Clinical Policy Bulletin: Lymphedema
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Policy

Diagnosis

Bioimpedance Devices for Detection of Lymphedema

Aetna considers bioimpedance devices experimental and investigational for the diagnosis or management of lymphedema because their effectiveness for these indications has not been established.

Treatments

Complex Decongestive Physiotherapy:

Aetna considers a course of complex decongestive physiotherapy (CDP), also called manual lymphoid drainage, medically necessary when both of the following criteria are met:

I. The member has any of the following conditions:
   A. Evidence of ulceration due to lymphedema; or
   B. Intractable lymphedema of the extremities, unrelieved by elevation; or
   C. One or more previous admissions to treat complications of intractable lymphedema (i.e., cellulitis, ulceration); and

II. The member has shown a past record of compliance and the member or his/her caregiver is capable of following the instructions associated with CDP.
**Lymphedema Pumps:**

Aetna considers lymphedema pumps (pneumatic compression devices) medically necessary durable medical equipment (DME) for home use for the treatment of lymphedema if the member has undergone a 4-week trial of conservative therapy and the treating doctor determines that there has been no significant improvement or if significant symptoms remain after the trial. The trial of conservative therapy must include use of an appropriate compression bandage system or compression garment, exercise, and elevation of the limb. The garment may be pre-fabricated or custom-fabricated but must provide adequate graduated compression.

**Note:** For members without DME benefits, lymphedema pumps are only covered for members with arm lymphedema due to mastectomy for breast cancer who meet the criteria for a lymphedema pump stated above.*

When medical necessity criteria for a pneumatic compression device are met, a non-segmented device or segmented device without manual control of the pressure in each chamber is generally considered medically necessary to meet the clinical needs of the member. A segmented device with manual control of the pressure in each chamber is considered medically necessary only if there is clear documentation of medical necessity in the individual case. A segmented device with manual control of the pressure in each chamber is considered medically necessary only when there is documentation that the individual has unique characteristics that prevent satisfactory pneumatic compression treatment using a non-segmented device with a segmented appliance/sleeve or a segmented device without manual control of the pressure in each chamber.

A 2-phase lymph preparation and drainage therapy device (e.g., Flexitouch Device, Tactile Systems Technology, Minneapolis, MN; LymphaPress Optimal, Lympha Press USA, Manalapan, NJ) is considered equally effective to standard segmented pneumatic compression devices.

For Aetna’s clinical policy on pneumatic compression devices for chronic venous insufficiency, see CPB 0500 - Intermittent Pneumatic Compression Devices.

**Note:** Although the literature suggests that the use of lymphedema pumps is commonly initiated in the hospital, there is no medical necessity for this practice unless the member has other complications of lymphedema (i.e., cellulitis) that would require hospitalization. The use of lymphedema pumps can be initiated in the clinic or in the home setting.

**Static Compression Sleeves:**

Aetna considers static compression sleeves (e.g., the ReidSleeve, ArmAssist) to be medically necessary supplies for members with intractable lymphedema of the arms. **Note:** 2 pairs of static compression sleeves per affected arm are considered medically necessary in the initial purchase (the 2nd pair is for use while the 1st pair is in the laundry); and no more than 2 replacements per affected arm every 6 months per year is considered medically necessary. For members whose plans exclude coverage of supplies, static compression sleeves are only covered for intractable lymphedema of the arms due to mastectomy for breast cancer.* See also CPB 0482 - Compression Garments for the Legs.

**Compression Garments for the Abdomen, Chest, Genitals, Trunk or Neck:**

Aetna considers compression garments for the abdomen, chest, genitals, trunk or neck experimental and investigational. There is a lack of peer-reviewed published literature evaluating the clinical utility of compression garments for these anatomical sites.

Aetna considers compression bras for post-mastectomy lymphedema experimental and investigational because their effectiveness for this indication has not been established.

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*Microsurgical Lymphatico-venous Anastomosis:*

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http://qawww.aetna.com/cpb/medical/data/1_99/0069_draft.html
Aetna considers microsurgical lymphatico-venous anastomosis experimental and investigational for the treatment of members with chronic obstructive lymphedema because the long-term effectiveness of this procedure has not been established by the peer-reviewed medical literature.

**Vascularized Lymph Node Transfer:**

Aetna considers vascularized lymph node transfer for the treatment of post-mastectomy lymphedema experimental and investigational because its effectiveness has not been established.

**Whole Body Vibration:**

Aetna considers whole body vibration for the treatment of lymphedema experimental and investigational because its effectiveness has not been established.

*Note: HR 4328 (Public Law 105-277) requires individual and employer group health plans (including indemnity, PPO, POS and HMOs), that provide medical and surgical benefits with respect to a mastectomy, to provide coverage for lymphedema treatment in a manner determined in consultation with the attending physician and the member for a participant or beneficiary who is receiving benefits for a mastectomy and who elects breast reconstruction after the mastectomy. Therapy is subject to annual deductibles and co-insurance provisions for physical therapy. Therapy is not subject to visit limitation provisions for physical therapy.*

**Background**

Lymphedema refers to edema (i.e., swelling) due to inadequate lymphatic circulation related to either: (i) defective development of the lymphatics (primary lymphedema); or (ii) destruction or obliteration of the lymphatic system (secondary lymphedema) due to either trauma, wounds, surgery, radiation therapy, or infection with a tropical filarial parasite. Primary lymphedema typically involves the lower extremities and typically afflicts females. When it arises at birth it is called lymphedema congenita, before the age of 35 it is called lymphedema praecox, and when arising later in life it is called lymphedema tarda. Secondary lymphedema occurs most commonly after lymph node dissections. For example, 10 to 20% of women with breast cancer who have undergone axillary dissection will experience lymphedema. Leg edema can result after groin dissection, most typically for melanoma. Lymphedema results in a feeling of heaviness, aching or tightness. In severe cases, mobility can be impaired. Development of angiosarcoma, know as the Stewart-Trewes syndrome, is a very rare complication of long standing severe lymphedema.

Lymphedema is usually staged by observing a patient’s physical condition. The International Society of Lymphology uses the following 3-stage scale for classification of a lymphedematous limb:

**Stage 1:** Early accumulation of fluid relatively high in protein content (e.g., in comparison with "venous" edema) that subsides with limb elevation. Pitting may occur.

**Stage II:** Limb elevation alone rarely reduces tissue swelling and pitting may or may not occur as tissue fibrosis develops.
Stage III: Lymphostatic elephantiasis. Pitting is absent and trophic skin changes such as acanthosis, fat deposits, and warty overgrowths develop.

An increasing number of lymphologists recognize an earlier stage of lymphedema, termed Stage 0, which refers to a latent or subclinical condition where swelling is not evident despite impaired lymphatic transport. Stage 0 may exist for months or years before the onset of overt lymphedema.

Cormeir and associates (2010) performed a systematic review and meta-analysis of the oncology-related literature excluding breast cancer to derive estimates of lymphedema incidence and to identify potential risk factors among various malignancies. The authors systematically reviewed 3 major medical indices (MEDLINE, Cochrane Library databases, and Scopus) to identify studies (1972 to 2008) that included a prospective assessment of lymphedema after cancer treatment. Studies were categorized according to malignancy, and data included treatment, complications, lymphedema measurement criteria, lymphedema incidence, and follow-up interval. A quality assessment of individual studies was performed using established criteria for systematic reviews. Bayesian meta-analytic techniques were applied to derive summary estimates when sufficient data were available. A total of 47 studies (7,779 cancer survivors) met inclusion criteria: melanoma (n = 15), gynecological malignancies (n = 22), genito-urinary cancers (n = 8), head/neck cancers (n = 1), and sarcomas (n = 1). The overall incidence of lymphedema was 15.5 % and varied by malignancy (p < 0.001): melanoma = 16 % (upper extremity, 5 %; lower extremity, 28 %); gynecological = 20 %; genito-urinary = 10 %; head/neck = 4 %; and sarcoma = 30 %. Increased lymphedema risk was also noted for patients undergoing pelvic dissections (22 %) and radiation therapy (31 %). Objective measurement methods and longer follow-up were both associated with increased lymphedema incidence. The authors concluded that lymphedema is a common condition affecting cancer survivors with various malignancies. The incidence of lymphedema is related to the type and extent of treatment, anatomical location, heterogeneity of assessment methods, and length of follow-up.

Lymphedema is diagnosed based upon the patients history and physical examination. The most widely accepted measure of lymphedema is limb circumference compared with that of the unaffected limb or compared with that of the same limb before the interventions or events that led to lymphedema. Imaging is usually not necessary unless an obstructive cause of the lymphedema is suspected (e.g., tumor).

Bioimpedance is a non-invasive method for estimating body composition based on the electrical conductive properties of various tissues. It is thought that bioimpedance devices can detect developing lymphedema before any clinical signs are visible. Devices using bioimpedance have been proposed as a diagnostic test of subclinical lymphedema (Stage 0) for the early identification of patients at risk of developing lymphedema. Proponents who support the approach to diagnose subclinical disease believe that early treatment of subclinical lymphedema will result in less severe chronic disease. One bioimpedance device is the ImpediMed LDex™ U400 (ImpediMed Limited, San Diego, CA), cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process in 2008. Thus, the manufacturer was not required to provide the evidence of clinical efficacy that is necessary to support a premarket approval (PMA). According to the FDA clearance letter, the device is “to aid in the clinical assessment of unilateral lymphedema of the arm in women.” The FDA labeling states that the device is “not intended to diagnose or predict lymphedema of an extremity.” ImediMed's L-Dex technology utilizes the characteristics of frequency dependent current flow to quantify changes in extracellular fluid in the patient's limb.
Czerniec and colleagues (2010) reported on measurement of lymphedema to determine the relationship between physical methods of measuring lymphedema and self-reported swelling. Lymphedema in women with (n = 33) and without (n = 18) unilateral arm lymphedema secondary to breast cancer was measured by self-report, bioimpedance spectroscopy, perometer, and the truncated cone method. The physical measurement tools were highly reliable (ICC((2,1)): 0.94 to 1.00) with high concordance (r(c): 0.89 to 0.99). Self-report correlated moderately with physical measurements (r = 0.65 to 0.71) and was moderately reliable (ICC((2,1)): 0.70). The authors concluded that lymphedema assessment methods are concordant and reliable but not interchangeable.

There is a lack of reliable evidence that intervention in the subclinical stage of lymphedema detected by bioimpedance improves outcomes over close monitoring and intervention when lymphedema becomes clinically evident by standard measures (e.g., limb volume measurement). A study by Stout Gergich et al (2008) has been cited to support initiation of lymphedema treatment at a subclinical stage. The study by Stout Gergich, et al. (2008) is not an National Institute of Health clinical practice guideline or clinical practice recommendation, but is a report of a case-control study to investigate the efficacy of a different technology, perometry, in the diagnosis and management of subclinical lymphedema in patients with early-stage breast cancer. Stout Gergich, et al. (2008) states that “The views expressed in this article are those of the author(s) and do not necessarily reflect the official policy or position of the Department of the Navy, Department of Defense, or the U.S. Government.” The article states that “further research is needed” to validate bioimpedance in the context of a surveillance tool.

In the study by Stout Gergich, et al. (2008), lymphedema was identified in 43 of 196 women who participated in a prospective breast cancer morbidity trial. This study used another method of measurement, perometry, to detect lymphedema at an early stage. Limb volume was measured pre-operatively and at 3-month intervals after surgery. If an increase of greater than 3 % in upper limb volume developed compared with the preoperative volume, then a diagnosis of lymphedema was made, and a compression garment intervention was prescribed for 4 weeks. Upon reduction of lymphedema, garment wear was continued only during strenuous activity, with symptoms of heaviness, or with visible swelling. Statistical analysis was a repeated-measures analysis of variance by time and limb (p less than or equal to 0.001) comparing the lymphedema cohort with an age-matched control group. The investigators reported that the time to onset of lymphedema averaged 6.9 months post-operatively. The mean (± standard deviation) affected limb volume increase was 83 ml (± 119 ml; 6.5 % ± 9.9 %) at lymphedema onset (p = 0.005) compared with baseline. After the intervention, a statistically significant mean 48 ml (± 103 ml; 4.1 % ± 8.8 %) volume decrease was realized (p less than 0.0001). The mean duration of the intervention was 4.4 weeks (± 2.9 weeks). Volume reduction was maintained at an average follow-up of 4.8 months (± 4.1 months) after the intervention. The study did not provide evidence, however, that clinical outcomes were improved by initiating lymphedema treatment at the subclinical stage versus initiating lymphedema treatment at the earliest stage where lymphedema becomes clinically apparent using standard measurements (e.g., limb circumference measurements).

An assessment by the Australia and New Zealand Horizon Scanning Network (2008) concluded: “The Impedimed Imp™ SFB7 device appears to be effective for diagnosis of lymphoedema, although the studies were small in nature and lacked high quality design. Larger studies in which the device is directly compared with the standard methods for
lymphoedema diagnosis are required. Additionally, varied stages of lymphoedema manifestation should be included."

An ad hoc group organized by the Avon Foundation for Women (2011) organized to discuss advances in the early detection and intervention of lymphedema recommended perometry or bioimpedance in the early detection of lymphedema. A reading of the full text of the recommendation reveals that the primary support for use of perometry or bioimpedance spectroscopy is the study by Stout Gergich, et al. (2008); the limitations of this study are summarized above.

The 2011 National Accreditation Program for Breast Centers (NAPBC) Standards lists lymphedema management and risk reduction practices among breast center supportive services. The NAPBC Standards lists the National Lymphedema Network resource center as a recommended resource on this topic. However, the NAPBC standards include no discussion of bioimpedance, or requirement for bioimpedance as a requirement for accreditation.

The National Lymphedema Network position statement, *Screening and Measurement for Early Detection of Breast Cancer Related Lymphedema*, updated April 2011, states that circumferential tape measurements are acceptable means of measuring limb volume. The current position statement states "bioelectrical spectroscopy (BIS) or infrared perometry are suggested as alternative or adjunctive methods to circumferential measurement."

A technology assessment of the diagnosis and management of secondary lymphedema prepared for the Agency for Healthcare Research and Quality (Oremus et al, 2010) concluded: "There is consistent evidence to indicate that lymphedema can be reliably measured using circumferential measures or volume displacement ... There is too little evidence to draw conclusions about the reliability of other tests such as tonometry, ultrasound, lymphoscintigraphy, or bioimpedance."

The Northern Ireland CREST Committee guidelines for lymphedema (2008) recommend circumferential limb volume measurement for assessing limb volume. Bioimpedance measurement is described as promising, noting that it should be considered over the next 5 years. The CREST guideline development group identified continued research into the reliability and validity of diagnostic methods such as bioimpedance analysis among priorities for future research in Northern Ireland.

The National Cancer Institute Physician Data Query (PDQ) on lymphedema (NCI, 2011) states that circumferential upper-extremity measurement is the most widely used method to diagnose upper-extremity lymphedema. Bioimpedance is listed among several other options for evaluating limb volume. The PDQ also stated that a study comparing various methods of assessing upper-limb lymphedema did not show any superiority of any one method; for support, the PDQ cited a study by Ridner, et al. (2007) comparing circumferential limb measurements to bioimpedance and perometry.

Several other guidelines that have been cited for support of bioimpedance spectroscopy make no recommendation for use of this technology. A report of an Institute of Medicine workshop (Hewitt, et al., 2006) includes no recommendation for, or reference to, bioimpedance spectroscopy for lymphedema. The workshop report identifies assessments of the value of lymphedema prevention, early diagnosis, and surveillance as areas in need of further research. A 2009 consensus document on diagnosis and treatment of peripheral lymphedema, from the International Society of Lymphology makes no reference to or recommendation for bioimpedance spectroscopy. Canadian guidelines on the care and treatment of lymphedema
(Harris, et al., 2001) make no recommendation for bioimpedance spectroscopy. The guidelines recommend circumferential measurements and state that other methods “are being evaluated in research settings.”

The federal Women’s Health and Cancer Rights Act of 1998 requires health insurance policies that cover mastectomy to also provide coverage for reconstructive surgery, prostheses, and physical complications of mastectomy, including lymphedema. However, the Act does not require health insurers to cover bioimpedance spectroscopy or other interventions of unproven value.

Results of available studies do not provide consistent evidence that bioimpedance is any more reliable than current methods for detection of lymphedema. In addition, there is a lack of clinical studies demonstrating that incorporation of bioimpedance into lymphedema management improves clinical outcomes. Long-term studies demonstrating the effectiveness of bioimpedance testing over conventional monitoring techniques for lymphedema are needed.

Conservative treatment of lymphedema focuses on a combination of physical therapies: elevation of the arm or leg, manual physical therapy, wearing of various types of compression stockings/bandages, or pneumatic pumps.

The use of elastic stockings is considered a valuable component of lymphedema therapy, and appears to be critical to the long term success of treatment. Compliance with elastic stocking may be problematic since they are frequently hot, uncomfortable, and considered unsightly by some. Lack of compliance may result in requests for further treatment, such as pneumatic pumps or complex decongestive physiotherapy. However, elastic garments are a component of all treatments of lymphedema and compliance has a major impact on the success of any treatment of lymphedema.

Pneumatic pumps can consist either of static uni-compartmental pumps where an equal amount of pressure is applied throughout the edematous limb, or a sequential pump which essentially attempts to “wring out” the edema by graded compression from distal to proximal. Due to the short cycles of pressure, higher pressures can be applied compared to the static pumps. Pressures higher than the systolic blood pressure are avoided; pressures up to 80 to 90 mm Hg are typical. At this point sequential pumps (such as the Lymphapress or the Wright linear sequential pump) appear to be more commonly used than static pumps. The Lymphapress device is composed of a series of overlapping cells that apply a sequential pattern of compression moving distally to proximally along the affected limb. Using this strategy, higher levels of pressure can be applied compared to other uni-compartmental devices which apply the same degree of pressure along the entire limb. The Lymphapress device seems to be effective in acutely decreasing lymphedema, and many patients have purchased this device for home use.

The Flexitouch Device (Tactile Systems Technology, Minneapolis, MN) is a 2-phase lymph preparation and drainage therapy device. The device consists of an electronic controller unit and garments which are worn on the trunk and upper and lower affected extremities and connected to the controller unit by tubing harnesses. The garment consists of 32 inflatable chambers that sequentially inflate and deflate at 1 to 3 second intervals, according to 1 of the 13 pre-programmed treatment patterns selected. Chamber pressure and treatment times can be adjusted. The manufacturer states that device’s sequential action evacuates lymph from the trunk and extremities and drains it into the venous system. The garments are made from stretch material and are fitted with Velcro enclosures, so custom fitting of garments is not required. There are no published studies comparing the effectiveness of this 2-phase lymph
preparation and drainage therapy device to standard segmented pneumatic compression devices.

Drug therapy with benzopyrone can also result in slow reduction of lymphedema. This drug is a proteolytic agent that acts by activating macrophages, which then break down the protein-rich lymphedema fluid, thus decreasing its viscosity and thereby facilitating its flow.

A technique developed in Germany, complex decongestive physiotherapy (CDP), has been introduced in the United States. It is most frequently offered in specialized clinics. Patients attend the clinics for 1 to 4 weeks; CDP consists of 4 basic components as follows:

1. **Meticulous skin and nail care.** The protein rich lymphedema fluid is highly susceptible to infection which can then further damage the lymphatics resulting in a vicious cycle. Thus meticulous skin and nail care is required. Emollients are often used to prevent drying and cracking of the skin and all fungal infections must be treated promptly.

2. **Manual lymphatic drainage (MLD).** This massage technique seems to be the unique component of this multi-disciplinary approach and is based on the concept that the lymphatic system is subdivided into individual lymphotomes which communicate through collateral channels. The idea behind MLD is to increase the collateral circulation between these lymphotomes, such that the lymphedema fluid can be shunted from an inadequately draining lymphotome into a normal one. Thus, unlike other massage techniques, MLD begins with massage of the contralateral truncal lymphotome and then progresses toward the edematous extremity. Theoretically, in this way the collateral circulation is opened and dilated and the lymphatic drainage is "decongested." There is no specific description of the technique of MLD, or theories as to how this technique can open and dilate collateral channels. Patients enrolled in the CDP clinic may undergo 1 to 2 such MLD sessions (about 45 mins each) each day.

3. **Bandaging.** After the MLD session, the lymphedematous limb is wrapped with a pure cotton, minimally elastic bandages in order to provide adequate tissue pressure which in turn prevents re-accumulation of lymphedema.

4. **Remedial Exercises.** These exercises are performed while wearing the bandages, and thus the muscles contract against a firm external force, further stimulating lymph flow.

During the clinical sessions the patients receive additional counseling in various aspects of self management, such as skin care, nutrition, weight control, etc. Prior to discharge from the clinic, the patient is fitted with an elastic support garment. It is recommended that this garment be worn as much as possible, and even at night. Some clinics may recommend wearing the bandages at night, and the compressive garment during the day. The use of these garments can be gradually reduced as the patient improves; however, typically, the patient will need to continue wearing the compressive garment at least part time. An initial course of CDP may require 30 days, or in the case of lower extremity care, 45 days.

No conservative treatment is entirely curative and all require a committed physical therapy team and a committed and compliant patient.

Surgery has been used in patients with severe lymphedema. Excisional surgical procedures involve resection of the redundant tissue that may develop in long-standing severe lymphedema and elephantiasis.

Physiologic surgical procedures attempt to provide or enhance lymphatic drainage with either anastomoses between lymphatic systems (i.e., linking subcutaneous tissues with the deep
lymphatics), creating lymphovenous anastomoses or creation of artificial lymph channels. These surgical techniques are controversial and rarely used.

Damstra and colleagues (2009) prospectively determined the effect of lympho-venous anastomosis (LVA) on breast cancer related lymphedema (BCRL) and reviewed the current literature. A total of 10 patients who were previously treated for breast cancer by surgery, radiotherapy, and chemotherapy, and were unresponsive to 12-weeks of non-operative treatment, underwent an LVA procedure. Objective measurements were gathered for circumferential measurement and water volumetry, and quality of life. Various types of lymphoscintigraphy were performed pre-operatively and post-operatively at 3 and 12 months. Treatment was embedded in a multi-disciplinary setting. Post-operative volume measurements initially showed a 4.8% reduction of lymphedema at 3 months and a 2% reduction after 1 year. Various scintigraphic parameters showed some improvement. Quality of life questionnaires reported minimal improvement. Reviewing the literature, only retrospective studies were found; these reported varying results for LVA procedures. The selection of patients, classification of lymphedema, indications and types of LVA, and additional therapeutic options were heterogeneous, not comparable, and lacked a validated method of effect-assessment. The authors concluded that their findings showed a minimal reduction in volume of lymphedema following LVA; in the literature, there was no convincing evidence of the success of LVA. They noted that non-operative treatment and elastic stockings are still preferred by most patients with lymphedema, especially in early stages with few irreversible changes.

In a randomized, single-blinded, controlled trial, Devoogdt et al (2011) determined the preventive effect of manual lymph drainage on the development of lymphedema related to breast cancer. A total of 160 consecutive patients with breast cancer and unilateral axillary lymph node dissection were included in this study. The randomization was stratified for body mass index (BMI) and axillary irradiation and treatment allocation was concealed. Randomization was done independently from recruitment and treatment. Baseline characteristics were comparable between the groups. For 6 months, the intervention group (n = 79) performed a treatment program consisting of guidelines about the prevention of lymphedema, exercise therapy, and manual lymph drainage. The control group (n = 81) performed the same program without manual lymph drainage. Main outcome measures included cumulative incidence of arm lymphedema and time to develop arm lymphedema, defined as an increase in arm volume of 200 ml or more in the value before surgery. Four patients in the intervention group and 2 in the control group were lost to follow-up. At 12 months after surgery, the cumulative incidence rate for arm lymphedema was comparable between the intervention group (24%) and control group (19%) (odds ratio 1.3, 95% confidence interval [CI]: 0.6 to 2.9; p = 0.45). The time to develop arm lymphedema was comparable between the 2 group during the 1st year after surgery (hazard ratio 1.3, 0.6 to 2.5; p = 0.49). The sample size calculation was based on a presumed odds ratio of 0.3, which is not included in the 95% CI. This odds ratio was calculated as (presumed cumulative incidence of lymphedema in intervention group/presumed cumulative incidence of no lymphedema in intervention group) × (presumed cumulative incidence of no lymphedema in control group/presumed cumulative incidence of lymphedema in control group) or (10/90) × (70/30). The authors concluded that manual lymph drainage in addition to guidelines and exercise therapy after axillary lymph node dissection for breast cancer is unlikely to have a medium to large effect in reducing the incidence of arm lymphedema in the short-term.

Lin et al (2009) evaluated the outcome of vascularized groin lymph node transfer using the wrist as a recipient site in patients with post-mastectomy upper extremity lymphedema.
Between January of 1997 and June of 2005, 13 consecutive patients with a mean age of 50.69 +/- 11.25 years underwent vascularized groin lymph node transfer for post-mastectomy upper extremity lymphedema. A vascularized groin lymph node nourished by the superficial circumflex iliac vessels was harvested and transferred to the dorsal wrist of the lymphedematous limb. The superficial radial artery and the cephalic vein were used as the recipient vessels. Outcome was assessed by upper limb girth, incidence of cellulitis, and lympho-scintigraphy. All flaps survived, and 1 flap required re-exploration, with successful salvage. No donor-site morbidity was encountered. At a mean follow-up of 56.31 +/- 27.12 months, the mean reduction rate (50.55 +/- 19.26 %) of the lymphedematous limb was statistically significant between the pre-operative and post-operative groups (p < 0.01). The incidence of cellulitis was decreased in 11 patients. Post-operative lympho-scintigraphy indicated improved lymph drainage of the affected arm, revealing decreased lymph stasis and rapid lymphatic clearance. A hypothesis was proposed that the vascularized groin lymph node transfer might act as an internal pump and suction pathway for lymphatic clearance of lymphedematous limb. The authors concluded that vascularized groin lymph node transfer using the wrist as a recipient site is a novel and reliable procedure that significantly improves post-mastectomy upper extremity lymphedema. Drawback of this study included small sample size and lack of a control group.

Gharb et al (2011) reported the outcome of vascularized lymph node transfer with hilar perforators compared with the conventional technique. A total of 21 patients affected by early stage II upper limb lymphedema were included in this study. Of them, 11 patients received a free groin flap containing lymph nodes, and 10 patients received vascularized inguinal lymph nodes with hilar perforators. Mean follow-up was 46 and 40 months, respectively. Complications, secondary procedures, circumference of the limb, and subjective symptomatology were registered. The differences were evaluated statistically. The limb circumferences decreased significantly in the new group. The number of secondary procedures was significantly higher in the standard group. There were 2 cases of partial flap loss and donor site lymphorrhea in the standard group. In both the groups, visual analog scale scores improved after the operation. The authors concluded that transfer of vascularized inguinal lymph nodes based on the hilar perforators improves the outcomes in the treatment of early lymphedema of the upper extremity. Drawback of this study included small sample size and lack of a control group.

Cormier and colleagues (2012) performed a systematic review of the literature to examine contemporary peer-reviewed literature (2004 to 2010) evaluating the surgical treatment of lymphedema. A comprehensive search of 11 major medical indices was performed. Selected articles were sorted to identify those related to the surgical treatment of lymphedema. Extracted data included the number of patients, specific surgical procedure performed, length of follow-up, criteria for defining lymphedema, measurement methods, volume or circumference reduction, and reported complications. A total of 20 studies met inclusion criteria; procedures were categorized as excisional procedures (n = 8), lymphatic reconstruction (n = 8), and tissue transfer (n = 4). The reported incidence of volume reduction of lymphedema in these studies varied from 118 % reduction to a 13 % increase over the follow-up intervals ranging from 6 months to 15 years. The largest reported reductions were noted after excisional procedures (91.1 %), lymphatic reconstruction (54.9 %), and tissue transfer procedures (47.6 %). Procedure complications were rarely reported. The authors concluded that a number of surgical approaches have demonstrated beneficial effects for select patients with lymphedema. Most of these reports, however, were based on small numbers of patients, use non-standardized or inconsistent measurement techniques, and lack long-term follow-up. The proposed benefits of any surgical approach should be evaluated in the context of the potential
morbidity to the individual patient and the availability of surgical expertise. In addition, although these surgical techniques have shown promising results, nearly all note that the procedures do not obviate the need for continued use of conventional therapies, including compression, for long-term maintenance.

Also, an UpToDate review on "Operative management of primary and secondary lymphedema" (Mehrara, 2012) stated that "similar to flap transfers, lymph node transfers are not commonly performed. Although these procedures may hold some promise, additional studies are required to evaluate their efficacy and to identify patient populations that are most likely to benefit .... Outcome data for lymph node transfer procedures are based upon small series of patients. Effective engraftment of non-vascularized transfer of lymph node grafts has not been clearly demonstrated. Harvesting of lymph nodes for transfer may cause lymphedema in the donor extremity".

An UpToDate review on "Lymphedema: Prevention and treatment" (Mohler and Mondry, 2012) did not mention the use of whole body vibration as a management toll.

Dylke et al (2013) examined if bioimpedance spectroscopy was suitable for detection of hand lymphedema. The hands of 50 participants without a history of lymphedema were measured with perometry and bioimpedance spectroscopy after positioning 2 ways for 3 minutes: (i) both hands rested at heart height; and (ii) the dominant hand at heart height and the non-dominant hand at head height. In addition, 10 women with secondary hand lymphedema were also measured. Impedance and volume measurements were found to be strongly related (dominant hand $r = -0.794$). Both measurements were reliable ($ICC(2,1) = 0.900$ to $0.967$ and $0.988$ to $0.996$, respectively). Impedance was more sensitive to small changes in hand volume due to the postural change (position x device interaction: $F = 23.9$, $p < 0.001$). Finally, impedance measurements had better discrimination of women with lymphedema than volume measurements. The authors concluded that bioimpedance spectroscopy is a promising tool for the detection of secondary hand lymphedema.

Cheng et al (2013) noted that vascularized groin lymph node flap transfer is an emerging approach to the treatment of post-mastectomy upper limb lymphedema. These investigators described the pertinent flap anatomy, surgical technique including different recipient sites, and outcome of this technique. A total of 10 cadaveric dissections were performed to clarify the vascular supply of the superficial groin lymph nodes; and 10 patients underwent vascularized groin lymph node flap transfer for post-mastectomy upper limb lymphedema using the wrist ($n = 8$) or elbow ($n = 2$) as a recipient site; and 10 patients who chose to undergo physical therapy (PT) were used as controls. Intra-operatively, indocyanine green (ICG) was injected subcutaneously on the flap margin to observe the lymph drainage. Outcomes were assessed using improvement of circumferential differentiation, reduction rate, and decreased number of episodes of cellulitis. A mean $6.2 \pm 1.3$ groin lymph nodes with consistent pedicles were identified in the cadaveric dissections. After ICG injection, the fluorescence was drained from the flap edge into the donor vein, followed by the recipient vein. At a mean follow-up of $39.1 \pm 15.7$ months, the mean improvement of circumferential differentiation was $7.3 \pm 2.7$ % and the reduction rate was $40.4 \pm 16.1$ % in the vascularized groin lymph node group, which were statistically greater than those of the PT group ($1.7 \pm 4.6$ % and $8.3 \pm 34.7$ %, respectively; $p < 0.01$ and $p = 0.02$, respectively). The authors concluded that the superficial groin lymph nodes were confirmed as vascularized with reliable arterial perfusion. They stated that vascularized groin lymph node flap transfer using the wrist or elbow as a recipient site is an effective approach to treating post-mastectomy upper limb lymphedema. The findings of this small study need to be validated by well-designed studies.
CPT Codes / HCPCS Codes / ICD-9 Codes

CPT codes covered if selection criteria are met:

97016
97140

CPT codes not covered for indications listed in the CPB:

38308
0239T

Other CPT codes related to the CPB:

29583
29584

HCPCS codes covered if selection criteria are met:

A4465 Non-elastic binder for extremity
E0650 Pneumatic compressor, non-segmental home model
E0651 Pneumatic compressor, segmental home model without calibrated gradient pressure
E0652 Pneumatic compressor, segmental home model with calibrated gradient pressure
E0655 Non-segmental pneumatic appliance for use with pneumatic compressor, half arm
E0660 Non-segmental pneumatic appliance for use with pneumatic compressor, full leg
E0665 Non-segmental pneumatic appliance for use with pneumatic compressor, full arm
E0666 Non-segmental 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
E0676  Intermittent limb compression device (includes all accessories), not otherwise specified
S8420 - S8428  Gradient pressure aids (sleeves, gloves, gauntlets)
S8950  Complex lymphedema therapy, each 15 minutes

**HCPCS codes not covered for indications listed in the CPB:**

E0656  Segmental pneumatic appliance for use with pneumatic compressor, trunk
E0657  Segmental pneumatic appliance for use with pneumatic compressor, chest
E0670  Segmental pneumatic appliance for use with pneumatic compressor, integrated, 2 full legs and trunk

**Other HCPCS codes related to the CPB:**

A6530 - A6549  Gradient compression stockings

**ICD-9 codes covered if selection criteria are met:**

457.0 - 457.2  Noninfectious disorders of lymphatic channels [lymphedema] [vascularized lymph node transfer not covered for the treatment of post-mastectomy lymphedema]

757.0  Hereditary edema of legs

**Other ICD-9 codes related to the CPB:**

681.00 - 682.9  Cellulitis and abscess

997.99  Other complications affecting other specified body systems, not elsewhere classified

The above policy is based on the following references:


37. Mohler ER, Mondry TE. Lymphedema: Etiology, clinical manifestations, and diagnosis. UpToDate [online serial]. Waltham, MA: UpToDate; 2010.


65. Mehrara B. Operative management of primary and secondary lymphedema. UpToDate [online serial]. Waltham, MA: UpToDate; reviewed September 2012.

http://qawww.aetna.com/cpb/medical/data/1_99/0069_draft.html 12/08/2014