# PNEUMATIC COMPRESSION DEVICES

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## INSTRUCTIONS:

"Medical Policy assists in administering UCare benefits when making coverage determinations for members under our health benefit plans. When deciding coverage, all reviewers must first identify enrollee eligibility, federal and state legislation or regulatory guidance regarding benefit mandates, and the member specific Evidence of Coverage (EOC) document must be referenced prior to using the medical policies. In the event of a conflict, the enrollee’s specific benefit document and federal and state legislation and regulatory guidance supersede this Medical Policy. In the absence of benefit mandates or regulatory guidance that govern the service, procedure or treatment, or when the member’s EOC document is silent or not specific, medical policies help to clarify which healthcare services may or may not be covered. This Medical Policy is provided for informational purposes and does not constitute medical advice. In addition to medical policies, UCare also uses tools developed by third parties, such as the InterQual Guidelines®, to assist us in administering health benefits. The InterQual Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. Other Policies and Coverage Determination Guidelines may also apply. UCare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary and to provide benefits otherwise excluded by medical policies when necessitated by operational considerations.”
POLICY DESCRIPTION:

This policy provides information on the use of pneumatic compression devices as a treatment option for patients with Lymphedema, venous insufficiencies, arterial insufficiencies and prevention of deep vein thrombosis. Pneumatic compression devices consist of an inflatable garment that wraps around the arm, leg and/or foot and pumps the extremity with compressed air; the garment is inflated and deflated with cycle times and different pressures. After many repeated cycles, the goal of this device is to reduce swelling and improve circulation.

COVERAGE RATIONALE / CLINICAL CONSIDERATIONS:

Single or multi-chamber, nonprogrammable pneumatic compression devices may be considered MEDICALLY NECESSARY when used to treat the following conditions or diagnoses:

1. **Lymphedema**, in the home setting it is considered MEDICALLY NECESSARY for patients who have failed a four week trial of conservative therapy.

   **NOTE:** A pneumatic compression device will not be covered as initial therapy for lymphedema in the home setting. A patient must first undergo a four-week trial of conservative therapy, which includes the use of an appropriate compression garment (graduated compression stocking/sleeve), exercise and elevation of the limb. A physician determines after such a trial that there has been no significant improvement, or if significant symptoms remain.

   Programmable pneumatic compression devices are considered NOT MEDICALLY NECESSARY for the treatment of lymphedema as an alternative to either a single compartment or multichamber, nonprogrammable lymphedema pump.

2. **Venous thromboembolism (VTE) prophylaxis**, for patients at high risk for deep venous thrombosis (DVT) and pulmonary embolism (PE), and who cannot fully ambulate due to major trauma, major surgery or other circumstances preventing ambulation.

   **NOTE:** High risk factors for VTE include:

   Non-surgical:
   - Prior DVT/PE
   - Age >60 years
   - Sepsis or severe infection
   - Hypercoagulable states
     - Antithrombin III deficiency
     - Protein C or S deficiency
     - Activated Protein C resistance (Factor V Leiden)
     - Antiphospholipid syndrome
     - Prothrombin 20210 defect
     - Dysfibrinolysis
   - Active cancer or cancer treatment
   - Kidney failure
   - Recent myocardial infarction (MI)
   - Nonhemorrhagic stroke
- Congestive heart failure (CHF) (decompensated)
- Low ejection fraction (EF)

**Surgical:**
- Major pelvic surgery (e.g., radical hysterectomy, pelvic exenteration)
- Major orthopedic surgery (e.g., total hip replacement, total knee replacement)

**Major Trauma:**
- Spinal cord paralysis injury
- Multiple limb fractures
- Lower extremity or pelvic fracture
- Use of clotting medications or transfusions

3. **Chronic venous stasis ulcers**, caused by chronic venous insufficiency (CVI) which have failed to heal after a six month trial of conservative, physician-directed medical therapy.

**NOTE:** Conservative therapy must include use of a compression bandage system or garment (garment must provide adequate, graduated compression), exercise, and elevation of the limb. Documentation of appropriate physician oversight must include evaluation of the patient’s condition to determine medical necessity of the device and a treatment plan defining the pressure to be used, frequency, duration of use, ongoing monitoring of use and response to treatment.

A multi-chamber, programmable pneumatic compression device **may be considered MEDICALLY NECESSARY** for treatment of **Chronic venous stasis ulcers** only when the patient has unique characteristics that prevent them from receiving satisfactory pneumatic compression treatment using a non-segmented device in conjunction with a segmented appliance or a segmented compression device without manual control of pressure in each chamber. E.g., Unique characteristics may be defined as:

- A need to reduce pressure over sensitive areas such as wound sites, ulcers, and painful areas, AND
- That the patient is unable to tolerate use of a non-calibrated, nonprogrammable device, AND
- That the calibrated pressure and programmability of the segmental pneumatic compressor with calibrated gradient pressure is required to address these sensitive areas.

Pneumatic compression devices for indications other than venous thromboembolism prophylaxis, chronic venous insufficiency of the lower extremities or lymphedema are **considered INVESTIGATIONAL AND/OR EXPERIMENTAL**, including, but not limited to, treatment of peripheral arterial occlusive disease/arterial insufficiency, rehabilitation for distal radial fractures, treatment of sensory impairment in the upper limb following stroke, upper extremity vascular ulcers, diabetic neuropathic ulcers, arterial ischemic ulcers, and all other indications.

**Clinical Considerations:**

Conservative therapy must include use of a compression bandage system or garment (garment must provide adequate graduated compression), exercise, and elevation of the limb.

Physician evaluation documentation must include: diagnosis and prognosis; symptoms and objective findings, including measurements which establish the severity of the condition; reason the device is required, including the treatments which have been tried and failed; treatment plan defining the pressure to be used, frequency and duration of use; ongoing monitoring of use, ability to tolerate the treatment.
session and parameters, and response to treatment.

According to the instructions supplied with the Aircast VenaFlow device, pneumatic compression should not be used for patients who have any of the following conditions (Aircast Inc., 2001):

- Known or suspected DVT
- Congestive heart failure
- Pulmonary edema
- Thrombophlebitis
- Severe arteriosclerosis
- Active infection
- Extremities that are not sensitive to pain
- Gangrene
- Vein ligation
- Recent skin grafts
- Extreme deformity of the leg
- Increased venous or lymphatic return is undesirable
- Gangrene that could be aggravated by the device cuff

Combining pharmacologic therapy with intermittent pneumatic compression devices may yield additional benefit in prevention of VTEs compared with either method used alone.

Placement of pneumatic compression devices before cesarean delivery is recommended for all women not already receiving thromboprophylaxis.

**BACKGROUND:**

Pneumatic compression devices are appliances that facilitate the initial reduction of extremity edema and swelling. Pneumatic compression devices are commonly used for the treatment of acute and chronic peripheral lymphedema to facilitate the mobilization of fluid from the limbs into the trunk and central body cavity. These devices have also been used in the treatment of venous stasis, chronic venous insufficiency (CVI) of the legs and consequent edema, stasis dermatis and cellulites, venous and arterial ulcers, and for the prevention of deep vein thrombosis. Optimal management of lymphedema requires the use of compression garments between treatments to maintain the reduction achieved.

Pneumatic compression devices consist of an inflatable garment for the arm or leg and an electrical pneumatic pump that fills the garment with compressed air. The garment is intermittently inflated and deflated with cycle times and pressures that vary among devices. This device is designed for use in both the home and hospital settings. Gradient elastic stockings, such as those made by Jobst, Sigvaris, Juzzo, or Medi, are generally viewed as the principle means of preventing complications of chronic venous insufficiency.

Early compression devices consisted of a single inflatable chamber that applied relatively uniform pressure to the whole limb. The development of multi-chambered devices provided patients with active, sequential compression in the distal to proximal direction, effectively “milking” the lymph from the problematic extremity. The latest major modification to pneumatic compression devices is the incorporation of a control mechanism, which permits the delivery of calibrated pressure gradients within a multi-chambered
device (e.g., the pump puts stronger pressure on the hand area than the upper arm). Some researchers believe that the most effective lymphedema pumps are multi-chambered and can apply both sequential and gradient pressure, which results in a repetitive squeezing and relaxing action that simulates normal muscle contraction. These devices vary in size, operation, complexity, and cost. Typically, pressures available through these devices range from 0 to 300 mm Hg. The suggested therapeutic range is dependent on diagnosis and patient characteristics, but is generally from 30 to 60 mm Hg. Available timed cycles vary in range from seconds to minutes and total treatment time per session ranges from 30 minutes to 8 hours depending on the diagnosis, condition of patient, and device.

Pumps can be divided into two broad categories:

- **Nonsegmented pneumatic compressor**: Single-chamber nonprogrammable pumps are the simplest pumps, consisting of a single chamber that is inflated at one time that applies uniform pressure. Examples of models include the following: Huntleigh-Flowplus® (Huntleigh Healthcare Inc.), Jobst-System 7000® (BSN-Jobst Inc.), Talley-Multicom 100® (Talley Group Ltd; Hampshire, UK), Wright Linear® Pump-Solo50 (Wright Linear Pump Inc.).

- **Segmented pneumatic compressor**: These pumps have multiple chambers, ranging from 2 to 12 or more. The chambers are inflated sequentially and have a fixed pressure in each compartment. They can either have the same pressure in each compartment or a pressure gradient, but they do not include the ability to manually adjust the pressure in individual compartments. The pressure is usually set by a single control on the distal segment. Examples of models include the following: BioCompression-Sequential Circulator 2000-2004® (Bio Compression Systems Inc.), Jobst-System 7500(II)® (BSN-Jobst Inc.), Huntleigh-Lymphatron® (Huntleigh Healthcare Inc.), Kendall-Home Rx (5550)® (Tyco Healthcare, Kendall division), Talley-Multicom 300® (Talley Group Ltd; Hampshire, UK), and Wright Linear® Pump-Solo 51 (Wright Linear Pump Inc.).

- **Single- or multichamber programmable pumps**: These are similar to the pumps described above, except that it is possible to make manual adjustments in the pressure in the individual compartments and/or the length and frequency of the inflation cycles. In some situations, including in patients with scarring, contractures, or highly sensitive skin, programmable pumps are generally considered to be the preferred option. Examples include the following: BioCompression-Sequential Circulator models 3000-3004® (Bio Compression Systems Inc.), Chattanooga -PresSsion 430 VGS® (Chattanooga Group Inc.), Talley-Multicom 500® (Talley Group Ltd; Hampshire, UK), Wright Linear Pump-AutoPro 52®, and Pro 52® (Wright Linear Pump Inc.).

Although pneumatic compression devices have been acknowledged as a potential component of the multidisciplinary, therapeutic approach to treating patients with peripheral lymphedema, conclusive documentation of the beneficial role of this modality has not been provided. The available data suggest that these pumps may benefit a subset of patients with lymphedema; however, the specific indications and most effective treatment regimens have not been clearly defined. Evidence suggests that adjunctive, intermittent pneumatic compression is an appropriate therapeutic option for patients whose limb volume has not been reduced by more conservative treatment, such as the use of a compression garment and/or decongestive lymphatic therapy.

**Treatment of Lymphedema:**

Lymphedema is an abnormal accumulation of fluid in tissues and swelling of the limbs or body cavities resulting from an obstruction of lymphatic flow. The condition is characterized by an abnormal collection
of excess tissue proteins, edema, chronic inflammation, and fibrosis. Fluid accumulation results in gradual and progressive enlargement of the affected extremity or other region of the body accompanied with declines in functional and immunological capabilities, increased weight, and morphological changes. Lymphedema can be subdivided into primary and secondary lymphedema. Primary lymphedema has no recognizable etiology, while secondary lymphedema is related to a variety of causes including surgical removal of lymph nodes, post-radiation fibrosis, spread of malignant tumors to regional lymph nodes with lymphatic obstruction, scarring of lymphatic channels, or congenital anomalies.

The reported incidence of lymphedema varies due to discrepancies in the definition and classification of the disorder and in the measurement of affected areas, assessment of patients for lymphedema at different times after treatment, and varying limb/body part involvement. In the United States, the highest incidence of lymphedema is observed among patients who undergo breast cancer surgery, particularly among those who undergo radiation therapy following axillary lymphadenectomy. Among this patient population, estimates of lymphedema frequency range from 10% to 40%.

Treatment may include mechanical measures such as compression garments, bandaging, manual massage, pneumatic compression devices (i.e., lymphedema pumps), drugs, or rarely surgery. The application of external pressure represents a reasonable and successful method for the mobilization of lymph from the affected limb in some patients. Pneumatic compression devices consisting of a single inflatable chamber or multiple chambers have been developed and used in the successful reduction of lymphedema. Multichambered devices allow the application of pressure sequentially, starting from the distal chamber and progressing proximally, theoretically encouraging an effective, unidirectional flow of lymph out of the limb.

**Deep Vein Thrombosis (DVT) prophylaxis:**

Prophylactic therapy for prevention of DVT is routinely utilized in the in-patient setting with major abdominal, pelvic, extremity or neurologic surgery, or following major trauma. DVT and pulmonary embolism (PE) are major complications associated with these surgeries resulting in significant morbidity and mortality.

Use of regional rather than general anesthesia, early mobilization, and other changes in patient care has been credited with reducing the incidence of DVT after surgical procedures. To achieve further reductions in the incidence of DVT, some practitioners rely on postoperative treatment with anticoagulants such as aspirin, low-molecular-weight (LMW) heparin, synthetic pentasaccharides, and warfarin. A potential disadvantage of this approach is that it increases the risk for bleeding complications, particularly in patients who are at high risk for bleeding. Another approach to DVT prevention relies on mechanical methods such as graduated compression stockings, continuous passive motion devices, venous foot pumps, and pneumatic compression pumps, which can be used in combination with anticoagulants. These modalities appear to act primarily by increasing the velocity of venous blood flow through the legs, counteracting the clotting process that can occur in blood that is moving slowly or that has temporarily stopped flowing through veins. In addition to the potential for preventing DVT, mechanical methods may reduce leg swelling after surgery. Although pneumatic compression and other mechanical methods for DVT prevention may be beneficial, this approach has limitations, including need to ensure patient compliance, lack of standards for devices and intensity of compression, and need to clean and maintain the devices, particularly compression pumps that would be reused by many patients.

Several different types of pneumatic compression systems have been evaluated for their capacity to
prevent deep vein thrombosis (DVT) after knee surgery. The least cumbersome of these systems are devices such as the A-V Impulse System™ (Novamedix Services Ltd.) and PlexiPulse® device (Ortho Plus Inc.), which apply pneumatic pressure to the soles of the feet. Pressure is applied starting at the toes and progressing toward the heel to help pump blood out of the feet and back toward the heart. Other commercially available systems such as the Aircast VenaFlow® System (Aircast, a subsidiary of DJO Global Inc.) or SCD™ System (Kendall Brands, a subsidiary of Covidien Inc.) apply pressure to the lower leg, entire leg, or foot and leg in waves that progress from the toes or ankle toward the thigh. A common feature of the design of these systems is their use of air pumps and inflatable chambers to apply waves of pressure. To maintain normal blood flow into the leg, pneumatic compression systems have cycles of inflation and deflation of the air chambers. Depending on the device used, the full cycle of pumping takes between 20 seconds and 2 minutes at pressures ranging from 35 to 180 millimeters of mercury (mm Hg). Since DVT can occur in the untreated leg of a patient who has undergone knee surgery, many practitioners apply pneumatic compression to both legs. Although treatment protocols vary, some clinicians encourage patients to use the device as much as possible day and night during the entire postoperative stay. Compliance with pneumatic compression treatment must be monitored since these systems can be switched off by patients.

Pneumatic compression therapy is reasonably safe and caused minor or no complications in the reviewed studies for prevention of DVT. The results of the available controlled studies suggest that pneumatic compression is a promising therapy, particularly in combination with other available treatments for prevention of DVT; however, the available studies provide somewhat inconsistent evidence concerning the efficacy of pneumatic compression relative to other strategies for DVT prevention.

Treatment of Chronic Venous Stasis Ulcers:
Compression therapy is an important part of treatment for chronic venous insufficiency (CVI) and venous leg ulcers. Compliance with the bandage system (stockings, bandages, and Unna’s boot) may be a problem for some patients who may require higher levels of compression.

The intermittent pneumatic compression (IPC) device is one means of intermittently increasing compression to relieve edema. This device can be used as an adjunct or alternative to compression bandaging in patients who are relatively immobile and therefore, unable to activate the calf muscle pump. In addition, pneumatic compression may be effective for patients who have previously failed treatment with other compression devices.

Treatment of Peripheral Arterial Disease (PAD):
Intermittent pneumatic compression (IPC) has been studied as a noninvasive treatment for patients with PAD, especially those with no options for revascularization, and as an alternative for amputation (Labropoulos et al., 2002; Slovut and Sullivan, 2008).
Pneumatic compression therapy for arterial insufficiency is a procedure and, therefore, not subject to FDA regulation. However, the equipment used as part of this procedure may fall under FDA regulation. The FDA considers pneumatic compression devices Class II devices intended for use in prevention of blood pooling in a limb by periodically inflating a sleeve around the limb.

Devices and systems to perform pneumatic compression are regulated by the FDA as Class II devices, and 195 of these systems have been approved via the FDA 510(k) process (CDRH, 2011). Systems utilized in the reviewed studies are listed below:

- ActiveCare® System (Medical Compression Systems Ltd.), approved March 8, 2006
- WalkCare™ P200 System (Medical Dynamics LLC), approved May 20, 1999
- Act-One™ System (New Dimensions in Medicine Inc.), approved December 27, 1994
- Aircast VenaFlow® System (Aircast, a subsidiary of DJO Global Inc.), approved October 25, 1993
- A-V Impulse System™ (Novamedix Services Ltd.), approved April 15, 1992 (K914461)
- SCD™ System (Kendall Brands, a subsidiary of Covidien Inc.), approved May 19, 1989
- Flowtron® Universal (Huntleigh Healthcare Inc.), cleared on March 26, 2002 (K010744)
- Art-Assist Model AA-1000 (ACI Medical Management Inc.), cleared on February 28, 1996 (K942530)

2. CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS):

CMS published a National Coverage Determination (NCD 280.6) for pneumatic compression devices in 2002.

**Lymphedema:** The NCD provides coverage for pneumatic compression devices in the home setting for the treatment of lymphedema only if patients have undergone 4 weeks of conservative therapy with a compression garment or compression bandage system and significant symptoms remain and the treating physician providing treatment determines that there has been no significant improvement. The conservative therapy must also include exercise and elevation of the affected limb.

**Chronic Venous Insufficiency With Venous Stasis Ulcers:** Pneumatic compression devices are covered in the home setting for the treatment of CVI of the lower extremities only if the patient has one or more venous stasis ulcer(s) which have failed to heal after a 6 month trial of conservative therapy directed by the treating physician. The trial of conservative therapy must include a compression bandage system or compression garment, appropriate dressings for the wound, exercise, and elevation of the limb.

**General Coverage Criteria:** Pneumatic compression devices are covered only when prescribed by a physician and when they are used with appropriate physician oversight, i.e., physician evaluation of the patient's condition to determine medical necessity of the device, assuring suitable instruction in the operation of the machine, a treatment plan defining the pressure to be used and the frequency and duration of use, and ongoing monitoring of use and response to treatment.

The determination by the physician of the medical necessity of a pneumatic compression device must include:

a. The patient's diagnosis and prognosis;

b. Symptoms and objective findings, including measurements which establish the severity of the condition;
c. The reason the device is required, including the treatments which have been tried and failed; and

d. The clinical response to an initial treatment with the device. The clinical response includes the change in pre-treatment measurements, ability to tolerate the treatment session and parameters, and ability of the patient (or caregiver) to apply the device for continued use in the home.

The only time that a segmented, calibrated gradient pneumatic compression device (HCPCs code E0652) would be covered is when the individual has unique characteristics that prevent them from receiving satisfactory pneumatic compression treatment using a nonsegmented device in conjunction with a segmented appliance or a segmented compression device without manual control of pressure in each chamber.

LCD (L33829) for Pneumatic Compression Devices effective 10/01/2015

POLICY SPECIFIC DOCUMENTATION REQUIREMENTS:
A Certificate of Medical Necessity (CMN) which has been completed, signed, and dated by the treating physician must be kept on file by the supplier and made available upon request. The CMN may act as a substitute for the detailed written order if it contains the same information as required in a detailed written order. The CMN for pneumatic compression pumps is CMS Form 846 (DME Form 04.04B). The initial claim must include an electronic copy of the CMN. In addition to the order information that the physician enters in Section B, the supplier can use the space in Section C for a written confirmation of other details of the order or the physician can enter the other details directly.

If question #1 on the CMN ("Does the beneficiary have chronic venous insufficiency with venous stasis ulcers?") is answered "Yes", documentation reflecting all of the following must be in the beneficiary's medical record and made available upon request:
- The location of venous stasis ulcer(s),
- How long each ulcer has been continuously present,
- Previous treatment with a compression bandage system or compression garment, appropriate dressings for the ulcer(s), exercise and limb elevation for at least the past 6 months,
- Evidence of regular physician visits for treatment of venous stasis ulcer(s) during the past 6 months.

If E0652 is billed, the following additional documentation supporting the medical necessity for this device must be substantiated by information in the beneficiary's medical records and available upon request:
- The treatment plan including the pressure in each chamber, and the frequency and duration of each treatment episode,
- Whether a segmented compressor without calibrated gradient pressure (E0651) or a non-segmented compressor (E0650) with a segmented appliance (E0671-E0673) had been tried and the results,
- Why the features of the device that was provided are needed for this beneficiary,
- The name, model number, and manufacturer of the device.

3. MINNESOTA DEPARTMENT OF HUMAN SERVICES (DHS):
Pneumatic compression devices are covered for eligible MHCP recipients with chronic venous insufficiency of the lower extremities or lymphedema that has not responded to other treatment options.
- Covered codes include E0650 and E0675 (pneumatic compressors), and E0653-E0673 (appliances for use with pneumatic compressor)
• Only compressors approved by the FDA are covered.
• Only appliances approved by the FDA for use on extremities are covered.
• Non-segmental pneumatic compression devices (E0650), and segmental pneumatic compression devices without calibrated gradient pressure (E0651), are covered without authorization for treatment of chronic venous insufficiency of the lower extremities when the recipient has had one or more lower extremity venous stasis ulcers and meets the following criteria:
  o The recipient has undergone at least six months of conservative therapy including:
    ▪ The use of appropriate compression bandage systems or compression garments
    ▪ Appropriate dressings for the wound
    ▪ Exercise
    ▪ Elevation of the limb
    ▪ Aggressive skin care
  o The venous stasis ulcer has failed to heal after a six month trial.
• Non-segmental pneumatic compression devices (E0650), and segmental pneumatic compression devices without calibrated gradient pressure (E0651), are covered without authorization for treatment of lymphedema when the recipient meets the following criteria:
  o The recipient has undergone at least six months of conservative therapy including:
    ▪ The use of appropriate compression bandage systems or compression garments
    ▪ Manual lymph massage
    ▪ Exercise
    ▪ Elevation of the limb
    ▪ Aggressive skin care
    ▪ Education in lymphedema self-management
  o No significant improvement has occurred or significant symptoms remain following four week trial.
• One segmental or non-segmental appliance for each affected extremity is covered per year for use with a medically necessary pneumatic compressor. A new order is required for replacement of an appliance.
• Prior to dispensing the pneumatic compressor and appliances, the medical supplier must obtain documentation from the physician detailing the conservative treatment that was tried and failed.
• Segmental pneumatic compression devices with calibrated gradient pressure (E0652) are covered with authorization when the recipient’s medical condition cannot be safely and effectively treated with non-segmental devices or with segmental devices without calibrated gradient pressure.
• Integrated appliances with 2 full legs and trunk (E0670) are covered with authorization for recipients that cannot use other appliances due to co-existing medical conditions, including obesity.
• High pressure, rapid cycling pneumatic compression devices (E0675) are covered with authorization for treatment of peripheral artery disease for patients who might otherwise require surgical treatment of the arterial insufficiency.

Non-Covered:
• Appliances for use on the trunk, pelvis or chest (E0656, E0657) are not reimbursed separately from the compressor.
• Pneumatic compressors/appliances for indications other than peripheral artery disease, chronic venous insufficiency of the lower extremities or lymphedema are considered investigative.
### CLINICAL EVIDENCE:

**Lymphedema:**

The literature review addresses two main questions: the efficacy and safety of pneumatic compression pumps compared to alternative treatments for lymphedema and the relative efficacy of different types of pumps. Due to the FDA-approval of lymphedema pumps that treat the truncal area in addition to the affected limb, there has recently been interest in the evidence on truncal clearance as part of lymphedema treatment. The updated literature searches did not identify any comparative studies that examined whether treating the truncal area in addition to the affected limb improves the outcomes of pneumatic compression pump treatment more than only treating the limb.

In 2010, the McMaster University Evidence-based Practice Center, under contract with the Agency for Healthcare Research and Quality (AHRQ), published a technology assessment on diagnosis and treatment of secondary lymphedema that included discussion of pneumatic compression pumps. The authors, Oremus and colleagues, identified a total of 10 studies; 6 moderate-to-high-quality randomized controlled trials (RCTs), 2 low-quality RCTs, and 2 observational studies. There was a high degree of heterogeneity between studies: 7 types of lymphedema pumps were used, pumps were compared to 6 different alternative interventions (including compression bandages, laser, and massage), and 5 studies used pumps in combination with other interventions. Six trials compared the addition of massage, including manual lymphatic drainage (a specialized type of massage performed by a trained therapist), to more conservative treatments such as bandaging or physical therapy. Five of the 6 studies included women with arm lymphedema after breast cancer treatment. Only 1 of these 5 studies found that massage led to greater reduction in arm volume than more conservative therapy. The sixth trial, which addressed lymphedema after ankle surgery, found significantly greater reduction in volume when manual lymph drainage massage was added to standard physical therapy versus physical therapy alone. Due to the relatively small number of studies and high degree of variability in study design, the authors concluded that there was insufficient evidence to determine whether any type of intermittent pneumatic compression (IPC) device and sleeve was more effective than another type.

In 2012, Oremus and colleagues published an updated systematic review on conservative treatments for secondary lymphedema. The authors identified a total of 36 studies, 30 of which were RCTs and 6 were observational studies. Six RCTs evaluated intermittent pneumatic compression. Study findings were not pooled. The authors reported that 2 RCTs showed that IPC was superior to decongestive therapy or self-massage but 3 other RCTs failed to show that IPC was superior to a different type of conservative treatment of lymphedema. In addition, the authors identified 1 RCT comparing types of IPC devices. The study by Pilch et al. (2009) found that a 3-chamber IPC sleeve was superior to a 1-chamber sleeve for reducing edema.

**Lymphedema pumps compared to alternative treatment:**

In 2002, Szuba and colleagues published an article that evaluated the Biocompression Systems Sequential Circulator lymphedema pump, a 4-chamber device, in 2 RCTs conducted in the U.S. among women with breast cancer.

Study 1: The study evaluated initial treatment of women with unilateral lymphedema (an increase of at least 20% in the volume of the swollen arm compared to the normal arm) who had completed cancer therapy at least 12 weeks earlier. Twelve women were randomly assigned to 10 days of outpatient...
treatment with decongestive lymphatic therapy (a multidisciplinary approach consisting of manual lymph drainage, compression bandaging, and massage) plus use of a lymphedema pump 30 minutes a day at 40-50 mm Hg, and 11 were randomly assigned to decongestive lymphatic therapy alone. At the 2-week follow-up, there was a statistically significant greater reduction in volume of the edematous arm in the group assigned to pump use (45%) compared to the nonpump group (26%), p<0.05. The difference in volume reduction between groups was not significantly different at 40 days at the end of Phase II; there was a mean reduction of 30% in the pump group and 27% in the nonpump group.

Venous ulcers:
A 2011 Cochrane review addressed intermittent pneumatic compression pumps for treating venous leg ulcers. The review identified a total of 7 RCTs. Four trials compared pneumatic compression pumps plus compression bandages or stockings to compression bandages or stockings only, 1 trial compared compression pumps to wound dressings only and 1 trial compared two intermittent pneumatic compression regimens. The trial comparing pumps to wound dressings, which was not blinded, found a significantly greater rate of wound healing with compression treatment. However, the more relevant comparison intervention is continuous compression provided by bandages or stockings. The 4 trials with this comparison had sample sizes ranging from 22 to 53. Blinding was unclear in 3 of the studies and the fourth was not blinded. In a pooled analysis of 3 of the 4 trials, there was not a statistically significant difference in the number of healed ulcers in the group receiving intermittent pneumatic compression or compression bandaging or stockings only, risk ratio (RR): 1.09 (95% confidence interval [CI]: 0.91-1.30). The fourth trial found a significantly higher healing rate in the pump group than the compression bandage/stocking group; in this trial, the rate of healing with compression bandages/stockings was particularly low.

APPLICABLE CODES:
Coding information generally will not be entered at the time of policy development. Coding information is provided by Claim Medical Management and added to the policy at a later date.

The Current Procedural Terminology (CPT®) codes and HCPCS codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other medical policies and coverage determination guidelines may apply.

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<th>HCPCS Code</th>
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<tr>
<td>A4600</td>
<td>Sleeve for intermittent limb compression device, replacement only, each</td>
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<tr>
<td>A6545</td>
<td>Gradient compression wrap, nonelastic, below knee, 30-50 mm Hg, each</td>
</tr>
<tr>
<td>E0650</td>
<td>Pneumatic compressor, non-segmental home model</td>
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<tr>
<td>E0651</td>
<td>Pneumatic compressor, segmental home model without calibrated gradient pressure</td>
</tr>
<tr>
<td>E0652</td>
<td>Pneumatic compressor, segmental home model with calibrated gradient pressure</td>
</tr>
<tr>
<td>E0655</td>
<td>Non-segmental pneumatic appliance for use with pneumatic compressor, half arm</td>
</tr>
<tr>
<td>E0660</td>
<td>Non-segmental pneumatic appliance for use with pneumatic compressor, full leg</td>
</tr>
<tr>
<td>E0665</td>
<td>Non-segmental pneumatic appliance for use with pneumatic compressor, full arm</td>
</tr>
<tr>
<td>E0666</td>
<td>Segmental pneumatic appliance for use with pneumatic compressor, trunk</td>
</tr>
<tr>
<td>E0667</td>
<td>Segmental pneumatic appliance for use with pneumatic compressor, chest</td>
</tr>
<tr>
<td>E0668</td>
<td>Non-segmental pneumatic appliance for use with pneumatic compressor, chest</td>
</tr>
<tr>
<td>E0669</td>
<td>Segmental pneumatic appliance for use with pneumatic compressor, half leg</td>
</tr>
<tr>
<td>CPT® Code</td>
<td>Description</td>
</tr>
<tr>
<td>-----------</td>
<td>-----------------------------------------------------------------------------</td>
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<tr>
<td>E0668</td>
<td>Segmental pneumatic appliance for use with pneumatic compressor, full arm</td>
</tr>
<tr>
<td>E0669</td>
<td>Segmental pneumatic appliance for use with pneumatic compressor, half leg</td>
</tr>
<tr>
<td>E0671</td>
<td>Segmental gradient pressure pneumatic appliance, full leg</td>
</tr>
<tr>
<td>E0672</td>
<td>Segmental gradient pressure pneumatic appliance, full arm</td>
</tr>
<tr>
<td>E0673</td>
<td>Segmental gradient pressure pneumatic appliance, half leg</td>
</tr>
<tr>
<td>E0676</td>
<td>Intermittent limb compression device (includes all accessories), not otherwise specified</td>
</tr>
<tr>
<td>A6545</td>
<td>Gradient compression wrap, nonelastic, below knee, 30-50 mm Hg, each</td>
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</tbody>
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<table>
<thead>
<tr>
<th>CPT® Code</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>29581</td>
<td>Application of multi-layer compression system; leg (below knee), including ankle and foot</td>
</tr>
<tr>
<td>29582</td>
<td>Application of multi-layer compression system; thigh and leg, including ankle and foot, when performed</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ICD-9 Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>451.0 - 451.2</td>
<td>Phlebitis and thrombophlebitis of superficial or deep vessels of lower extremities</td>
</tr>
<tr>
<td>451.81</td>
<td>Phlebitis and thrombophlebitis of iliac vein</td>
</tr>
<tr>
<td>453.40 - 453.42</td>
<td>Venous embolism and thrombosis of deep vessels of lower extremity</td>
</tr>
<tr>
<td>453.8</td>
<td>Venous embolism and thrombosis of other specified veins</td>
</tr>
<tr>
<td>454.0 - 454.8</td>
<td>Varicose veins of lower extremities, with ulcer, with inflammation, with ulcer and inflammation, or with other complications</td>
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<tr>
<td>457.1, 457.2, 457.8</td>
<td>Other lymphedema, lymphangitis, and other noninfectious disorders of lymphatic channels</td>
</tr>
<tr>
<td>459.10 - 559.19</td>
<td>Postphlebitic syndrome</td>
</tr>
<tr>
<td>459.2</td>
<td>Compression of vein</td>
</tr>
<tr>
<td>459.30 - 459.31</td>
<td>Chronic venous hypertension without complication or with ulcer</td>
</tr>
<tr>
<td>459.33</td>
<td>Chronic venous hypertension with ulcer and inflammation</td>
</tr>
<tr>
<td>459.81</td>
<td>Venous (peripheral) insufficiency, unspecified</td>
</tr>
<tr>
<td>646.10 - 646.14</td>
<td>Edema or excessive weight gain in pregnancy, without mention of hypertension</td>
</tr>
<tr>
<td>671.00 - 671.04</td>
<td>Varicose veins of legs in pregnancy and the puerperium</td>
</tr>
<tr>
<td>707.04</td>
<td>Decubitus ulcer of hip</td>
</tr>
<tr>
<td>707.06</td>
<td>Decubitus ulcer of ankle</td>
</tr>
<tr>
<td>707.07</td>
<td>Decubitus ulcer of heel</td>
</tr>
<tr>
<td>707.10 - 707.19</td>
<td>Ulcer of lower limbs, except decubitus</td>
</tr>
<tr>
<td>757.0</td>
<td>Hereditary edema of the legs</td>
</tr>
<tr>
<td>782.3</td>
<td>Edema</td>
</tr>
<tr>
<td>799.3</td>
<td>Debility, unspecified [covered for members who are bedridden due to trauma, orthopedic surgery, neurosurgery or other circumstances preventing ambulation]</td>
</tr>
<tr>
<td>905.0 - 909.9</td>
<td>Late effects of injuries, poisonings, toxic effects, and other external causes</td>
</tr>
<tr>
<td>V15.51 - V15.59</td>
<td>Personal history of injury</td>
</tr>
<tr>
<td>V45.4</td>
<td>Arthrodesis status</td>
</tr>
<tr>
<td>V45.89</td>
<td>Other postsurgical status [not covered for the management of edema following femoro-popliteal bypass surgery]</td>
</tr>
<tr>
<td>V49.84</td>
<td>Bed confinement status [covered for members who are bedridden due to trauma, orthopedic surgery, neurosurgery or other circumstances preventing ambulation]</td>
</tr>
<tr>
<td>V54.0 - V54.9</td>
<td>Other orthopedic aftercare</td>
</tr>
<tr>
<td>V58.71 - V58.78</td>
<td>Aftercare following surgery to specified body systems, not elsewhere classified</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ICD-10 Codes</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>I26.x*</td>
<td>Pulmonary embolism</td>
</tr>
<tr>
<td>I80.x*</td>
<td>Phlebitis and thrombophlebitis</td>
</tr>
</tbody>
</table>
L40.50  Psoriatic arthritis
MO5   Rheumatoid arthritis
M16   Osteoarthritis of the hip
M24.35 Pathological dislocation of hip, not elsewhere classified
M24.45 Recurrent dislocation, hip
M24.85 Other specific joint derangements of hip, not elsewhere classified
M87.05 Idiopathic aseptic necrosis of pelvis and femur
S72   Fracture of femur
S73   Dislocation and sprain of joint and ligaments of hip

* The x represents a range of codes; it is dependent on the specific diagnosis.

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REFERENCES:


13. Food and Drug Administration (FDA) [website]. Center for Devices and Radiological Health (CDRH). Search product code field JOW. Updated 11/11/2015. Available at:

POLICY HISTORY:

<table>
<thead>
<tr>
<th>DATE</th>
<th>ACTION/DESCRIPTION</th>
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<tr>
<td>06/27/2013</td>
<td>Reviewed and approved by the Quality Improvement Advisory and Credentialing Council (QIACC).</td>
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<tr>
<td>11/15/2013</td>
<td>Published to UCare.org.</td>
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<tr>
<td>12/7/2015</td>
<td>Revised policy reviewed and approved by Medical Policy Committee.</td>
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<tr>
<td></td>
<td>• Policy number revised to 2016M0025B.</td>
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<tr>
<td></td>
<td>• Added information on peripheral arterial disease.</td>
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<tr>
<td>12/17/2015</td>
<td>Reviewed and approved by the Quality Improvement Advisory and Credentialing Council (QIACC).</td>
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<tr>
<td>01/01/2016</td>
<td>Published to UCare.org.</td>
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QUESTIONS AND ANSWERS:

Q1:  
A1:  

ATTACHMENTS: