



CIGNA MEDICAL COVERAGE POLICY

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

Subject Lymphedema Pumps and Compression Garments

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Hyperlink to Related Coverage Policies

- Breast Reconstruction Following Mastectomy or Lumpectomy
- Complex Lymphedema Therapy (Complete Decongestive Therapy)
- Cryounits/Cooling Devices
- Physical Therapy
- Pneumatic Compression Devices for the Treatment of Vascular Diseases of the Lower Extremities

INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2011 CIGNA

Coverage Policy

Coverage for 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 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.

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

CIGNA covers a standard lymphedema pump as medically necessary 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

When a lymphedema pump has been found to be medically necessary according to the above criteria, CIGNA covers the following lymphedema pumps as medically necessary:

- nonsegmental/segmental (HCPCS codes E0650, E0651)
- segmental with calibrated gradient pressure (HCPCS code E0652[†]), when there is evidence of **BOTH** of the following:
 - failure of relief with a nonsegmental or segmental device
 - documented need for specified pressure to a localized area (e.g., scar tissue, ulcer)

CIGNA does not cover a two-phase lymph preparation and drainage therapy device/system (HCPCS code E0652[†]) because it has not been demonstrated to be superior to a standard segmented, calibrated gradient system and thus is not medically necessary.

[†]HCPCS code E0652 covered when used to report a standard segmented, calibrated gradient system. Not covered when used to report a two-phase lymph preparation and drainage therapy devices/system.

CIGNA does not cover EITHER of the following because they are considered experimental, investigational or unproven:

- chest (HCPCS code E0657) and/or trunk (HCPCS code E0656) pneumatic appliances for use with lymphedema pumps
- compression garments for trunk or chest

General Background

Lymphedema is a failure of the lymphatic transport system resulting in the accumulation of lymphatic and edema fluid in the soft tissue. Under normal circumstances, the lymphatic system regulates tissue fluid balance by maintaining equilibrium between tissue fluid filtration and reabsorption. This is accomplished through the drainage of excess fluid containing protein, lipids, microorganisms, cells and debris from the tissue, with the fluid being filtered and returned to the bloodstream. 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.

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 sleeves include:

- Jobst[®] Armsleeve (BSN-JOBST, Inc., Charlotte, NC)

- Juzo® compression arm sleeves (Juzo, Cuyahoga Falls, OH)
- FarrowWrap® (Farrow Medical Innovations, Bryan, TX).

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)

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). 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.

Lymphedema Pumps

Pneumatic compression pumps have been used as a treatment for lymphedema for many years. 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. 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).

Lymphedema pumps include, but are not limited to, the following:

- Nonsegmented pneumatic compressor: 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: This device has multiple outflow ports on the compressor that lead to distinct segments on the appliance, which inflates in a sequential manner.
 - 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).
 - 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)

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 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 M, 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 treated 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, 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”.

Two-Phase Lymph Preparation and Drainage Therapy Devices: Newer lymphedema devices/systems have been developed that provide treatment in two phases—a preparatory and a drainage phase. In addition to leg and arm garment/appliances that are used with standard lymphedema pumps, these devices include the use of unique garments/appliances to be worn on trunk, chest, and torso area.

Two-phase lymph preparation and drainage therapy devices/systems include:

- Flexitouch[®] Lymphedema 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 system is a two-phase lymph preparation and drainage therapy system device for treatment of primary lymphedema, post-mastectomy lymphedema, edema following sports injuries, post-immobilization edema, and venous insufficiencies. The website notes that the system provides action in two phases: lymph preparation and lymph drainage. It is proposed that this two-phase action utilizes a light, therapeutic sequential action to gently prepare the trunk and extremities for lymph evacuation and to assist in draining excess fluid from the limb to the venous 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. The manufacturer notes that this system has been shown to be similar to self-administered CLT and allows for home treatment.
- Lympha Press Optimal[™] Lympha Press[®] Plus (Mego Afek, Manalapan, NJ): According to the vendor website, this device includes “pretherapy[™]”, which is based on the principles of manual lymph drainage. 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.

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 two-phase lymph preparation and drainage therapy devices/systems 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): Lymphedema pumps 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).

Professional Societies/Organizations

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 CLT.

International Society of Lymphology (ISL): In 2009 the ISL published an updated consensus document regarding the diagnosis and treatment of peripheral lymphedema (ISL, 2009). 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.
- 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.

Summary

While there is limited scientific evidence in the form of well-designed clinical trials supporting the use of lymphedema pumps and sleeves, the practicing medical community generally considers them safe and effective

nonsurgical options for the treatment of lymphedema. The use of a lymphedema pump 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).

Two-phase lymph preparation and drainage therapy devices/systems 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: This list of codes may not be all-inclusive.

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
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
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

†**Note:** Covered when used to report standard segmented, calibrated gradient systems. Not covered when used to report two-phase lymph preparation and drainage therapy devices/systems.

ICD-9-CM Diagnosis Codes	Description
457.0	Post-mastectomy lymphedema syndrome
457.1	Other lymphedema
457.2	Lymphangitis
757.0	Hereditary edema of legs

Experimental/Investigational/Unproven/Not Covered

HCPCS Codes	Description
E0656	Segmental pneumatic appliance for use with pneumatic compressor, trunk
E0657	Segmental pneumatic appliance for use with pneumatic compressor, chest
E1399†	Durable medical equipment, miscellaneous

† **Note:** Experimental/Investigational/Unproven/Not Covered when used to report compression garments or pneumatic appliances for use with pneumatic compressors for the trunk or chest.

*Current Procedural Terminology (CPT®) ©2010 American Medical Association: Chicago, IL.

References

1. Boris M, Weindorf S, Lasinski BB. The risk of genital edema after external pump compression for lower limb lymphedema. *Lymphology*. 1998 Mar;31(1):15-20.
2. Brennan MJ, Miller LT. Overview of treatment options and review of the current role and use of compression garments, intermittent pumps, and exercise in the management of lymphedema. *Cancer*. 1998 Dec 15;83(12 Suppl American):2821-7.
3. Canadian Agency for Drugs and Technologies in Health (CADTH). Health Technology Inquiry Service. Manual lymph drainage or intermittent pneumatic compression for adult patients with secondary lymphedema: clinical effectiveness. Health Technology Assessment. April 2010. Accessed April 1, 2011. Available at URL address: <http://www.cadth.ca/index.php/en/hta/reports-publications/search>
4. Cannon, S. Pneumatic compression devices for in-home management of lymphedema: two case reports. *Cases J*. 2009 Mar 23, 224.
5. Centers for Medicare & Medicaid Services (CMS). Decision memo for lymphedema pumps (CAG-00016N). 2001 May 3. Accessed April 10, 2010. Available at URL address: <http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=50>
6. Centers for Medicare & Medicaid Services (CMS). Transmittal 151. Revision to the coverage issues manual 60-16 - 60-19. 2002 Jan 14. Accessed April 10, 2010. Available at URL address: <http://www.cms.hhs.gov/transmittals/downloads/R150CIM.pdf>
7. Commonwealth of Australia. Report to the Australian Health Ministers' Advisory Council. Review of current practices and future directions in the diagnosis, prevention and treatment of lymphoedema in Australia. February 2006. Accessed March 11, 2011. Available at URL address: <http://www.msac.gov.au/internet/msac/publishing.nsf/Content/Review+of+lymphoedema+in+Australia>

8. Cormier JN, Askew RL, Mungovan KS, Xing Y, Ross MI, Armer JM. Lymphedema beyond breast cancer: a systematic review and meta-analysis of cancer-related secondary lymphedema. *Cancer*. 2010 Nov 15;116(22):5138-49.
9. Dedecker K, Waldrige I. Simulated manual lymph drainage therapy in home treatment of lymphedema. [white paper]. Tactile Systems Technology, Inc. 2005.
10. Devoogdt N, Van Kampen M, Geraerts I, Coremans T, Christiaens MR. Different physical treatment modalities for lymphoedema developing after axillary lymph node dissection for breast cancer: a review. *Eur J Obstet Gynecol Reprod Biol*. 2010 Mar;149(1):3-9.
11. Dini D, Del Mastro L, Gozza A, Lionetto R, Garrone O, Forno G, et al. The role of pneumatic compression pumps in the treatment of postmastectomy lymphedema. A randomized phase III study. *Ann Oncol* 1998 Feb;9(2):187-90.
12. ECRI Institute. Hotline Response [database online]. Plymouth Meeting (PA): ECRI Institute; 2010 Nov 23. Flexitouch System for Treatment of Lymphedema. 2010 Nov 23. Accessed March 30, 2011. Available at URL address: <http://www.ecri.org>.
13. ECRI Institute. Hotline Response [database online]. Plymouth Meeting (PA): ECRI Institute; 2009 Feb 19. Nonelastic Compression Garments for Treatment of Lymphedema. 2010 Feb 19. Accessed March 30, 2011. Available at URL address: <http://www.ecri.org>.
14. Erickson VS, Pearson ML, Ganz PA, Adams J, Kahn KL. Arm edema in breast cancer patients. *J Natl Cancer Inst*. 2001 Jan 17;93(2):96-111.
15. Flexitouch[®] system physician information. Accessed March 30, 2011. Available at URL address: <http://www.tactilestystems.com/flexitouch/physicians.html>
16. Golshan M, Smith B. Prevention and management of arm lymphedema in the patient with breast cancer. *J Support Oncol*. 2006 Sep;4(8):381-6.
17. Hammond T. Can truncal edema be treated with pneumatic compression? National Lymphedema Network. Apr-Jun 2009.
18. Harris SR. Clinical practice guidelines for the care and treatment of breast cancer: 11. Lymphedema. *CMAJ*. 2001 Jan 23;164(2):191-9.
19. International Society of Lymphology. The diagnosis and treatment of peripheral lymphedema. Consensus document of the International Society of Lymphology. 2009. Accessed March 11, 2011. Available at URL address: <http://www.u.arizona.edu/~witte/ISL.htm>
20. Kärki A, Anttila H, Tasmuth T, Rautakorpi UM. Lymphoedema therapy in breast cancer patients: a systematic review on effectiveness and a survey of current practices and costs in Finland. *Acta Oncol*. 2009;48(6):850-9.
21. Kerchner K, Fleischer A, Yosipovitch G. Lower extremity lymphedema update: pathophysiology, diagnosis, and treatment guidelines. *J Am Acad Dermatol*. 2008 Aug;59(2):324-31. Epub 2008 May 29.
22. Kligman L, Wong RK, Johnston M, Laetsch NS. The treatment of lymphedema related to breast cancer: a systematic review and evidence summary. *Support Care Cancer*. 2004 Jun;12(6):421-31.
23. Lawenda BD, Mondry TE, Johnstone PA. Lymphedema: a primer on the identification and management of a chronic condition in oncologic treatment. *CA Cancer J Clin*. 2009 Jan-Feb;59(1):8-24.

24. Macdonald JM, Sims N, Mayrovitz HN. Lymphedema, lipedema, and the open wound: the role of compression therapy. *Surg Clin North Am.* 2003 Jun;83(3):639-58.
25. Maul SM, Devine JA, Wincer CR. Development of a framework for pneumatic device selection for lymphedema treatment. *Medical Devices: Evidence and Research* 2009 (2): 57-65.
26. Mayrovitz HN. Interface pressures produced by two different types of lymphedema therapy devices. *Phys Ther.* 2007 Oct;87(10):1379-88. Epub 2007 Aug 21.
27. Mayrovitz HN, Brown-Cross D, Mayrovitz BL., Humble-Golla A. Lymphedema: Role of Truncal Clearance as a Therapy Component. *Home Health Care Management Practice* 2009 0: 1084822309331484.
28. Mayrovitz HN. The standard of care for lymphedema: current concepts and physiological considerations. *Lymphat Res Biol.* 2009;7(2):101-8.
29. McMaster University Evidence-based Practice Center. Oremus M, Walker K, Dayes I, Parminder R. Diagnosis and treatment of secondary lymphedema. [technology assessment]. 2010 May 28. Prepared for: Agency for Healthcare Research and Quality (AHRQ).
30. Morrell RM, Halyard MY, Schild SE, Ali MS, Gunderson LL, Pockaj BA. Breast cancer-related lymphedema. *Mayo Clin Proc.* 2005 Nov;80(11):1480-4.
31. Moseley A, Carati C, Piller N. A systematic review of common conservative therapies for arm lymphoedema secondary to breast cancer treatment. *Ann Oncol.* 2007 Apr;18(4):639-46. Epub 2006 Oct 3.
32. National Cancer Institute (NCI). Lymphedema [Physician Data Query (PDQ[®])]. Last Modified: 7/22/2010. Accessed March 30, 2011. Available at URL address: <http://www.cancer.gov/cancertopics/pdq/supportivecare/lymphedema/healthprofessional/AllPages>
33. National Lymphedema Network (NLN) [website]. Air Travel. May 2008. Accessed March 30, 2011. Available at URL address: <http://www.lymphnet.org/lymphedemaFAQs/positionPapers.htm>
34. National Lymphedema Network (NLN). Position statement of the national lymphedema network. Treatment. February 2011. Accessed March 11, 2011. Available at URL address: <http://www.lymphnet.org/lymphedemaFAQs/positionPapers.htm>
35. Oremus M, Walker K, Dayes I, Parminder R; McMaster University Evidence-based Practice Center. Diagnosis and treatment of secondary lymphedema. [technology assessment]. 2010 May 28. Prepared for: Agency for Healthcare Research and Quality (AHRQ).
36. Peninsula Medical, Inc. ReidSleeve classic [product information]. Accessed March 30, 2011. Available at URL address: <http://www.reidsleeve.com/rsleeve.htm>
37. Poage E, Singer M, Armer J, Poundall M, Shellabarger MJ. Demystifying lymphedema: development of the lymphedema putting evidence into practice card. *Clin J Oncol Nurs.* 2008 Dec;12(6):951-64.
38. Ridner SH. Breast cancer lymphedema: pathophysiology and risk reduction guidelines. *Oncol Nurs Forum.* 2002 Oct;29(9):1285-93.
39. Ridner SH, McMahan E, Dietrich MS, Hoy S. Home-based lymphedema treatment in patients with cancer-related lymphedema or noncancer-related lymphedema. *Oncol Nurs Forum.* 2008 Jul;35(4):671-80.
40. Rockson SG, Granger DN, Skeff KM, Chaite W. Lymphatic biology and disease: is it being taught? Who is listening? *Lymphat Res Biol.* 2004;2(2):86-95.

41. Sawan S, Mugnai R, Lopes Ade B, Hughes A, Edmondson RJ. Lower-limb lymphedema and vulval cancer: feasibility of prophylactic compression garments and validation of leg volume measurement. *Int J Gynecol Cancer*. 2009 Dec;19(9):1649-54.
42. Segers P, Belgrado JP, Leduc A, Leduc O, Verdonck P. Excessive pressure in multichambered cuffs used for sequential compression therapy. *Phys Ther*. 2002 Oct;82(10):1000-8.
43. Sieggreen MY, Kline RA. Current concepts in lymphedema management. *Adv Skin Wound Care*. 2004 May;17(4 Pt 1):174-8.
44. Swedish Council on Technology Assessment in Health Care (SBU). Manual Lymph Drainage Combined With Compression Therapy for Arm Lymph-edema Following Breast Cancer Treatment (Alert). 2005. Accessed March 11, 2011. Available at URL address: http://www.sbu.se/upload/Publikationer/Content0/3/Manual_Lymph_Drainage_Compression_Arm_Lymphedema_Breast_Cancer_200504.pdf
45. U.S. Federal Drug Administration (FDA). 510 (k) premarket notification: biotouch massage therapy system. KO13061. July 2002. Accessed March 30, 2011. Available at URL address: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=5862>
46. U.S. Federal Drug Administration (FDA). 510 (k) premarket notification: Flexitouch® System. K062818. October 2006. Accessed March 30, 2011. Available at URL address: http://www.accessdata.fda.gov/cdrh_docs/pdf6/K062818.pdf
47. Warren AG, Brorson H, Borud LJ, Slavin SA. Lymphedema: a comprehensive review. *Ann Plast Surg*. 2007 Oct;59(4):464-72.
48. Wilburn O, Wilburn P, Rockson SG. A pilot, prospective evaluation of a novel alternative for maintenance therapy of breast cancer-associated lymphedema [ISRCTN76522412]. *BMC Cancer*. 2006 Mar 29;6:84.

Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	5/15/2008	0354	Lymphedema Pumps and Sleeves
Great-West Healthcare	1/1/2007	07.348.01	Pneumatic Compression Devices

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