality of life domains improved more with therapeutic than sham devices (social function 14% versus 1%, respectively; p=0.03; daytime function 21% versus 6%, respectively, p=0.02; sleep quality 16% versus 8%, respectively, p=0.05; emotional well-being 17% versus 10%, respectively, p=0.15). Both Epworth sleepiness scale (6.5 +/- 4.0 versus 11.3 +/- 3.9, respectively, p=0.04) and fatigue (4.1 +/- 2.1 versus 6.9 +/- 2.0, respectively, p=0.01) improved more with therapeutic devices than sham devices. Complete relief occurred in

one-third of subjects using therapeutic and in no subjects using sham devices. The authors reported that PCDs resulted in clinically significant improvements in symptoms of RLS in comparison to the use of sham devices and may be an effective adjunctive or alternative therapy for RLS. Moreover, the authors stated that before PCD therapy is ready for more wide-spread use, it will be important to see validating studies in various populations of RLS patients. This study did not report long-term outcomes. Additionally the authors reported that while effective for RLS treatment, the role of PCDs may be limited. RLS medications are effective, relatively safe, and usually well tolerated. Additionally, medications are obviously easier to use than PCDs, which require patients to remain immobile for one hour each day.

Fracture and Soft-Tissue Healing: In a review of the literature, Khanna et al. (2008) stated that current methods of fracture care use various adjuncts to try and decrease time to fracture union, improve fracture union rates and enhance functional recovery; and one such modality is IPC. A total of nine studies on the use of IPC in fracture and soft-tissue healing (e.g., distal radius, ankle, calcaneal fractures, acute ankle sprains) were identified. These studies demonstrated that IPC facilitates both fracture and soft-tissue healing with rapid functional recovery. The authors reported that IPC appears to be an effective modality to enhance fracture and soft-tissue healing however the number of subjects is small, and adequately powered randomized controlled trials are needed to produce stronger clinically relevant evidence.

In a Cochrane review, Handoll et al. (2006) examined the effects of rehabilitation interventions in adults with conservatively or surgically treated distal radial fractures. Of the fifteen trials one trial included the use of intermittent pneumatic

Professional Societies/Organizations

The American College of Cardiology (ACC) and the American Heart Association (AHA) guidelines for management of patients with PAD does not mention the use of pneumatic compression devices (Hirsch, et al., 2006). The 2011 focused update to this guideline does not mention pneumatic compression devices (Rooke, et al., 2011).

The 2012 American College of Chest Physicians Evidence-Based Clinical Practice Guidelines on the Prevention of VTE in Orthopedic Surgery Patients: Antithrombotic Therapy and Prevention of Thrombosis does not address pneumatic compression therapy for patients in the home setting for the prevention of VTE. The guideline states, "Intermittent pneumatic compression devices to prevent VTE for acutely ill hospitalized medical patients at increased risk of thrombosis who are bleeding or at high risk for major bleeding, the expert panel suggests the optimal use of mechanical thromboprophylaxis with graduated compression stockings (GCS) (Grade 2C) or intermittent pneumatic compression (IPC) (Grade 2C), rather than no mechanical thromboprophylaxis. When bleeding risk decreases, and if VTE risk persists, the expert panel suggests that pharmacologic thromboprophylaxis be substituted for mechanical thromboprophylaxis (Grade 2B)" (Khan, et al., 2012).

Summary

While there is limited evidence in the peer-reviewed medical literature supporting the efficacy of pneumatic compression devices for the treatment of patients with refractory edema from chronic venous insufficiency (CVI) with significant ulceration of the lower extremities who have failed standard therapy (i.e., a compression bandage system or garment, dressings for the wounds, exercise, and elevation of the limb), the treatment is considered standard of care for this subset of patients. There is insufficient evidence in the published, scientific literature to support the effectiveness of pneumatic compression devices in the treatment of other conditions (e.g., arterial ischemic ulcers or diabetic neuropathic ulcers of the lower extremities, prevention of venous thromboembolism (VTE) including deep vein thrombosis (DVT) and pulmonary embolism, fracture and soft-tissue healing and restless leg syndrome).

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.

2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Covered when medically necessary for the treatment of refractory edema of the lower extremities

from chronic venous insufficiency (CVI) with venous stasis ulcer(s):

HCPCS Codes	Description
E0650	Pneumatic compressor; non-segmental home model
E0651	Pneumatic compressor; segmental home model without calibrated gradient pressure
E0652	Pneumatic compressor; segmental home model with calibrated gradient pressure
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
E0669	Segmental pneumatic appliance for use with pneumatic compressor, half leg
E0671	Segmental gradient pressure pneumatic appliance; full leg
E0673	Segmental gradient pressure pneumatic appliance; half leg
E0675	Pneumatic compression device, high pressure, rapid inflation/deflation cycle, for arterial insufficiency (unilateral or bilateral system)
E0676	Intermittent limb compression device (includes all accessories), not otherwise specified

ICD-9-CM Diagnosis Codes	Description
454.0	Varicose veins of lower extremity with ulcer
454.2	Varicose veins of lower extremity with ulcer and inflammation
459.2	Compression of vein
459.81	Venous (peripheral) insufficiency, unspecified
707.10-707.19	Ulcer of lower limbs, except pressure ulcer
782.3	Edema

Experimental/Investigational/Unproven/Not Covered:

ICD-9-CM Diagnosis Codes	Description
	All other codes

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