



Cigna Medical Coverage Policy

Subject **Pneumatic Compression Devices and Compression Garments**

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Coverage Policy

Coverage for the treatment of lymphedema, including lymphedema pumps and compression garments, may be governed by federal and/or state mandates. Lymphedema compression garments are generally covered under the core medical benefits of the plan.

Coverage for pneumatic compression devices/lymphedema pumps used 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.

Unless excluded from the benefit plan, the following conditions of coverage apply.

Compression Garment

Cigna covers the purchase of a lymphedema compression garment for the extremities (e.g., sleeve, gauntlet, and stocking) as medically necessary for the treatment of lymphedema.

Pneumatic Compression Device in the Home Setting

Cigna covers a pneumatic compression device in home setting as medically necessary for EITHER of the following:

- for the treatment of intractable lymphedema when there is failure of a four-week trial of conservative medical management including ALL of the following:
 - home exercise program
 - limb elevation
 - compression bandage or compression garment use
- for the treatment of refractory edema of the lower extremities from chronic venous insufficiency (CVI) with venous stasis ulcer(s), (HCPCS code E0650–E0652[†], E0660, E0666–E0667, E0669–E0671, E0673, E0675, E0676) 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 a pneumatic compression pump has been found to be medically necessary according to the above criteria, Cigna covers the following devices as medically necessary limited to the lowest-cost alternative:

- 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 a requirement of specified pressure to a localized area

Continuation of Use

Cigna covers continuation of use of a pneumatic compression device as medically necessary when BOTH of the following criteria are met:

- there is adherence with the use of equipment as ordered by the healthcare professional
- clinical documentation from the health care professional confirms clinical improvement (e.g., improvement in venous stasis ulcers, decrease in edema or lymphedema)

Not Covered

Cigna does not cover an advanced pneumatic compression pump or a pump with additional features (HCPCS code E0652[†]) (e.g., specific programming to treat problem areas, a pre-therapy phase) because it has not been demonstrated to be superior to a standard segmented, calibrated gradient system, and is not considered the lowest-cost alternative and thus is not medically necessary. These devices include but are not limited to:

- Flexitouch[®] System
- Lympha Press Optimal[™]

[†]HCPCS code E0652 covered when used to report a standard segmented, calibrated gradient system. Not covered when used to report an advanced pneumatic compression pump or a pump with additional features.

Cigna does not cover ANY of the following because each is considered experimental, investigational or unproven:

- a chest (HCPCS code E0657) and/or trunk (HCPCS code E0656, E0670) pneumatic appliance for use with a pneumatic compression pump
- a compression garment for trunk or chest
- a pneumatic compression device, with or without a cooling component, utilized in the home setting for ANY other indication including but not limited to the prevention of deep vein thrombosis.

General Background

There are several types of pneumatic compression 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. Pumps may be classified as single-chambered, multi-chambered with fixed sequential inflation, or multi-chambered with sequential inflation and manually calibrated gradient chamber pressure. Older models include intermittent single-chamber nonsegmented pumps that provide even pressure throughout the limb; however, they allow backflow of lymphatic fluid. This can cause an increase of fluid in the distal arm. Newer devices have multiple segmented chambers and have the ability to provide sequential compression. Multiple-chamber units typically inflate from distal to proximal, producing a wave of pressure that ascends to the extremity, with the same pressure being delivered in each garment section. Proponents contend that this wave brings edema fluid with it, allowing the retained fluid to be brought to functional lymphatics.

Segmental pumps that have a calibrated gradient pressure feature are typically used only in patients who require limited pressure to be applied to a specific area (e.g., significant scars or the presence of contracture or pain caused by the clinical condition).

Pneumatic compression pumps include, but are not limited to, the following:

- Nonsegmented pneumatic compressor (E0650): This device has a single outflow port on the compressor. Although there is a single tube, air from this single tube may be transmitted to a sleeve with multiple compartments and would be functionally equivalent to a segmented pneumatic compressor with a segmented sleeve; or the device can be used with a nonsegmented sleeve. An example of this type of pump is the Huntleigh Flowtron® Hydroven 3 Pump (ArjoHuntleigh, Addison IL.)
- Segmented pneumatic compressor (E0651, E0652): This device has multiple outflow ports on the compressor that lead to distinct segments on the appliance, which inflates in a sequential manner.
 - (E0651) A segmented device without calibrated pressure is one in which either (a) the same pressure is present in each segment, or (b) there is a predetermined pressure gradient in successive segments but no ability to individually set or adjust pressures in each of the several segments. The pressure is usually set by a single control on the distal segment. Examples of models include: Wright 51 Non-Gradient (Wright Therapy Products, Oakdale, PA), BHI Sequential Compression Pump (Biomedical Horizons, Inc., Scottsdale, Arizona).
 - (E0652) A segmented device with calibrated gradient pressure is characterized by a manual control on at least three outflow ports that can deliver individually determined pressure to each segmental unit. Examples include but are not limited: Chattanooga 4333 Multi 6 Compression Therapy System (Chattanooga Group, Chattanooga, TN), Talley Multipulse™ 500 sequential compression system (Talley Medical USA, Lansing, MI), Wright 52 Gradient (Wright Therapy Products, Oakdale, PA)

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, Cryounits/Cooling Devices.

There are pneumatic compression devices used for the treatment of arterial disease (E0675). The sleeves used with the base devices (E0650—E0652, E0675) are separate items (Centers for Medicare and Medicaid Services [CMS], 2013; 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). The garments/sleeves are included with the base device (E0676). At times replacement sleeve may be needed to replace the initial sleeve (CMS, 2013).

Established uses for pneumatic compression devices in the home setting are for the treatment of chronic venous insufficiency (CVI) and lymphedema.

Advanced Pneumatic Compression Devices: Newer pneumatic pumps have been developed that provide treatment with additional features. In addition to leg and arm garment/appliances that are used with standard pumps, these devices may include the use of unique garments/appliances to be worn on trunk, chest, and torso area.

These advanced pneumatic compression devices include (E0652):

- Flexitouch® System (Tactile Systems Technology, Minneapolis, MN): This device consists of an electronic controller unit and patented garments, worn on the trunk, chest, and upper and/or lower affected extremities and connected to the controller unit by tubing harnesses. According to the manufacturer website, “the Flexitouch system is an advanced pneumatic compression device clinically proven to stimulate the lymphatic system.” The system consists of programmable, segmented pneumatic compression device with calibrated gradient pressure along with patented separate trunk and limb components that, when combined, consist of up to 32 separate chambers. The system provides treatment for truncal lymphatics in addition to the affected limb. According to the manufacturer website, the Flexitouch system offers multiple treatment options to provide customized treatment for patients with lymphedema, chronic edema, and non-healing wounds. The website notes, “The Flexitouch’s programmability allows for a number of treatment configurations based on individual patient need and that this flexibility in programming means it can do everything other pumps do, with the added benefit of specific programming to treat problem areas.”
- Lympha Press Optimal™ (Mego Afek, Manalapan, NJ): According to the vendor website, this device includes “pretherapy”, which is based on the principles of manual lymph drainage. It starts proximally (near or over the torso, depending on the garment), to decongest these areas prior to sequential compression therapy and provides extra treatment for lymphedema occurring at the upper arm or leg. It is used with unique torso garments. These include the Lympha Pants II™ for complete treatment of abdominal and genital lymphedema, or the Lympha Jacket II™ for complete treatment of truncal lymphedema.

Literature Review—Advanced Pneumatic Compression Device: Muluk et al. (2013) reported on a prospective cohort study of 196 patients to examine the effectiveness of an advanced pneumatic compression device (APCD) (Flexitouch pump) on limb volume (LV) reduction in the treatment of lymphedema. Patients had at least stage II lymphedema. Primary outcome was limb volume with secondary outcomes to compare pre-and post-treatment patient reported outcomes and clinical reported outcomes after treatment. Follow-up clinical assessment was done approximately 60 ± 27 days (range 17-242; median 55.5) after the baseline measurements and initial APCD treatment. Ninety per cent of the APCD treated patients had a 35% reduction in the limb volume. Mean LV reduction was 1,150 mL or 8% ($p < .0001$). Limitations of the study included the lack of comparator and randomization, other lymphedema treatment components were not standardized, and LV measurements were done at variable time points after initiation of therapy.

Fife et al. (2012) conducted a randomized, controlled trial that compared an advanced pneumatic compression device (APCD) to a standard PCD (SPCD) in 36 patients with arm lymphedema after breast cancer treatment. The patients were randomized to an APCD (Flexitouch system, HCPCS E0652) or SPCD (Bio Compression 2004, HCPCS E0651) used for home treatment one hour a day for 12 weeks. Outcomes included arm volumes that were determined from arm girth measurements and suitable model calculations, and tissue water volume that was determined based on measurements of the arm tissue dielectric constant (TDC). The APCD-treated group had an average of 29% reduction in edema compared to a 16% increase in the SPCD group. Mean changes in TDC values were 5.8% reduction for the APCD group and a 1.9% increase for the SPCD group. This study did not compare different types of advanced pneumatic compression devices, but rather compared a standard PCD to an advanced PCD. In addition, while the patients had not received treatment with PCD within the past three months, it is not noted if they had received PCD therapy in the past. Limitations of the study include the small sample size, absence of recording of symptoms, quality and life and functional outcomes.

Ridner et al. (2011) reported on a randomized, controlled trial to compare the therapeutic benefit of truncal/chest/arm advanced pneumatic compression therapy (experimental group) ($n=21$) verses arm only pneumatic compression (control group) ($n=21$) in self-care for arm lymphedema without truncal involvement using the Flexitouch System. The outcomes included self-reported symptoms, function, arm impedance ratios, circumference, volume, and trunk circumference. While the findings indicated a statistically significant reduction in both the number of symptoms and overall symptom burden within each group, there were no statistically

significant differences in these outcomes between the two groups. No statistically significant overall change or differential pattern of change between the groups in function was found. A statistically significant reduction in bioelectrical impedance and arm circumference within both of the groups was realized; however, there was no statistically significant difference in reduction between groups. The findings indicate that both treatments appear to be 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.

Ridner et al. (2008) conducted a study to compare treatment protocol adherence, satisfaction and perceived changes in emotional and functional status between patients with lymphedema using the home-based Flexitouch system. One hundred fifty-five patients were included in the study—93 with cancer related symptoms and 62 with noncancer-related lymphedema. A survey was completed before treatment and a post-therapy survey was completed during the maintenance phase of the protocol. Participants without cancer were more adherent to the prescribed protocol. Both groups were found to be satisfied with the system, perceived it to be effective and reported improvement in physical and emotional status. The limitations of the study included: post-therapy questionnaires were obtained from 64% of the participants, the findings in this study were self-reported, and there was no control group.

Wilburn, et al. (2006) reports on a prospective, randomized crossover study involving 10 patients that compared the efficacy of the Flexitouch to massage for treatment of lymphedema of the arm (Each phase included self-administered treatment with Flexitouch or massage for one hour daily for 14 days. Each phase was preceded by a one-week treatment washout, which included use of a garment only. It was noted that post-treatment arm volume was reduced with the Flexitouch, but not with massage. The device appeared to be well-tolerated by patients. This study was limited by the small sample size and short duration of treatment. In addition, there was no comparison to standard pneumatic lymphedema pumps or complex lymphedema therapy.

The published evidence does not demonstrate that the use of advanced pneumatic compression devices is superior to standard segmented, calibrated gradient pumps/systems. In addition evidence is lacking to support the treatment of truncal, abdominal or torso appliances for use with lymphedema pumps. It has not been demonstrated through well-designed trials published in the peer-reviewed scientific literature whether there is incremental clinical value in using torso components in addition to limb appliances. Impact on meaningful health outcomes through the added use of these torso/trunk components is not known at this time. Which patients would most benefit from these devices has not been clearly defined in the literature.

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.

Pneumatic compression pumps for use with lymphedema are approved under the U.S. Food and Drug Administration (FDA) 510(k) process. They are classified as Class II devices, cardiovascular therapeutic devices, and compressible limb sleeves. Manufacturers include, but are not limited to: Advantage (Microtek Medical Inc., Jacksonville, FL); Bio Compression Inc. (Moonachie, NJ); Thera-Con (Bethesda, MD); Kendall (Tyco Healthcare Group, LP, Mansfield, MA); Talley (Talley Group Ltd., Romsey, UK); Jobst (BSN-JOBST, Inc., Charlotte, NC); and Wright Linear Pump, Inc. (Oakdale, PA).

The Flexitouch system received initial 510(k) approval from the FDA as a class II device under the name Biotouch® Massage Therapy System (Tactile Systems Technology, Inc., Shakopee, MN), as a compressible limb sleeve. The 510(k) summary notes that the predicate device is the Progressive Medical Technology, Inc., Multipulse Sequential Compression Unit. The summary notes that the intended use is to treat patients at home under medical supervision for the following indications: primary lymphedema, post-mastectomy edema, edema following trauma or sports injury, post-mobilization edema, venous insufficiencies, and lymphedema (FDA, 2002).

In 2006, the Flexitouch system received 510(k) approval as powered inflatable tube massager, Class II device. The predicate devices listed in this 510(k) summary are the BioCompression Systems, model SC-3008 sequential circulator, Medical Compression Systems Ltd. Active Care® system, and Tactile Systems Technology, Inc Flexitouch system. In addition to the above-noted indications, the summary lists the following

indications: reducing wound healing time, and treatment and assistance in healing: stasis dermatitis; venous stasis ulcers; arterial and diabetic leg ulcers (FDA, 2006).

In 2012, Tactile Systems Technology Inc. received 510(k) approval for Flexitouch® system. The device is noted in the FDA approval to have the same technological characteristics as to the predicate device PD32-120. The Flexitouch system is a prescription pneumatic compression system consisting of a garment set and a pneumatic sequential controller. The garments are wrapped around the affected body regions so that the garment fits snugly. The garments have multiple chambers that are filled with air to provide for low-level compression in the treated areas. The Flexitouch system is intended for use by medical professionals and patients at home who are under medical supervision in treating many conditions such as:

- Primary lymphedema
- Post mastectomy edema
- Edema following trauma and sports issues
- Post immobilization edema
- Venous insufficiencies
- Lymphedema
- Reducing wound healing time
- Treatment and assistance in healing: stasis dermatitis; venous stasis ulcers;
- arterial and diabetic leg ulcers

Lymphedema

Primary lymphedema is a result of congenital defects of the lymphatic system and is rare. Secondary lymphedema is acquired and due to an obstruction or interruption in the lymphatic system. In the United States, the most common causes of lymphedema are cancer and treatment related to cancer. Patients undergoing surgery for breast cancer that includes node dissection or axillary radiation therapy are at high risk of developing lymphedema. The goals of lymphedema treatment are to decrease the excess volume as much as possible and maintain the limb at its smallest size.

When provided as the sole treatment modality, lymphedema pumps are generally reserved for patients with intractable lymphedema for whom an adequate trial of more conservative medical treatment has failed. Established conservative medical treatments include the use of bandaging and compression garments, limb elevation, and home exercise programs. Segmental pumps that have a calibrated gradient pressure feature are typically used only in patients who require limited pressure to be applied to a specific area (e.g., significant scars or the presence of contracture or pain caused by the clinical condition).

Literature Review–Lymphedema: There is no consensus in the scientific literature on optimal pump selection and use. The scientific evidence supporting the use of pneumatic pumps as a solitary treatment modality for lymphedema is extremely limited and of poor quality. There is some evidence to indicate that using pumps as an adjunct to complex lymphedema treatment (CLT) has beneficial effects on the outcome of the therapy. Comparative studies evaluating the most effective pumping times, pressure levels or kind of pump are lacking (Harris, 2001). Optimal pressure ranges, inflation/deflation cycles, and length and frequency of individual pumping sessions have not been established (Brennan, 1998; Kerchner, et al., 2008). There is some evidence to suggest that sequential multi-chambered pumps are more effective than single-chambered pumps. One randomized trial attempted to evaluate pneumatic compression pumps for the treatment of lymphedema. Dini et al. (1998) randomized 80 post-mastectomy women to either intermittent pneumatic compression or no treatment. Women in the treatment group underwent a two-week cycle of five pump sessions per week, followed by a five-week break in treatment and then another two-week cycle of treatment. There was no statistically significant difference in response rates between the two groups. The authors concluded that pneumatic compression pumps have a limited role in the management of patients with lymphedema.

A technology assessment requested by Centers for Medicare and Medicaid Services (CMS) was conducted by McMaster University Evidence-based Practice Center for the Agency for Healthcare Research and Quality (AHRQ) (Oremus, et al., 2010) diagnosis and treatment of secondary lymphedema. The review included randomized controlled trials or observation studies with comparison groups (e.g., cohort, case control). The assessment included the following:

- Regarding the question of whether one type of pneumatic compression device and sleeve (e.g., non-segmented compression device, sequential segmented compression , or segmented compression with

- calibrated gradient pressure) is more effective in reducing lymphedema than another for any type of lymphedema along the continuum, or patient characteristics—the review found that there was a lack of evidence from which to determine whether one type of intermittent pneumatic compression device and sleeve were more effective in reducing lymphedema based on specific sets of patient characteristics
- There was no evidence concerning the optimal criteria to initiate or stop treatment for secondary lymphedema.
- There was significant heterogeneity in terms of treatments, inclusion and exclusion criteria, and treatment protocols to suggest the optimality of one type of treatment over another.
- There is no evidence to suggest an optimal frequency or duration of treatment, the most efficacious treatment combinations, the length of time for which persons should be tested or treatment for lymphedema and whether certain tests or treatments may benefit some types of patients more than others.

Devoogdt et al. (2010) published a systematic review of combined physical therapy (CPT), intermittent pneumatic compression and arm elevation for the treatment of lymphedema secondary to an axillary dissection for breast cancer. After CPT, the maintenance phase consists of skin care, exercises, wearing a compression sleeve and manual lymphatic drainage if needed. The review included 10 randomized controlled trials (RCT), one pseudo-randomized controlled trial and four non-randomized experimental trials that investigated the effectiveness of combined physical therapy and its different parts, of intermittent pneumatic compression and arm elevation. Five studies (three RCT and two pseudo-RCTs) examined intermittent pneumatic compression. It was noted that the effectiveness of skin care, exercises, wearing a compression sleeve and arm elevation has not been investigated by a controlled trial. The studies indicate that intermittent pneumatic compression is effective, but once the treatment is interrupted, the lymphedema volume increases. The authors concluded that the long-term effect of compression is not yet proven.

A systematic review of the common conservative therapies for arm lymphedema secondary to breast cancer treatment was conducted by Mosely et al. (2007). The review included the following treatments: complex physical therapy, manual lymphatic drainage, pneumatic pumps, oral pharmaceuticals, low level laser therapy, compression bandaging and garments. The review found that the more intensive and health professional based therapies, such as complex physical therapy, manual lymphatic drainage, pneumatic pump and laser therapy generally yielded the greater volume reductions. Self-initiated therapies such as compression garment wear, exercise and limb elevation were found to yield a lesser volume reduction. The review included randomized, controlled, parallel and cross-over, case-control and cohort studies. A meta-analysis could not be performed due to the treatment and data heterogeneity. Five studies were included that examined pneumatic pump therapy. Two of these studies demonstrated that volume reduction could be achieved from pump therapy alone, although one study utilized higher pressure that was usually recommended. Three studies demonstrated that better results in volume reduction were achieved when the pneumatic pump was used in combination with other treatments, including: manual lymphatic drainage, compression garments and self massage. In addition, it was noted that three studies demonstrated that continuing pump therapy or wearing a compression garment were beneficial in maintaining the reduction in volume. The review concluded that, “Despite the range of positive outcomes identified in this review, the evidence to support them is, in some instances, poor. Therefore, there is still a need for large scale, high level clinical trials in this area”.

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).

Literature Review—Chronic Venous Insufficiency (CVI): 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).

Prevention of Venous Thromboembolisms (VTE)

DVT is generally 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. 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.

Textbook literature discusses the prevention of VTE stating that, "the trend toward earlier hospital discharge has been accompanied by an increased incidence of post-discharge 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).

Literature Review—Prevention of Venous Thromboembolisms (VTE):

Colwell, et al (2014) a noninferiority study of the mobile compression device compared to the standard pharmacological prophylaxis, including warfarin, enoxaparin, rivaroxaban, and dabigatran, with symptomatic end points and similar patient demographics. The study included following primary knee arthroplasty (1,551 patients) or hip arthroplasty (1,509) patients from ten sites. The compression device was used perioperatively and continued for a minimum of ten days. Patients with symptoms of deep venous thrombosis or pulmonary embolism underwent duplex ultrasonography and/or spiral computed tomography. All patients were evaluated at three months postoperatively to document any evidence of deep venous thrombosis or pulmonary embolism. The authors hypothesized that the mobile compression device would have approximately the same efficacy as pharmacological prophylaxis without the risk of major bleeding. The study adopted a 1.0% margin in the noninferiority study, with the hypothesis that a 1.0% difference in venous thromboembolism rates between the mobile compression device registry cohort and the pharmacological comparators would not constitute a clinically meaningful difference. Twenty-eight (0.92%) of the patients had venous thromboembolism (twenty distal deep venous thrombi, three proximal deep venous thrombi, and five pulmonary emboli). One death occurred, with no autopsy performed. The authors found that symptomatic venous thromboembolic rates observed in patients who had an arthroplasty of a lower-extremity joint using the mobile compression device were noninferior, at a margin of 1.0%, to the rates reported for pharmacological prophylaxis, including warfarin, enoxaparin, rivaroxaban, and dabigatran, except in the knee arthroplasty group, in which the mobile compression device fell short of the rate reported for rivaroxaban by 0.06%. Limitations of the study included the lack of randomization, the registry had a limited data set, and neither bleeding rates nor compliance were documented, compliance was not documented in the study. In addition, the study was not designed to establish conclusions regarding the use or nonuse of aspirin in addition to the mobile compression device- of the twenty-eight patients who had a venous thromboembolic event, 46% were on the aspirin protocol.

In a Cochrane review, Kakkos et al. (2008) 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.

Literature Review—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 in the home setting, 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; Khanna, et al., 2008; Eliasson and Lettieri, 2007; Handoll, et al., 2006; Labropoulos, et al., 2002).

Restless Leg Syndrome (RLS): In a prospective, randomized, double-blinded, sham-controlled trial (n=35), Lettieri and Eliasson (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 compression. The authors reported that there was not enough evidence available to determine the best form of rehabilitation for people with wrist fractures.

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 (American Heart Association [AHA], 2012; Brewster, 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 (ACI Medical, Inc.).

Compression Garments

Lymphedema or compression garments for the extremities have been widely used in the treatment of lymphedema. Compression garments may be elastic and non-elastic and may be used alone or in combination with other treatments, including lymphedema pumps and complex lymphedema treatment (CLT). They are used for the purpose of preventing an increase in lymphedema and maintaining the reduction of lymphedema after treatment. A sleeve may be needed for lymphedema of the arm and a glove or gauntlet may also be used if lymphedema is present in the hand. If there is lymphedema of the lower extremity, a compression stocking may be needed. The garment may need replacement when elasticity is lost, approximately every 4–6 months.

Elastic garments may be custom-fitted or prefabricated and have varying degrees of elasticity. The type of sleeve used is dependent on the size needed and whether the patient correctly fits the parameters of the prefabricated garment. It is important that the garment fit correctly and provide adequate, graduated compression.

Compression garments include:

- Jobst[®] Armsleeve (BSN-JOBST, Inc., Charlotte, NC)
- Juzo[®] compression arm sleeves, gauntlets, stockings (Juzo, Cuyahoga Falls, OH)
- FarrowWrap[®] (Farrow Medical Innovations, Bryan, TX) includes stockings, arm sleeves, gauntlet
- Mediven[®] lymphedema garments (Medi, Whitsett, NC) available in arm sleeve, gauntlet, stockings, combination styles, and glove
- Tribute[®] (Solaris, West Allis, WI) includes upper and lower extremity garments

Non-elastic Compression Garments: Non-elastic compression garments utilize a non-elastic textile that is fastened by adjustable hooks and loops to provide compression. They can be worn during the day or night. Both custom-made and prefabricated garments are available.

Non-elastic compression garments include:

- ReidSleeve[®], and Optiflow[®] sleeves (Peninsula Medical, Inc., Scotts Valley, CA)
- ArmAssist[®] and LegAssist[®] (BiaCare, Zeeland, MI)
- CircAid[®] (CircAid Medical Products Inc., San Diego, CA)
- ReadyWrap[®] (Solaris, West Allis, WI) includes upper and lower extremity garments. They are considered low-stretch.

Compression Garments for Chest or Trunk: The role of chest and trunk garments in the treatment of lymphedema is unclear. These garments include a vest, such as the made-to-order JoViPak[®] vest (JoViPak, Kent, WA), and the Tribute[®] vest or torso garment (Solaris, West Allis, WI). Evidence supporting the use of trunk or chest compression garments is lacking. The impact on meaningful health outcomes through the use of these garments is not known at this time. Which patients would most benefit from these devices has not been clearly defined in the literature.

U.S. Food and Drug Administration (FDA): The FDA classifies compression sleeves as Class I devices, therapeutic medical binders. They are exempt from the premarket notification procedure.

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 National Lymphedema Network (NLN): The NLN published a position statement regarding treatment of lymphedema (NLN, 2011). This consensus document indicates that complete decongestive therapy (CDT) is the current international standard of treatment for managing lymphedema. Regarding the use of lymphedema pumps, it is noted that:

- Intermittent Pneumatic Compression Therapy (IPC), also known as compression pump therapy, can be useful in some patients as an adjunct to Phase I CDT or a necessary component of a successful home program
- IPC is not considered a “standalone” treatment. It is utilized along with standard CDT to maintain control of lymphedema at home. To maintain edema control, a compression garment, or short stretch bandages, should be worn between pump treatments and also when IPC therapy is discontinued.
- Patients who require IPC may need a pump that treats the trunk of the body and not just the limb with the swelling.
- Compression garments are essential for long-term control of lymphedema volume. The patient should be fitted with a compression garment following maximal volume reduction resulting from Phase I of complex lymphedema treatment (CLT).

Use Outside of the US

International Society of Lymphology (ISL): In 2013 the ISL published an updated consensus document regarding the diagnosis and treatment of peripheral lymphedema (ISL, 2013). The document makes the following comments regarding lymphedema treatment:

- Treatment of peripheral lymphedema is divided into conservative (i.e., nonoperative methods) and operative methods. Both methods include an understanding that meticulous skin hygiene and care is of extreme importance to the success of all treatment approaches.
- Intermittent pneumatic compression is included in the document as a standard treatment for lymphedema. After external compression therapy, form-fitting stockings or sleeves are used to maintain edema reduction.
- Newer devices that simulate manual massage and design improvements for area of coverage, ease of use, and sequence/actions may increase patient compliance.
- An assessment should be made of limb volume before, during and after treatment. Treatment outcomes should be reported in standardized manner in order to assess effectiveness of treatment protocols.

Joint guidelines from the European Federation of Neurological Societies, European Neurological Society, European Sleep Research Society on management of restless legs syndrome do not include the use of pneumatic compression pump for treatment of restless legs syndrome (Garcia-Borreguero, et al., 2012).

Summary

While there is limited scientific evidence in the form of well-designed clinical trials supporting the use of lymphedema pumps and compression garments, the practicing medical community generally considers them safe and effective nonsurgical options for the treatment of lymphedema. The use of a pneumatic compression pump for lymphedema is appropriate after a four-week trial of conservative medical management that includes exercise, elevation and compression garments. Standard segmental lymphedema pumps with calibrated gradient pressure are appropriate for patients with a failure of relief with use of a nonsegmental or segmental device and a documented need for specified pressure to a localized area (e.g., scar tissue, ulcer).

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), these devices are considered standard of care for this subset of patients in the home setting. 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, fracture and soft-tissue healing and restless leg syndrome) and in the prevention of venous thromboembolism (VTE) including deep vein thrombosis (DVT) and pulmonary embolism in the home setting.

Advanced pneumatic compression devices have not been demonstrated to be superior to standard segmented, calibrated gradient systems and thus are considered not medically necessary. The clinical effectiveness of

garments/appliances for chest and trunk area cannot be determined and their role in the management of lymphedema has not been established.

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
- 3) ICD-10-CM Diagnosis Codes are for informational purposes only and are not effective until 10/01/2015.

Lymphedema compression garments

Covered when medically necessary:

HCPCS Codes	Description
A4465	Non-elastic binder for extremity
A6530	Gradient compression stocking, below knee, 18-30 mmhg, each
A6531	Gradient compression stocking, below knee, 30-40 mmhg, each
A6532	Gradient compression stocking, below knee, 40-50 mmhg, each
A6533	Gradient compression stocking, thigh length, 18-30 mmhg, each
A6534	Gradient compression stocking, thigh length, 30-40 mmhg, each
A6535	Gradient compression stocking, thigh length, 40-50 mmhg, each
A6536	Gradient compression stocking, full length/chap style, 18-30 mmhg, each
A6537	Gradient compression stocking, full length/chap style, 30-40 mmhg, each
A6538	Gradient compression stocking, full length/chap style, 40-50 mmhg, each
A6539	Gradient compression stocking, waist length, 18-30 mmhg, each
A6540	Gradient compression stocking, waist length, 30-40 mmhg, each
A6541	Gradient compression stocking, waist length, 40-50 mmhg, each
S8420	Gradient pressure aid (sleeve and glove combination), custom made
S8421	Gradient pressure aid (sleeve and glove combination), ready made
S8422	Gradient pressure aid (sleeve), custom made, medium weight
S8423	Gradient pressure aid (sleeve), custom made, heavy weight
S8424	Gradient pressure aid (sleeve), ready made
S8425	Gradient pressure aid (glove), custom made, medium weight
S8426	Gradient pressure aid (glove), custom made, heavy weight
S8427	Gradient pressure aid (glove), ready made
S8428	Gradient pressure aid (gauntlet), ready made

Standard pneumatic compression pumps

Covered when medically necessary:

HCPCS Codes	Description
E0650	Pneumatic compressor, nonsegmental home model
E0651	Pneumatic compressor, segmental home model without calibrated gradient pressure
E0652 [†]	Pneumatic compressor, segmental home model with calibrated gradient pressure
E0655	Nonsegmental pneumatic appliance for use with pneumatic compressor, half arm
E0660	Nonsegmental pneumatic appliance for use with pneumatic compressor, full leg
E0665	Nonsegmental pneumatic appliance for use with pneumatic compressor, full arm

E0666	Nonsegmental pneumatic appliance for use with pneumatic compressor, half leg
E0667	Segmental pneumatic appliance for use with pneumatic compressor, full leg
E0668	Segmental pneumatic appliance for use with pneumatic compressor, full arm
E0669	Segmental pneumatic appliance for use with pneumatic compressor, half leg
E0671	Segmental gradient pressure pneumatic appliance, full leg
E0672	Segmental gradient pressure pneumatic appliance, full arm
E0673	Segmental gradient pressure pneumatic appliance, half leg
E0675	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

[†]**Note:** Covered when used to report standard segmented, calibrated gradient systems. Not covered when used to report an advanced pneumatic compression pump or a pump with additional features.

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
457.0	Post-mastectomy lymphedema syndrome
457.1	Other lymphedema
457.2	Lymphangitis
459.2	Compression of vein
459.81	Venous (peripheral) insufficiency, unspecified
707.10- 707.19	Ulcer of lower limbs, except pressure ulcer
757.0	Hereditary edema of legs
782.3	Edema

ICD-10-CM Diagnosis Codes (effective 10/01/2015)	Description
I83.001- I83.029	Varicose veins of lower extremity with ulcer
I83.201- I83.229	Varicose veins of lower extremity with both ulcer and inflammation
I87.1	Compression of vein
I87.2	Venous insufficiency (chronic) (peripheral)
I89.0	Lymphedema, not elsewhere classified
I89.1	Lymphangitis
I97.2	Postmastectomy lymphedema syndrome
L97.101- L97.929	Non-pressure chronic ulcer of lower extremity
Q82.0	Hereditary lymphedema
R60.0	Localized edema

Experimental/Investigational/Unproven/Not Covered:

ICD-9-CM Diagnosis Codes	Description
	All other codes

ICD-10-CM Diagnosis Codes (effective 10/01/2015)	Description
	All other codes

Experimental/Investigational/Unproven/Not Covered when used to report chest and/or trunk pneumatic appliances for use with pneumatic compression pumps or compression garments for the trunk and/or chest:

HCPSCS Codes	Description
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
E1399	Durable medical equipment, miscellaneous

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