Purpose

The purpose of this literature review is to consider the scientific evidence for the use of pneumatic compression devices (PCD) in the treatment of lymphedema. The review will attempt to determine:

1. Does the medical literature support the use of one type of PCD compared to another?
2. If the medical literature supports the use of one type of PCD compared to another, are there specific patient populations or disease conditions that support the medical necessity of one type of PCD (e.g., PCD with manually-controlled pressures vs. without manual control)?

Types of Pneumatic Compression Devices and Appliances (sleeves)

There are 3 basic types of PCDs:

1. A non-segmented pneumatic compressor (Healthcare Common Procedure Coding System (HCPCS) code E0650) is a device which has a single outflow port on the compressor. This outflow port may be connected to a sleeve/appliance with multiple compartments or segments (E0671-E0673) and may achieve a sequential pressure gradient through the design of the tubing and/or air chambers in the sleeve/appliance.
2. A segmented pneumatic compressor without calibrated gradient pressure (E0651) is a device which has multiple outflow ports on the compressor which lead to distinct segments on the appliance which inflate sequentially. These devices achieve sequential compression by either (a) application of the same pressure in each segment or (b) application of a predetermined pressure gradient in successive segments but no ability to individually set or adjust pressures in each of one or several segments. In these devices, the pressure is usually set by a single control on the distal segment. They are used with sleeves/appliances (E0667-E0669) that are multi-chambered thus allowing for sequential, gradient compression.
3. A segmented device with calibrated gradient pressure (E0652) is characterized by a manual control on at least three outflow ports which can deliver an individually determined pressure to each segmental unit. These PCDs are also used with a multi-chambered sleeve/appliance to achieve sequential, gradient compression.

Evidence Review Criteria

A PUBMED search was conducted using the search terms "pneumatic" and "compression" combined with "lymphedema." Only English language full text articles were reviewed. The search was limited to articles published from 1980 to 2008. The relative strength of the evidence presented in the clinical studies was assessed according to the guidance provided by the Centers for Medicare & Medicaid Services (CMS) to contractor medical directors for developing local coverage determinations (LCDs).

According to CMS instructions, coverage policies should be based on:

1. Published authoritative evidence derived from definitive randomized clinical trials or other definitive studies; and,
2. General acceptance by the medical community (standard of practice), as supported by sound medical evidence based on:
   a. Scientific data or research studies published in peer-reviewed medical journals; or,
   b. Consensus of expert medical opinion (i.e., recognized authorities in the field); or,
   c. Medical opinion derived from consultations with medical associations or other health care experts.
The instructions continue by stating:

Acceptance by individual health care providers or even a limited group of health care providers normally does not indicate general acceptance by the medical community. Testimonials indicating such limited acceptance, and limited case studies distributed by sponsors with financial interest in the outcome, are not sufficient evidence of general acceptance by the medical community. The broad range of available evidence must be considered and its quality shall be evaluated before a conclusion is reached.

While this review is not conducted to develop an LCD, its purpose will support coverage decisions made by the contractor medical director. Consequently, the review will be conducted in accordance with guidance provided by CMS. In addition to articles and position papers retrieved by the search described above, several manufacturers of PCDs were asked for clinical material supporting PCD use.

**Evidence Evaluation**

While numerous articles were reviewed noting that PCD has become standard of care in most countries, conclusive documentation of the benefits of this treatment modality are lacking. The opinion expressed by the Supportive Care Guidelines Group of Cancer Care Ontario and the Ontario Ministry of Health and Long Term Care is illustrative of this dilemma when they state that “The lack of sufficient high quality evidence precludes definitive recommendations from being made.” While this statement was made in relation to treatment options for women with breast cancer and lymphedema, the document further states, “There is some evidence which suggests that physical therapies such as compression therapy and manual lymphatic drainage may improve established lymphedema but further studies are needed.”

Szuba *et al.*, conducted a randomized, prospective study at the Stanford Center for Lymphatic and Venous Disorders clinic comparing decongestive lymphatic therapy (DLT) alone or DLT with adjunctive intermittent compressive therapy. The study utilized a Sequential Circulator 2004 (BioCompression Systems, Inc.), a PCD categorized as E0651. DLT is a multi-disciplinary, physiotherapeutic treatment modality that includes manual lymphatic drainage (MLD), compression bandaging of the impacted limb with minimally elastic bandages and decongestive exercises. This report by Szuba included two studies. Study 1, included 23 women treated for breast cancer and compared DLT alone to DLT plus PCD in an initial 40 day period. Study 2, termed “maintenance therapy”, included 27 women who had completed an initial one month of intensive DLT but had less than one year of DLT experience. All patients were fitted with and wore a Class II compression garment.

In Study 1 (Initial Treatment), 12 patients were randomized to DLT plus PCD (Group 1) and 11 to DLT alone (Group 2). After two weeks of treatment, there was a statistically significant volume reduction in the affected extremity of 45.3% vs. 26% for Group 1 compared to Group 2, respectively. At the end of 40 days, volume reduction was 30.3% for Group 1 and 27.1% for Group 2. The difference in volume reduction between the two groups at 40 days was not statistically significant nor was the change from the time of the two week evaluation; however, it did demonstrate that the effects of treatment are durable.

In Study 2 (Maintenance Treatment), 27 patients were recruited and 25 completed the study. Patients were followed for one month and were randomized to receive self-administered maintenance therapy with DLT alone versus DLT plus PCD. Similar to Study 1, there was a statistically significant reduction in limb volume in the group randomized to the DLT plus PCD group. Twenty-four patients were followed for subsequent 6 month period with 19 electing to continue use of a PCD. These patients experienced an additional reduction in limb volume compared to the five patients electing to discontinue pump use.

Szuba’s study was small and only included patients with lymphedema subsequent to breast cancer treatment. There was no description of the randomization process and follow-up time was relatively short. In addition, like many studies, patients used a compression garment or compression bandage systems between treatments. Since authors do not comment on the compliance with garment use, its impact on the results of PCD use are uncertain. Compliant use of a compression garment between sessions could clearly impact the volume reductions attributed to PCD use. Taking that caveat into consideration, this study did demonstrate that the use of an E0651 PCD was efficacious in reducing upper extremity edema.
Rockson and colleagues conducted a randomized, prospective, cross-over study of massage versus PCD (Flexitouch - Tactile Systems, Inc.) in 10 patients with unilateral breast cancer-associated lymphedema of the arm. The Flexitouch system utilizes a garment that extends onto the thoracic wall or pelvic/abdominal region, the benefit purported to be encouragement of excess fluid to follow existing pathways of lymph movement from the trunk to the central circulation. All patients used self-administered massage and compression garments prior to randomization. The study was conducted for 14 days after a 1 week washout where only compression garments were used (no massage). The Flexitouch arm achieved statistically significant reduction in volume compared to the massage alone cohort. The authors observed that even in short term use, the device confers therapeutic benefit over that which can be attained through standard therapies. However, they also note that this was a small study of limited length and the protracted use of this device must be considered in relationship to the retail cost of between $10,800 and $12,400 (2005 pricing). Additional weaknesses are the lack of comparison to standard garments that encircle the limb only and the failure to specify treatment pressures.

Dini et al. (1998) conducted the most widely cross-referenced randomized study examining the impact of treatment with pneumatic compression versus no treatment on post-mastectomy patients with lymphedema. This study 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 weakness of this study is the lack of detailed information about the pump system used. The authors state that PCD sessions had cycle pressures of 60 mmHg; however, there is no description of the system used or whether a sequential gradient appliance was used.

Johansson and colleagues prospectively compared manual lymph drainage (MLD) utilizing the Vodder technique to sequential pneumatic compression applied to the upper extremity in 28 women with post-surgical arm lymphedema following breast cancer and axillary node dissection. Pneumatic compression was applied with the Lymphapress device (E0651 + E0667) utilizing 40-60 mmHg of pressure for 2 hours per day.

Compression garments were used in both the MLD and PCD patients between treatments. Following a two week run-in using a standard compression sleeve (garment), 24 patients were randomized. At the two week follow-up, there was no significant difference between the two treatments (MLD vs. PCD) in either absolute volume reduction or in percent reduction in lymphedema. The authors note that the poorer result for the PCD patients compared to other studies (10, 15) may be due to the short duration of treatment (2 hours per day). Arguing against this hypothesis is the comparison of the MLD and PCD demographics. The SPC group had an average edema duration of 6.5 months versus 14.0 months in the MLD group. Studies have shown that the duration of the edema can significantly impact the success of lymphedema treatment due to scaring and fibrous changes in the underlying tissues; therefore, the PCD patients with the shorter duration should have had an “advantage” towards improved fluid reduction over the MLD patients. This was not seen.

Bergen, et al. studied thirty-five patients to determine the optimal method of mechanical compression for both primary and secondary lymphedema. Each limb was treated by three types of compression devices: a single cell pump composed of one bladder inflated to 50 mmHg around the edematous area, a three compartment pump inflated to 50 mmHg, and a ten-cell gradient pressure pump inflated to 30 mmHg proximally and 80 mmHg distally (E0651 + E0667). Post-treatment measurements demonstrated minimal change in limb volume with the single chamber pump with the three compartment device being slightly better. Results with the multi-compartment pump showed a significant decrease in edema over the 2 hour treatment for patients with primary or secondary lymphedema. Further analysis by study participant type (primary lymphedema, secondary lymphedema without radiation, and secondary lymphedema with radiation therapy) showed no difference in results between these three groups. Limitations of this study are related primarily to the study design itself. The authors do not provide any information on the time between treatments, what area of the limb was covered by each PCD and the order of the pumps used (the patients served as their own controls using pre- and post-treatment with each type of pump). Interpretation of the study is further complicated by disparities and heterogeneity in the duration, severity, and type of lymphedema, age range of the participants, and the influence from previous therapy.
Pappas et al. performed a case series non-randomized follow-up study on the long-term effects of sequential high-pressure intermittent pneumatic compression (SIPC) therapy followed by application of elastic stockings in 49 patients with primary and secondary lymphedema. Most of the participants had undergone some form of treatment prior to the study: forty were wearing elastic stockings, five used uni-compartmental compression device, two had had surgery. A multi-compartmental sleeve of 9 to 12 cells was used with a maximum compression per cycle of 110 mmHg for 20 seconds distally and 80 mmHg for 2 seconds proximally (E0651 + E0667). This was applied for 6 - 8 hours over a 2 - 3 day hospital stay. Custom fitted compression stockings of 40 mmHg were then applied to the limb at the post treatment girth.

Treatment outcomes were divided into three groups:

**Group 1 (n=7)** – 80% had lymphedema for ≥ 10 years
**Result:** No response and were excluded from study

**Group 2 (n=10)** – 80% had lymphedema for ≥ 10 years
**Result:** Partial response. Partial response represents at least a 2 cm reduction initially, but after 4-6 months < 3 of the 9 measured levels maintaining within 1 cm of the initial post-treatment girth

**Group 3 (n=26)** – 50% had lymphedema for ≥ 5 years
**Result:** Full response. Full response represents maintaining the girth measurement within 1 cm of post-treatment girth at more than 3 levels

About half of the participants in Groups 2 and 3 chose to use the compression device at home up to 4 hours a day. Those in Group 3 who initially responded to treatment but were edematous upon removal of the device had daily or alternate day SIPC treatment at home. All patients used compression stockings between treatments. Patients were followed up at 4 – 6 month intervals over a mean time of 25 + 4 months. A total of 60% of patients had a reduction to limb girth at the nine levels of leg which were measured and 20% had reduction from the distal calf to the toe on long-term follow-up. Nineteen percent had minimal limb girth reduction. There appeared to be no effect of gender, duration of lymphedema, type of lymphedema, nor which limb was involved on predicting the outcome of the treatment. Pappas concluded that the degree of tissue compliance or subcutaneous fibrosis as well as the mechanics of the external pneumatic device itself (such as peak pressure, compression cycle, sequence, and distribution of compression) are the predictive measures in lowering edema by compression techniques. For the best effect they proposed compression of the limb not exceed the systolic pressure and used values around 80-90 mmHg. Four of the participants, all from the poor response group, experienced infection during the follow-up period in spite of instituting extra skin care measures. Weakness in this study design is evident in the exclusion of non-responders and those with arm edema. No comparison was made amongst the categories of those using the device daily and those choosing not to use it. There is diversity of participants in the type, duration and amount of lymphedema, gender, amount of pressure used and duration of each treatment in the home setting.

Klein et al. examined the Wright Linear Pump, specifically in the lower extremity. Exclusion criteria consisted of presence of infection, metastasis, chronic heart failure and renal disease. Seventy-three subjects were treated over a 48-hour period with a gradient, three compartment device applied to the lower limb for 2-hours. After a one hour rest period the device would be applied with increasing duration to a maximum of 8 hours.

The protocol was dependent on patient tolerance of pain. The distal pressure was determined by the mean of the systolic and diastolic with the other two cells diminishing in pressure by 20 mmHg each. The total treatment cycle was 120 seconds with 90 seconds of pressure distally, 70 seconds for the middle cell and 50 seconds proximally. The limb was elevated and wrapped between treatments. In the 48-hour treatment protocol, measurements were taken at 5 levels of the leg. Ninety percent of patients showed a decrease in circumference at the ankle and mid-calf area, ranging from 1.6 – 2.1 cm. All patients had some improvement after the 48 hours post-treatment. Their results suggested that men responded better than women. Although Klein noted that the reduction in circumference at the five levels of the treated limb were significant, comparative measurements of the normal, control extremity were not made thus calculation of the absolute reduction in lymphedema was not possible. As with the other studies cited above, there was variability in the participants’ degree of lymphedema, etiology, duration and amount of compression pressure.
In 1985 Richmand et al. examined the impact of sequential compression using a Lympha-Press multi-compartmental sleeve (E0651 + E0667) on 24 patients. The study was prospective but not randomized. There was heterogeneity with respect to the etiology of the lymphedema (primary vs. secondary), duration of lymphedema, location of edema (upper vs. lower extremity) and prior therapies including one patient with previous surgery (Charles Procedure) for lymphedema. In addition, the patients were studied in an inpatient setting, confined to bed with the affected extremity elevated.

Results were only presented for lower extremity volume reduction despite 7 of 24 patients enrolled for upper extremity conditions. Lower extremity volume was reduced by approximately 45%. Follow-up at 3-6 months to determine the extent of treatment persistence was complicated by subject drop out. Only 4 of 7 patients in the upper extremity and 8 of 18 in the lower extremity cohort were available for follow-up data. Authors note that all patients compulsively wore well-fitted elastic sleeves and gauntlets to help maintain volume reduction. This study is poorly designed and has significant methodologic shortcomings. The lack of data on upper extremity treatment success, the large number of patients lost to follow-up and the short duration of treatment (1-2 days inpatient) make generalization of the results to long term treatment difficult. Moreover, as many authors point out in various reviews, the use of compression garments between PCD treatments is critical to achieving sustained results.

Zelikovski and colleagues reported their experience with 262 patients using the Lympha-Press PCD on both upper and lower extremity edema. From the description of the device used, it appears to be an E0651. They concluded that results were encouraging and noted 36-70% reduction of lymphedema in 88% of patients with upper limb lymphedema while lower extremity lymphedema “almost completely disappeared.” This was not a randomized trial and contained very little statistics detailing the patients treated, etiologies of lymphedema or the methods used to measure fluid reduction. Moreover, while they note 262 patients were treated, the reductions noted above were for 112 patients (42%), mainly post-mastectomy lymphedema. There is no detail provided on the outcomes of the other 150 patients. Finally, it should be noted that Zelikovski developed the Lympha-Press device and has a financial interest in the outcome of any study.

**Evidence Reviews/Meta-Analysis**

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 and most are detailed individually above; however, the Zelikovski study from 1980 was reviewed for this analysis but excluded because the pressures used were significantly higher than what is now recommended. In addition as noted above, Zelikovski is the developer of the Lympha-Press device and has a potential bias due to financial interest in research outcomes. Two of these studies (Dubois and Zelikovski) demonstrated that volume reduction could be achieved from pump therapy alone, although one study utilized higher pressure that was usually recommended. Three studies (Johansson, Dubois, Swedborg) 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 (Dubois, Swedborg, Zelikovski). 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.”

In 2001, Erickson and colleagues reviewed the research literature related to management of arm edema in women with breast cancer. The authors review the evidence for the various modalities of a comprehensive treatment program and address pneumatic compression, with and without physical therapy, as effective in reducing lymphedema. However, they also make the following conclusion:
Although intermittent compression is often used, a number of issues about its use remain to be resolved, including the optimum amount of pressure, the most efficacious treatment schedule and whether maintenance therapy is needed after the initial reduction of edema.

In 1998, the American Cancer Society (ACS) conducted a lymphedema workshop that attempted to summarize the evidence surrounding the management of lymphedema. Numerous topics were covered including physical therapy, surgical options, various modalities of decongestive therapy and compressive therapy. Two sections specifically addressed compressive therapy with pneumatic compression devices. Brennan and Miller discuss the use of pneumatic compression and note they are a mainstay of lymphedema therapy. When assessing the medical literature for a particular type of pump, the authors conclude that "no individual pump appears to have a distinct advantage or to be inherently superior over any other" and "no comparative studies assessing the relative efficacy of pumps are available." They contrast conflicting studies where a multi-chamber device was found superior to a single-chamber device (Klein study) with Zanolla's finding noting excellent reduction in swelling from a single-chamber device compared to a multi-chamber product.

The proceedings of a workgroup at the ACS meeting, lead by Dr. Stanley Rockson, addressed the diagnosis and management of lymphedema. The purpose of the workgroup was to derive a consensus statement regarding the diagnosis and treatment of lymphedema following breast cancer surgery. According to the workgroup's consensus, treatment of lymphedema is best achieved through multiple modalities and well-fitted compression garments must be used to control ongoing edema between physical therapy or intermittent compression sessions. Speaking specifically about intermittent compression pumps, the consensus of the group was they may warrant a role in therapy when used in concert with decongestive lymphatic therapy and other established treatments such as low-stretch bandaging, exercise and manual lymphatic therapy. As an adjunct, the authors state that:

...[I]ntermittent compression pumps, which are most effective when used adjunctively in manual lymphatic therapy. The use of these sequential gradient pumps in the absence of a multidisciplinary treatment program should be avoided.

Despite the comprehensive nature of the workshop and multiple literature reviews and references to intermittent compression, there was no recognition or discussion of sequential gradient compression utilizing manual control of pressures in individual chambers, the type of PCD represented by Healthcare Common Procedure Coding System (HCPCS) code E0652.

In 1993, the Agency for Health Care Policy and Research Office of Technology Assessment conducted a technology review of lymphedema pumps. The review concentrated on single-chambered pneumatic devices vs. multichambered devices, with or without pressure calibrations. The review encompassed published medical literature from 1966-1992 and highlighted 9 studies, all included in this review. The report summarized the evidence as follows:

All pneumatic compression devices appear to be similarly effective in the treatment of lymphedema. Since the patients selected varied from study to study and the characteristics of the lymphedema among the patients were not defined, neither the criteria for selection of patients to be treated with one or another device or the difference in effectiveness of the devices could be ascertained.

Hayes, Inc., a subscription-based technology assessment company, reviewed PCDs for the treatment of peripheral lymphedema in 2005 and updated the review in January. This evidence-based medicine review concluded, in part, that 1) there is no consensus in the scientific literature on pump selection and use; 2) The evidence supporting the use of pneumatic compression therapy as a solitary treatment modality for peripheral lymphedema is extremely limited and of poor quality; 3) no comparative studies have been published to determine the most effective pumping times, pressure levels/ranges, inflation/deflation cycles, length and frequency of individual pumping sessions, or type of pump for patients with peripheral edema; and 4) there is some evidence to suggest that sequential multichambered pumps are more effective than single-chambered pumps.

The Treatment of Lymphedema Related to Breast Cancer Evidence Summary Report #13-1 was developed by members of the Supportive Care Guidelines Group sponsored by the Cancer Care Ontario (Canada) and the Ontario Ministry of Health and Long-term Care. This report was
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developed as part of the Practice Guidelines Initiative of the Program in Evidence-based Care. The report’s stated purpose was to evaluate the best available research evidence to guide clinical decisions and to promote responsible use of health resources. This specific guideline addressed the medical evidence to date of the treatment options for women with lymphedema following treatment for breast cancer.

MEDLINE, CANCERLIT, and Cochrane Library databases were reviewed and supplemented by the Steering Committee for Clinical Practice Guidelines for the Care and Treatment of Breast Cancer (see below). In the Interpretive Summary section, the workgroup concluded that pneumatic compression, when compared to no intervention, was not associated with a significant improvement of the magnitude that the study was powered to detect; however, the direction of the observed responses favored pneumatic compression (Dini study – reference 5 in bibliography). Authors also concluded that further research is required to determine whether pneumatic compression provides additional benefit over compression garments alone.

Clinical Guidelines

Harris and colleagues participated in a committee convened by the Canadian Health Ministry and Health Canada to develop a set of clinical practice guidelines for the care and treatment of breast cancer. The results were published in the Canadian Medical Association Journal in 2001. The guidelines relied upon scientific evidence published in English-language literature from 1996-2000. Although the guidelines make numerous recommendations, the recommendation specific to pneumatic compression devices states:

One randomized trial has demonstrated a trend in favour of pneumatic compression pumps compared with no treatment. Further randomized trials are required to determine whether pneumatic compression provides additional benefit over compression garments alone (Dina study – reference 5 in bibliography).

While the Dina study was the only literature reference that met the criteria of a randomized, controlled trial, the guidelines did review the result of a number of other less rigorous published studies. They note mixed results and limitations due to small sample size, mixed populations, lack of control groups and lack of outcome measures that assessed symptoms such as pain and heaviness. The authors further note that no comparative studies have been published to determine optimal treatment times, pressure levels or type of pump. They note that the literature is suggestive but not unanimous that sequential, multichambered pumps are more effective than single-chamber pumps but do not specifically address manually-controlled pressure gradient pumps (E0652).

Cohen, et al., published Lymphedema – Strategies for Management in a 2001 supplement to the journal Cancer. This supplement contained multiple sections addressing the care of breast cancer patients. In the section on management of lymphedema, the authors state:

Although at one time pneumatic compression pumps represented the standard treatment for lymphedema in the United States, controversy about their use exists today. Some studies corroborate their usefulness in the treatment of lymphedema while another randomized study discounts their effectiveness...

In short, no clear guidelines exist in the selection or use of pumps. A variety of pumps, with single or multiple chambers and various maximal pressures, lengths of pumping times and frequency of use, have been recommended... Although some patients report ongoing benefit in the use of a pump as part of a home program, others experience little benefit.

A supplier of pneumatic compression devices provided an additional document that is reportedly unpublished entitled, “Comprehensive Treatment Guidelines – Establishing Disease Management Guidelines for Lymphedema.” The author, Cyndi Ortiz, is a lymphedema compression therapist with numerous citings and contributions on the internet to lymphedema blogs, frequently asked questions and patient support sites. The document outlines the three different types of pumps (one chamber intermittent, sequential non-gradient, gradient sequential) and recommends the use of a gradient sequential pump as this more closely mimics the body’s pressure gradient system. There is no discussion or distinction in her guidelines between sequential gradient pumps with or without manual control.
Position Statements

International Society of Lymphology – Consensus document of the International Society of Lymphology entitled “The Diagnosis and Treatment of Peripheral Lymphedema” was published in 2003. According to the ISL, the document “attempts to amalgamate the broad spectrum of protocols advocated worldwide for the diagnosis and treatment of peripheral lymphedema into a coordinated proclamation representing a ‘consensus’ of the international community.” The consensus document includes intermittent pneumatic compression or “pneumomassage” as a non-surgical treatment option; however, the document does not recommend any type of compression pump (i.e., single or multichamber, sequential gradient, etc.), frequency or pressure setting.

National Lymphedema Network – According to their website, the National Lymphedema Network (NLN) is an internationally recognized non-profit organization founded in 1988 to provide education and guidance to lymphedema patients, healthcare professionals and the general public by disseminating information on the risk reduction and management of primary and secondary lymphedema. The NLN is described as a “driving force behind the movement in the U.S. to standardize quality treatment for lymphedema patients nationwide.”

The NLN has developed position papers on various topics related to the diagnosis and management of lymphedema. The NLN states that “NLN position papers are drafted by the NLN Medical Advisory Committee (MAC) to reflect professional positions on key issues related to lymphedema and lymphology. These documents are reviewed every two years or when new scientific advances related to the topic occur.”

The most recent position statement by the NLN MAC related to treatment of lymphedema was approved by the NLN Board of Directors on August 10, 2006. The position statement outlines the components of complete decongestive therapy (CDT) which include manual lymph drainage (MLD), multi-layer shortstretch compression bandages, remedial exercise, skin care, education in lymphedema self-management and elastic compression garments. According to the position statement, intermittent pneumatic compression or “pressotherapy” is not a component of conventional CDT but may be used as an adjunct. It defines pressotherapy as involving the insertion of the affected extremity into a multi-cell inflatable appliance, which is attached to an air compressor. The document further notes that “sequential inflation and deflation of the cells creates a distal to proximal compression wave that moves the water component of the lymph and interstitial fluid out of the affected territory.” There is no discussion of the different types of PCDs or their relative merits. With regard to pressures utilized, the position statement gives a “general range from 30-60 mmHg.” Inflation cycle time or duration, number of treatments and duration of treatment are not discussed.

Summary

This review of the scientific literature attempts to determine if there is differentiation between the different types of pneumatic compression devices and if so, are there specific patient characteristics or disease conditions which merit the use of one device over another.

According to instructions issued to Medicare contractors by CMS, one must consider the broad range of available evidence and evaluate the quality of the evidence. This exercise reviewed peer-reviewed, published clinical trials, guidelines and consensus statements from clinical experts and medical associations, position statements from organizations with expertise in the subject of lymphedema treatment and other evaluations of pneumatic compression technology.

With regard to the quality of the evidence, numerous authors commented that the studies supporting the use of pneumatic compression devices are universally poor. There are few randomized, prospective, controlled trials and the ones that were reviewed had conflicting results. Most clinical guidelines and position statements relied upon expert opinion and consensus; however, all were lacking in specificity with respect to the questions at hand.

Applying the CMS instructions for the evidence basis for coverage decisions to the questions posed, one can summarize the scientific literature as follows:

Question 1: Does the published medical literature support the use of one type of pneumatic compression device compared to another?
A. Published authoritative evidence derived from definitive randomized clinical trials or other definitive studies
   Answer: No. There is a general trend towards support of a multi-chamber device over a single chamber device though evidence is conflicting.

B. General acceptance by the medical community (standard of practice), as supported by sound medical evidence based on:

   1. Scientific data or research studies published in peer-reviewed medical journals
      Answer: No. There is no scientific data or published research supporting general acceptance of one type of pneumatic compression device over another. There is a trend towards support of a multi-chamber device over a single chamber device.

   2. Consensus of expert medical opinion (i.e., recognized authorities in the field);
      Answer: No. There is no consensus of the expert medical opinions reviewed that one type of pump is more efficacious than another.

   3. Medical opinion derived from consultations with medical associations or other health care experts.
      Answer: No. Review of medical association statements and position papers from health care experts in the treatment of lymphedema have no statements regarding the superiority of one type of pump over another; however, Cyndi Ortiz did recommend use of a sequential gradient pump since, in her opinion, it better mimics the body’s own lymphatic drainage mechanism.

Question 2: Are there specific patient characteristics and/or disease conditions that favor one type of pneumatic compression devices over another?

A. Published authoritative evidence derived from definitive randomized clinical trials or other definitive studies
   Answer: No. While there is a general trend towards support of a multi-chamber device over a single chamber device, information on patient selection (other than having lymphedema), frequency of treatment, treatment duration and pressures utilized are lacking.

B. General acceptance by the medical community (standard of practice), as supported by sound medical evidence based on:

   1. Scientific data or research studies published in peer-reviewed medical journals
      Answer: No. There is no scientific data or published research supporting general acceptance of one type of pneumatic compression device over another; therefore, no unique patient characteristics can be derived.

   2. Consensus of expert medical opinion (i.e., recognized authorities in the field);
      Answer: No. Since there is no consensus of the expert medical opinions reviewed that one type of pump is more efficacious than another, there is similarly no consensus on which patients should use a particular type of pump.

   3. Medical opinion derived from consultations with medical associations or other health care experts.
      Answer: No. Review of medical association statements and position papers from health care experts in the treatment of lymphedema have no statements regarding the use of a specific type of pump with a specific type of patient or disease process.

In summary, this review of the scientific data and literature to date does not reveal any conclusive evidence to support the medical necessity of one type of pneumatic compression device over another. There is a trend towards support of multi-chamber over single chamber. Furthermore, the argument that sequential gradient compression is more physiologic than non-gradient makes intuitive sense despite lack of literature support. There is a glaring absence of any guideline, position statement, text or opinion to detail situations in which manual control of an individual segment is required (E0652). While CMS allows coverage for E0652 when the patient has “unique characteristics” that prevent satisfactory use of another type of device, the literature fails to provide any guidance on what “unique characteristics” merit E0652 use.
References


