



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

Subject Pneumatic Compression Devices for Vascular Diseases of the Lower Extremities

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Table of Contents

Coverage Policy	1
General Background	2
Coding/Billing Information	5
References	7
Policy History	10

Hyperlink to Related Coverage Policies

- Complex Lymphedema Therapy (Complete Decongestive Therapy)
- Cyrounits/Cooling Devices
- Hyperbaric Oxygen Therapy, Systemic & Topical
- Lymphedema Pumps and Compression Garments
- Negative Pressure Wound Therapy/Vacuum-Assisted Closure (VAC) for Non-Healing Wounds

INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement (GSA), 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. Proprietary information of CIGNA. Copyright ©2011 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 (HCPCS code E0650–E0652, E0660, E0666–E0667, E0669–E0671, E0673) 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 for the treatment of arterial ischemic ulcers or diabetic neuropathic ulcers of the lower extremities, because it is considered experimental, investigational or unproven for these indications.

CIGNA does not cover end-diastolic pneumatic compression therapy (HCPCS code E0675, G0166) [Current Procedural Terminology (CPT) 92971] for the treatment of peripheral vascular disease or any associated complications because it is considered experimental, investigational or unproven.

General Background

Peripheral vascular disease (PVD) is a term applicable to a variety of vessel occlusive diseases, whether they stem from the venous or arterial system.

Pneumatic Compression Devices for the Treatment of 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 deep venous thrombosis (Cantelmo and Brewster, 2009; Freischlag, et al., 2008).

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 (Cantelmo and Brewster, 2009; Freischlag, et al., 2008).

Pneumatic compression devices have been proposed for the treatment of venous stasis, venous and arterial ulcers, and for the prevention of deep vein thrombosis. Pneumatic compression devices consist of an inflatable garment for the leg 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).

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).

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).

Pneumatic Compression Devices for the Treatment of 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. 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).

Literature Review

Current evidence in the peer-reviewed medical literature supporting the efficacy of pneumatic compression devices for individuals with PAD of the lower extremities is limited to small pilot or case series studies with short-term follow up. There is a paucity of randomized controlled trials with long-term health outcomes. One systematic review has been published to date.

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.

End-Diastolic Pneumatic Compression for the Treatment of Peripheral Vascular Disease

End-diastolic pneumatic compression has been investigated as a technique to promote the peripheral circulation to treat peripheral vascular disease and its associated complications. End-diastolic pneumatic compression incorporates a heart monitor so compression can be timed to the end-diastolic portion of the heart rhythm to improve arterial flow which is proposed to expel venous blood and lymphatic fluid from the legs. An example of an end-diastolic pneumatic compression device is the Circulator Boot System[™] [Circulator Boot Corporation, Malvern, PA]. The boot can be timed to compress after every, or every other, or every third heartbeat. This timing decreases pressure on the leg before cardiac systole, to allow the heart to empty its blood more easily. The compression boot can be adjusted to treat any segment of the leg (ECRI, 2007, Circulator Boot Corporation).

U.S. Food and Drug Administration (FDA)

The Circulator Boot received 510(k) approval in 1980. Modifications have been made to the Circulator Boot with the latest 510(k) approval on May 7, 2009. The FDA indications for use state the Circulator Boot System, alone or in combination with other drug or device therapies, may be used to treat the following conditions: poor arterial blood flow in extremities, diabetes complicated by the above or other conditions possibly related to arterial insufficiency, venous diseases (once risk of emboli minimized), and athletic injuries (FDA, 2009).

Literature Review

Current evidence in the peer-reviewed medical literature supporting the efficacy of end-diastolic pneumatic compression devices for individuals with PAD of the lower extremities is limited to case series studies. There is a paucity of randomized controlled trials with long-term health outcomes.

Vella et al. (2000) treated 29 patients with ischemic leg ulcers with Circulator Boot therapy. Out of a total of 29 patients with a transcutaneous oxygen pressure of less than 20 mm Hg at the area of ulceration, 19 had favorable outcomes following Circulator Boot therapy. Outcome was classified as favorable if the wound completely healed, the ulcer decreased in size or the affected limb improved sufficiently to allow successful revascularization. Ten patients failed to receive benefit from therapy and had an increase in size of the ulcer or went on to amputation.

Dillon (1997) reported on the clinical effectiveness of end-diastolic pneumatic compression therapy and of local antibiotics in treating limb lesions associated with diabetes and peripheral arterial, venous, and neuropathic disease. Office and hospital data were kept over 15 years on 2177 episodes of leg problems for 1514 legs of 1035 patients referred because of failure of standard therapies. When possible, the fate of the untreated legs served as a control. There was deterioration in the control or uninvolved leg compared to the treated leg. The overall percentage of legs having major amputations was below 4%. The lack of randomization limits interpretation of the data in this study.

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 or end-diastolic pneumatic therapy for the treatment of PAD and its complications (Hirsch, et al., 2006). There has been no update to this guideline since 2006.

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).

There is insufficient evidence in the published, scientific literature to support the effectiveness of end-diastolic pneumatic therapy (e.g., The Circulator Boot System™) for the treatment of patients with peripheral vascular disease and any associated complications (e.g., venous stasis ulcers, ischemic ulcers, stasis dermatitis, necrotizing cellulitis, claudication pain, or thrombophlebitis). Additional studies are needed to compare the health outcomes of end-diastolic pneumatic compression therapy versus standard treatment.

Coding/Billing Information

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

Covered when medically necessary for the treatment of refractory edema of the lower extremities from chronic venous insufficiency (CVI) with venous stasis ulcer(s):

HCPSC 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

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 when used to report the treatment of arterial ischemic ulcers or diabetic neuropathic ulcers of the lower extremities:

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

ICD-9-CM Diagnosis Codes	Description
707.06	Pressure ulcer, ankle
707.07	Pressure ulcer, heel

Experimental/Investigational/Unproven/Not Covered when used to report end-diastolic pneumatic compression device therapy for the treatment of peripheral vascular disease or any associated complications:

CPT* Codes	Description
92971	Cardioassist-method of circulatory assist; external

HCPCS Codes	Description
E0675	Pneumatic compression device, high pressure, rapid inflation/deflation cycle, for arterial insufficiency (unilateral or bilateral system)
G0166	External counterpulsation, per treatment session

ICD-9-CM Diagnosis Codes	Description
443.89	Other specified peripheral vascular disease

443.9	Peripheral vascular disease, unspecified
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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	5/15/2008	0363	Pneumatic Compression Devices for Vascular Diseases of the Lower Extremities
Great-West Healthcare	1/1/2007	07.348.01	Pneumatic Compression Devices

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