

# Cigna Medical Coverage Policy- Therapy Services Complex Lymphedema Therapy (Complete Decongestive Therapy)

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**Coverage for the treatment of lymphedema, including complex lymphedema therapy, may be governed by federal and/or state mandates. Under many benefit plans, complex lymphedema therapy is subject to the terms, conditions and limitations of the applicable benefit plan's Short-Term Rehabilitative Therapy benefit and schedule of copayments.**

**If coverage is available for complex lymphedema therapy, the following conditions of coverage apply.**

## **GUIDELINES**

### **Medically Necessary**

**Complex lymphedema therapy (complete decongestive therapy) is considered medically necessary for the treatment of intractable lymphedema when ALL of the following are met:**

- Documented failure of a reasonable course of conservative medical management that includes home exercises, limb elevation, and compression garments.

- The lymphedema is directly responsible for impaired functioning in the affected limb.
  - The complex lymphedema therapy is prescribed by or under the supervision of an appropriate healthcare provider.
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## **DESCRIPTION**

Complex lymphedema therapy (CLT) is a non-invasive treatment for lymphedema with the aim to reduce and control the amount of swelling in the affected limb and restore function. Complex lymphedema therapy (CLT) is a noninvasive treatment that is considered a standard of care for lymphedema. This method has also been referred to as complete decongestive physiotherapy (CDP), and complex decongestive therapy (CDT). The treatment aim is to reduce and control the amount of swelling in the affected limb and restore function. The objective of the technique is to redirect and enhance the flow of lymph through intact cutaneous lymphatics. Programs are generally provided on an outpatient basis in the office setting or in a lymphedema rehabilitation center or clinic (Lasinski and Boris, 2002; MacDonald, et al., 2003).

The typical CLT program consists of two phases of treatment—a treatment phase and a maintenance phase. Phase I, the treatment phase, usually last two to four weeks. This phase consists of four components (Lawenda, et al., 2009):

- Skin and nail care: The purpose is to inspect skin, provide moisture and prevent infection.
- Manual lymph drainage (MLD): This is a light, massage-like technique that is performed for 30-60 minutes and is used to stimulate residual lymphatic vessels to carry excess fluid from the affected extremity.
- Compression bandaging: This involves wrapping multi-layered bandages around affected limb.
- Therapeutic exercise: This includes movement of the limb through a range of motion with bandaging in place.

Most patients will be able to progress to a home-based, self-managed program after an initial in-office program of 1–2 weeks. Instruction in self-management should begin in the first week of therapy. Both patients and family are taught bandaging and exercise techniques, as well as the essentials of skin and nail care. After the initial one- to two-week program, patients should be re-evaluated to determine whether continued in-office therapy is necessary or if treatment can be provided in the home.

Phase II, the maintenance phase, consists of life-long self-care to maintain the size of the limb. In this phase, the patient maintains and optimizes the results by applying the techniques learned in the treatment phase including: skin and nail care, wearing an elastic sleeve during the day, bandaging the affected limb overnight and exercises (Petrek, 2000).

### **Duration and Frequency**

A program of complex lymphedema therapy provided 2–5 times per week for two weeks is generally considered medically necessary for the treatment of primary or secondary lymphedema, in the absence of any contraindications. Programs that go beyond a four-week period are generally considered not medically necessary.

### **Contraindications**

Absolute contraindications to lymphedema therapy include:

- acute infections of the affected limb
- venous or arterial obstruction (deep vein thrombosis)
- active malignancy, confirmed or suspected local disease
- unwillingness or inability of the member to participate in the treatment

Relative contraindications to lymphedema therapy include:

- suspicion of deep vein thrombosis prior to starting treatment
- congestive heart failure
- when the local massage is performed in area of irradiated soft tissue

## **GENERAL BACKGROUND**

Lymphedema is defined as the excessive and persistent accumulation of protein rich fluid that collects in the interstitial spaces, due to an inefficiency of the lymphatic system (Szuba et al., 2002; Leal et al., 2009). Lymphedema occurs primarily as a result of malformation, underdevelopment, or acquired disruption of the lymphatic circulation (Szuba et al., 2002). Primary lymphedema is due to congenital defects of the lymphatic system, which can affect from one to as many as four limbs or other parts of the body and is considered rare (National Lymphedema Network, 2011). Secondary lymphedema is acquired and is due to an obstruction or interruption in the lymphatic circulation. Secondary lymphedema can develop as a result of surgery, radiation, infection or trauma. It is a common treatment-related side effect experienced by cancer patients. Patients that undergo surgery for breast cancer that includes node dissection or axillary radiation therapy are at high risk of developing lymphedema.

Historically, lymphedema has been classified into three (3) stages based on its severity and on observation of the patient's condition. Currently, the International Society of Lymphedema is recognizing a Stage 0 in patients, which refers to a latent or sub-clinical condition where swelling is not evident despite impaired lymph circulation. Patients often report a feeling of heaviness in the limb, however many patients are asymptomatic in the latency stage. Stage 0 may be present for months or years prior to a patient exhibiting signs and symptoms of edema. Stage I lymphedema is referred to as spontaneously reversible lymphedema (Lawenda et al., 2009, Bicego et al., 2006) and typically involves pitting edema, an increase in limb girth (usually upper extremity), and heaviness. Stage II is also known as spontaneously irreversible lymphedema and it is marked by spongy consistency of the tissue and non-pitting edema (Bicego et al., 2006). Tissue fibrosis marks the beginning of hardening of the limbs and increased girth of extremity and is often found in Stage II (Bicego et al., 2006). Stage III is the most advanced stage and is often referred to as lymphostatic elephantiasis. During Stage III the swelling is irreversible with tissue being fibrotic and unresponsive including patients who present with very large limb(s) size. It is associated with a significant increase in the severity of the fibrotic response, tissue volume, and other skin changes such as papillomas, cysts, fistulas, and hyperkeratosis (Lawenda et al., 2009; Zuther, 2005). With regards to Stage 0, the literature is insufficient to conclude that the use of CDT is either clinically effective or ineffective in the treatment of subclinical or latent stage of breast cancer related lymphedema.

The best practice or gold standard for lymphedema treatment is considered complex decongestive therapy (CDT), also known as complex lymphedema therapy (CLT). CDT is a noninvasive treatment and consists of four basic components as follows: skin and nail care, manual lymph drainage (MLD), followed by bandaging/compression, education, and exercise. The goal of CDT is to reduce and control the amount of swelling in the affected limb and restore function. A treatment option that is used to manage secondary lymphedema is intermittent pneumatic compressions (IPC) which is often added to CDT. Low-level laser therapy (LLLT) is another treatment option that may be an effective treatment when used in conjunction with other standard lymphedema treatments. However, low-level laser is currently considered experimental, investigational and/or unproven. Exercise demonstrates improvements in function and QoL, but not in limb reduction. The goal of all conservative treatment is to reduce and control the amount of swelling in the affected limb and restore function.

## **LITERATURE REVIEW**

Lymphedema is a common sequela of cancer or its treatment that affects the lymphatic transport system that results in failure of lymph node drainage. Secondary lymphedema is often a debilitating, chronic, progressive condition that commonly occurs after treatment of breast cancer. A number of health professional and patient instigated conservative therapies have been developed to help treat this condition. A systematic review conducted by Moseley et al. (2007) reviewed the common conservative therapies used for management of secondary arm lymphedema as follows: complex physical therapy, manual lymphatic drainage, pneumatic pumps, oral pharmaceuticals, low level laser therapy, compression bandaging and garments, limb exercises and limb elevation. This study found that the more intensive and health care professional driven therapies, such as complex physical therapy (skin and nail care, manual lymphatic drainage, a multilayer compression bandage and therapeutic exercises), manual lymphatic drainage, pneumatic pump and laser level light therapy generally yielded the greater volume reductions, compared to self-instigated therapies such as compression garment wear, exercises and limb elevation. These self-care methods showed reductions, however in lesser volumes. All conservative therapies reviewed in this study

produced improvements in subjective arm symptoms and quality of life (QoL) issues, where these were measured.

Stout et al. (2008) completed a study on Stage 0 lymphedema. They used infrared optoelectronic technology to identify those at risk for edema based on volume measurements. This technology allows for changes to be noted before they are actually visible to the eye. When these changes are noted, treatment initiated immediately may prevent the development of further stages of lymphedema. However, there is no standard for the treatment of early-stage, subclinical lymphedema. When the diagnosis of breast cancer related lymphedema is delayed, therapeutic management requires intensive decongestive therapy and life-long maintenance. This study suggested that an early intervention protocol with 20- to 30-mm Hg compression garments, significantly reduced the affected limb volume to near baseline measures and prevented progression to a more advanced stage of lymphedema for at least the first year postoperatively. Further research is warranted to confirm the long-term clinical and cost effectiveness of this early intervention model compared with a traditional model in treating breast cancer related lymphedema.

### **Complete Decongestive Therapy (CDT), Manual Lymphatic Drainage (MLD) and Compression Methods**

A prospective trial of complete decongestive therapy for upper extremity lymphedema after breast cancer was reviewed by Mondry et al. (2004). Patients completed two to four (2-4) weeks (median, 2 weeks) of treatment; including skin and nail care, manual lymphatic drainage, a multilayer compression bandage and therapeutic exercises. Edema of the affected limb was reassessed on a weekly basis. Authors concluded that decreasing girth correlated significantly with decreasing visual analogue scale scores for pain, but not with increasing QoL. Data gathered showed median girth reduced 1.5 cm and median volume reduced 138mL. This study concluded that compliance with the treatment regimen at home decreased with duration of the program and girth reductions contributed to less pain. Increased frequency of treatment sessions provides marked improvement in girth, volume, and weight but resulted in poorer compliance. Longer latency more successfully reduces girth, volume, and pain and increases QoL. QoL and pain are improved by treatment and continue to improve after treatment has ended. A randomized controlled trial conducted by McNeely et al. (2004) looked at the addition of manual lymph drainage to compression therapy for managing breast cancer-related lymphedema. The authors of this study compared the reduction in arm lymphedema volume achieved from manual lymph drainage massage in combination with multi-layered compression bandaging to that achieved by compression bandaging alone. Treatment group one received manual lymph drainage (MLD)/compression bandaging (CB). This group received 45 minutes of daily MLD and CB, Monday-Friday for four (4) weeks. The second treatment group received short stretch bandaging, Monday-Friday for four (4) weeks. Authors concluded that a significant reduction in lymphedema volume was found over the four (4) week period for both the manual lymph drainage/compression bandaging and compression bandaging alone groups. No significant differences existed between groups (McNeely et al., 2004).

Koul et al. (2007) assessed the results of combined decongestive therapy and manual lymphatic drainage in patients with breast cancer-related lymphedema over a two year period. This study was a non-randomized clinical trial that reviewed data from 250 patients with a final analysis reviewed from 138 patients. The pre- and post-treatment volumetric measurements were compared and correlated with age, body mass index, and type of surgery, chemotherapy, and radiotherapy. One group was treated with all four (4) parts of combined decongestive therapy for one (1) hour daily for up to several weeks, depending on the severity and response. Combined decongestive therapy consisted of manual lymphatic drainage, compression, exercises for the arm and shoulder, and deep breathing to help promote venous and lymphatic flow. Patients were also fitted with custom-made garments to be worn daily while awake and removed at bedtime. Self-lymph drainage at least once daily was also recommended. A second treatment group received MLD alone. They were also fitted for custom compression garments. Self-lymph drainage was also recommended. A third treatment group received one hour of home instruction and counseling, including simple self drainage techniques, skin care, and exercise. They also received custom compression garments. Results noted a significant reduction in arm volumes at one (1) year after the beginning of treatment with some or all components of combined decongestive therapy in patients with lymphedema after breast cancer treatment. Patients with moderate to severe lymphedema had a maximal response after combined decongestive therapy, and patients enrolled in the home program had mild lymphedema and less dramatic responses to treatment. Authors concluded that combined decongestive therapy and manual lymphatic drainage with exercises were associated with a significant reduction in the lymphedema volume in all groups assessed. Long-term management of breast cancer-related lymphedema after intensive decongestive therapy was studied by Vignes et al. (2007). The authors' aim

was to describe the effect of the maintenance therapy on lymphedema volume reduction and to analyze the impact of the different components of treatment in women with upper limb lymphedema after breast cancer treatment. The treatment consisted of an intensive phase of CDT, including manual lymph drainage (30 minutes, five [5] times a week), low stretch compression bandaging (24 hours daily), exercises after bandages were applied to enhance lymphatic flow from peripheral to central compartments and skin care. Maintenance therapy consisted of education (3 bandages per week). Authors concluded that bandaging and elastic sleeves are a key component to maintenance therapy after intensive CDT.

A systematic review was conducted by Karki et al. (2009) on the effects and harms of physiotherapy methods of lymphedema therapy in breast cancer patients. Fourteen randomized controlled studies were included, two of which had moderate risk of bias and the remainder had high risk. There was moderate evidence that compression bandages alone decreased lymphedema, and that pneumatic pumps had no effect on lymphedema compared to no treatment. With the remainder of the studies that had high risk of bias, the interventions and comparisons varied across all trials. This review found moderate evidence to support that compression bandages decreased lymphedema. There was no evidence regarding volume reduction outcomes in any other body part except the upper limb. Evidence on other physiotherapy methods and combinations is limited due to poor quality of the studies. Devoogdt et al. (2010) conducted a systematic review of combined physical therapy, intermittent compression and arm elevation for treatment of lymphedema secondary to axillary dissection for breast cancer. The review included ten randomized controlled trials and non-randomized, experimental trials. The review found that combined physical therapy can be considered as an effective treatment modality for treatment of lymphedema; however the effectiveness of its different components remains uncertain. Szolnoky et al. (2009) compared manual lymphatic drainage with manual lymphatic drainage plus intermittent pneumatic compression for treatment of unilateral arm lymphedema in 27 women previously treated for breast cancer. One treatment group received complex decongestive physiotherapy (CDP), which included manual lymph drainage (MLD) using the Vodder technique. Treatment sessions were for 60 minutes per day for 10 consecutive business days by a specific physiotherapist, followed by skin care, bandaging, and exercise. MLD was performed on the neck, breast, and abdomen. The second treatment group received complex decongestive physiotherapy plus intermittent pneumatic compression (CDP+IPC). This included the same MLD using the Vodder technique for 30 minutes per day for 10 days, followed by 30 minutes of IPC with a Lympha Mat device at a pressure of 50 mmHg. Patient also received skin care, bandaging, and exercise. Each treatment method was effective in reducing limb size, but the combination treatment of CDP+IPC showed statistically significant greater reductions in limb size when compared to CDP alone, with no negative side effects noted. No other statistically significant changes were noted in the patients' subjective reports with either treatment method at any time.

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:

- Complex decongestive therapy (CDT) has been observed to have a significant effect on edema reduction and is recognized internationally as a successful treatment for lymphedema.
- There is no single treatment that is considered usual care for lymphedema. At this time, CDT, which is a combination of therapies, is suggested as the main method of conservative care for lymphedema. CDT includes manual lymphatic drainage (MLD), application of compression low stretch bandages, exercise and skin care.

A randomized controlled-group study conducted by Kim et al. (2010) investigated the differences between the effects of complex decongestive physiotherapy with and without active resistive exercise for the treatment of patients with breast cancer-related lymphedema. Treatment group one received CDT (manual lymphatic drainage, compression therapy, and exercise, including resistance training) five (5) times a week for two weeks followed by self-administered treatment for another six weeks. The control group received the CDT without the resistance training added to the exercise program. Authors concluded that active resistive exercise with CDT did not create additional swelling and assisted with reduction of arm volume. QoL was also improved for this group. The National Lymphedema Network (NLN) published a position statement regarding treatment of lymphedema (NLN, 2011). Included in the document were the following statements regarding Complex decongestive therapy (CDT):

- CDT is the main treatment for lymphedema. Experts who treat lymphedema consider CDT the “gold standard” of treatment. The treatment has been shown to be safe and effective. CDT is the current international standard of care for managing lymphedema.
- CDT has been shown to be effective in large numbers of case studies demonstrating limb volume reductions of 50–70% or more, improved appearance of the limb, reduced symptoms, improved quality of life, and fewer infections after treatment. Even people with progressive lymphedema for 30 years or more before starting CDT have been shown to respond.
- Patient adherence during Phase II CDT is critical for preserving volume reduction.
- It is recommended that CDT adaptations or other lymphedema treatments be used on a case by case basis under the supervision of a healthcare provider (e.g., physician, nurse, physician assistant, therapist) with demonstrated expertise in lymphedema management.

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

- Complex Lymphedema Therapy (CDT) is included in the statement as a standard treatment for lymphedema that is backed by longstanding experience. The first phase includes skin care, light manual massage, range of motion exercise and compression with multilayered bandage-wrapping. The second phase aims to conserve and optimize results obtained in Phase 1.
- An assessment should be made of limb volume before, during and after treatment. Treatment outcomes should be reported in a standardized manner in order to assess effectiveness of treatment protocols.

Huang et al. (2013) completed a systematic review and meta-analysis on the effects of MLD on breast cancer-related lymphedema. They investigated whether manual lymphatic drainage (MLD) could prevent or manage limb edema in women after breast-cancer surgery. In total, 10 RCTs with 566 patients were identified. Authors concluded that the current evidence from RCTs does not support the use of MLD in preventing or treating lymphedema. However, clinical and statistical inconsistencies between the various studies confounded our evaluation of the effect of MLD on breast-cancer-related lymphedema. Lasinski (2013) summarized the evidence on the management of lymphedema and provided recommendations. Complete decongestive therapy (CDT) is effective in reducing lymphedema, although the contribution of each individual complete decongestive therapy component has not been determined. In general, levels of evidence for complete decongestive therapy are moderate. Fu et al. (2014) aimed to provide healthcare professionals with evidence-based clinical practice guidelines for lymphedema treatment and management through a systematic review. Findings of the systematic review support complete decongestive therapy, compression bandages, and compression garments with highest evidence for best clinical practice. Weight management, full-body exercise, education, prevention, and early intervention protocols are likely to be effective for clinical practice.

Shao et al. (2014) sought to determine whether the use of an intermittent pneumatic pump (IPC) could manage lymphedema effectively. Seven randomized controlled trials, with 287 patients, were included. Results showed that the use of the IPC could alleviate lymphedema, but no significant difference between routine management of lymphedema with or without pneumatic pump existed. Authors concluded that current trials fail to show the effectiveness of the addition of an IPC to the routine management of BCRL. Leung et al. (2015) evaluated the available evidence for the treatment of secondary lower limb lymphoedema in patients with malignancies. Authors concluded that few studies have evaluated the clinical effectiveness and potential side effects of treatments for lower limb lymphoedema. Moreover, symptoms and quality-of-life assessments were inconsistently reported. All included studies report lower limb volume reduction after treatment, which includes complex decongestion therapy, graded compression stockings and lymphovenous microsurgical shunts. Adequately powered randomized controlled trials of these interventions are recommended. Ezzo et al. (2015) assessed the efficacy and safety of MLD in treating BCRL. Six trials were included. Authors concluded that MLD is safe and may offer additional benefit to compression bandaging for swelling reduction. Compared to individuals with moderate-to-severe BCRL, those with mild-to-moderate BCRL may be the ones who benefit from adding MLD to an intensive course of treatment with compression bandaging. This finding however, needs to be confirmed by randomized data. In trials where MLD and sleeve were compared with a non-MLD treatment and sleeve, volumetric outcomes were inconsistent within the same trial. Findings were contradictory for function (range of motion), and inconclusive for quality of life. For symptoms such as pain and heaviness, 60% to 80% of participants reported feeling better regardless of which treatment they received. One-year follow-up suggests that once swelling had

been reduced, participants were likely to keep their swelling down if they continued to use a custom-made sleeve. Finnane et al. (2015) sought to summarize efficacy findings of reviews on lymphedema treatment. Overall, there was wide variation in review methods. The quality of studies included in reviews, in study design and reporting overall, has been poor. Reviews consistently concluded that complex physical therapy is effective at reducing limb volume. Volume reductions were also reported after the use of compression garments, pumps, and manual lymphatic drainage. However, greatest improvements were reported when these treatments formed a combined treatment program. Large, well-designed, evaluated, and reported randomized, controlled trials are needed to evaluate and compare treatments.

Elastic therapeutic taping (e.g., Kinesio taping) has been proposed as a treatment intervention for lymphedema, given its properties and hypothesized mechanism to lift the skin away from the adjacent muscle and allow intercellular fluid to flow more freely. For example, lymph will move more easily out of lymph channels and into larger lymph ducts for uptake. Bialoszewski et al. (2009) studied the effects of KT in reducing edema of lower limbs in patients subjected to limb lengthening. Twenty-four (24) patients developed post-surgical lymphedema. They were randomized into two (2) groups. One group received taping and the other received standard physiotherapy (lymphatic drainage). Both methods reduced edema significantly pre- and post-treatment (after 10 days); however the application of the KT produced a significantly faster reduction of edema compared to standard lymphatic drainage methods. A study by Tsai et al. (2009) hypothesized whether KT could replace the bandage in decongestive lymphatic therapy (DLT) for breast-cancer-related lymphedema. The pilot study looked at standard DLT combined with pneumatic compression (PC) or modified DLT using KT combined with PC; both types of treatments resulted in reduced girth measurements of the upper extremity and other outcomes in forty-one (41) patients with breast-cancer-related lymphedema. Results demonstrated no significant differences between the two types of treatments. Thus, use of KT could replace the bandage typically used in DLT. Morris et al. (2013) reported on a systematic review with the purpose of this study was to investigate the effect of Kinesio Tex tape (KTT) from randomized controlled trials (RCTs) in the management of clinical conditions. The review included eight RCTs: six included patients with musculoskeletal conditions; one with breast-cancer-related lymphedema; and, one included stroke patients with muscle spasticity. Six studies included a sham or usual care tape/bandage group. The review found limited to moderate evidence that KTT is no more clinically effective than sham or usual care tape/bandage. The authors concluded that there currently exists insufficient evidence to support the use of KTT over other modalities in clinical practice. Kalron and Bar-Sela (2013) reported on a systematic review that assessed the effects of therapeutic Kinesio Taping (KT) on pain and disability in participants suffering from musculoskeletal, neurological and lymphatic pathologies. Twelve met inclusion criteria. The final 12 articles were subdivided according to the basic pathological disorders: musculoskeletal (N=9) (four randomized, controlled trials (RCT), three single blinded RCT, one cross-over trial and one case-control study); neurological (N=1) (RCT); and, lymphatic (N=2) (RCT). Regarding lymphatic disorders, inconclusive evidence was reported. The authors concluded that although KT has been shown to be effective in aiding short-term pain, there is no firm evidence-based conclusion of the effectiveness of this application on the majority of movement disorders within a wide range of pathologic disabilities. Gatt et al. (2016) aimed to determine the effectiveness and safety of kinesiotaping (KT) in the management of cancer-related lymphoedema (CRL) compared to compression bandaging or hosiery. Five studies were included in the meta-analysis of the primary outcome limb volume ( $n = 203$ ,  $KTn = 91$ ,  $compression n = 112$ ). No significant difference existed between the interventions. An increased risk of skin complications with KT was reported in five studies affecting between 10% and 21% of patients. Where lymphoedema-related symptoms were reported KT was found to be superior to compression. Paradoxically, patients receiving bandaging reported a higher QoL. Thus authors concluded that KT was not found to be more comfortable than bandaging and should only be used with caution where bandaging cannot be used.

Zasadzka et al. (2018) compared the effectiveness of multi-layer compression bandaging (MCB) and complex decongestive therapy (CDT) for treating lymphedema in elderly patients. One hundred three patients (85 women and 18 men) aged  $\geq 60$  years, with unilateral lower limb lymphedema. The subjects were divided into two groups: 50 treated with CDT and 53 with MCB. Pre- and post-treatment BMI, and average and maximum circumference of the edematous extremities were analyzed. Results noted a reduction in swelling in both groups was achieved after 15 interventions. Both therapies demonstrated similar efficacy in reducing limb volume and circumference, but MCB showed greater efficacy in reducing the maximum circumference. Authors concluded that compression bandaging is a vital component of CDT. Maximum lymphedema reduction during therapy and maintaining its effect cannot be achieved without it. Sezgin Ozcan et al. (2018) evaluated the effects of complex decongestive therapy (CDT) on upper extremity functions, the severity of pain, and quality of life. A total of 37 women with breast cancer-related lymphedema (BCRL) [age,  $53.6 \pm 11.2$  (28-72)] were included in this study.

All patients underwent CDT-phase 1 program, including meticulous skin care, manual lymphatic drainage, remedial exercises, and compression bandages. The mean of the posttreatment volume of the affected limb was lower compared to pretreatment volume. A statistically significant reduction in pain and heaviness VAS scores and improvement of shoulder mobility among upper extremities with lymphedema ( $p < 0.001$ ) was noted after CDT. The mean of posttreatment DASH score was lower and all subgroups of the SF-36 parameters were increased after the CDT application. Also, being under 65 years old, having a body mass index above 30 and short duration of lymphedema were found to be related to greater improvement in upper extremity functions. Authors concluded that CDT provides enhancement of upper extremity functions and quality of life in patients with BCRL. Tzani et al. (2018) investigated strategies and methods for physiotherapeutic rehabilitation of lymphedema. Approaches for conservative management of lymphedema included the following: manual lymphatic drainage, lymphedema rehabilitation exercises, compression therapy, skin care, pneumatic compression, elevation of the extremities, thermal therapy, complete decongestive physiotherapy (CDT), taping, and aqua lymphatic therapy. Treatment of lymphedema with CDT, which is a combination of four methods (manual lymphatic drainage, lymphedema rehabilitation exercises, compression therapy, skin care), can achieve a 45-70% reduction in lymphedema volume. Upon review of the literature, CDT was found to be the most effective treatment as it reduces the symptoms of lymphedema and improves patients' functionality, mobility, and quality of life.

Watanabe et al. (2020) authored an article on the development and themes of diagnostic and treatment procedures for secondary leg lymphedema in patients with gynecologic cancers. They note that for the treatment of lymphedema, complex decongestive physiotherapy (CDP) including manual lymphatic drainage (MLD), compression therapy, exercise and skin care, are generally performed. In recent years, CDP has often required effective multi-layer lymph edema bandaging (MLLB) or advanced pneumatic compression devices (APCDs). If CDP is not effective, microsurgical procedures can be performed. They conclude that the most important concern is the prevention of secondary lymphedema, which is achieved through approaches such as skin care, weight control, gentle limb exercises, avoiding sun and heat, and elevation of the affected leg.

### **Other Treatments**

#### **Low Level Laser Therapy (LLLT)**

Carati et al. (2003) performed a double blind, placebo controlled randomized, single crossover trial use of low-level laser therapy (LLLT) for a treatment option for patients with post mastectomy lymphedema (PML). Participants received either one cycle or two cycles of LLLT to the axillary region of their affected arm. The authors monitored for reduction in affected limb volume, upper body extracellular tissue fluid distribution, dermal tonometry and range of motion. The result yielded that two cycles of low level laser treatment improved lymphedema; however limb volume reduction was not immediate and was reported two to three (2-3) months post-treatment (Carati et al., 2003). A study conducted by Dirican et al. (2011) reviewed the authors' short-term experience with low-level laser therapy in the treatment of breast-cancer related lymphedema. Treatment consisted of laser therapy using 300mJ for one minute to 17 different points on the surgical scar tissue of the axilla. Patients were also treated with compression garments or bandaging. Two of the patients in the study also had sessions using an intermittent compression device. Authors concluded that patients with breast cancer gain additional benefits in the form of volume reduction from low level laser therapy when used in conjunction with other standard treatments (Dirican et al., 2011). Further studies are needed to confirm these findings. Smoot et al. (2015) examined the literature on effectiveness of LLLT in reducing limb volume and pain in adults with breast cancer related lymphedema (BCRL). They concluded that moderate strength evidence supports LLLT in the management of BCRL. The overall review of literature investigated conservative therapies for secondary arm lymphedema that can be divided into intensive treatments administered by trained healthcare professionals and limb maintenance that are carried out by the patient. Treatments that are predominantly administered by healthcare professionals, such as CDT, MLD, and pneumatic pump therapy generally yielded the larger reduction in limb volume. LLLT may be a potential treatment option, but more well-designed studies are needed. Maintenance therapies generally carried out by the patient in a self-care program (e.g. wearing compression garments, performing limb exercises, limb elevation, and self-massage) yielded smaller limb reduction. Baxter et al. (2017) evaluated the effectiveness of LLLT in the management of BCRL in a systematic review. Primary outcome measures were limb circumference/volume, and secondary outcomes included pain intensity and range of motion. Eleven clinical trials were identified, of which seven randomized controlled trials (RCTs) were chosen for analysis. Results indicated that there is strong evidence (three high quality trials) showing LLLT was more effective than sham treatment for limb circumference/volume reduction at a short-term follow-up. There is moderate evidence (one high quality trial) indicating that



LLLT was more effective than sham laser for short-term pain relief, and limited evidence (one low quality trial) that LLLT was more effective than no treatment for decreasing limb swelling at short-term follow-up. Authors concluded that based upon their current systematic review, LLLT may be considered an effective treatment approach for women with BCRL. However, due to the limited numbers of published trials available, there is a need for well-designed high-quality trials in this area and the optimal treatment parameters for clinical application have yet to be determined.

### Exercise

Kwan et al. (2011) conducted a systematic review of the contemporary literature to distill the weight of the evidence and provide recommendations for exercise and lymphedema care in breast cancer survivors. Seven studies were identified addressing resistance exercise, seven studies on aerobic and resistance exercise, and five studies on other exercise modalities. Studies concluded that slowly progressive exercise of varying modalities is not associated with the development or exacerbation of breast cancer-related lymphedema and can be safely pursued with proper supervision. Combined aerobic and resistance exercise appear safe, but confirmation requires larger and more rigorous studies. Authors concluded that strong evidence is now available on the safety of resistance exercise without an increase in risk of lymphedema for breast cancer patients. Buchan et al. (2016) compared the effect of progressive resistance- or aerobic-based exercise on breast cancer-related lymphedema extent and severity, as well as participants' muscular strength and endurance, aerobic fitness, body composition, upper-body function and QoL. Authors concluded that participating in resistance- or aerobic-based exercise did not change lymphedema status, but led to clinically relevant improvements in function and QoL, with findings suggesting that neither mode is superior with respect to lymphoedema impact. As such, personal preferences, survivorship concerns and functional needs are important and relevant considerations when prescribing exercise mode to those with secondary lymphedema. Overall, the consensus of managing lymphedema includes an appropriate diagnosis based on the patient's history and physical examination and a determination that there is consistent evidence to indicate that lymphedema can be reliably measured using circumferential measures or volume displacement. Complex decongestive therapy is suggested as the main method of conservative care for lymphedema and is a combination of therapies that includes manual lymphatic drainage (MLD), application of compression low stretch bandages, skin care, education, and exercise. Johansson et al. (2015) reported on the evidence-based or traditional treatment of cancer-related lymphedema. Authors concluded that with accumulating evidence and experience, it is time to consider if altering these treatment principles is needed. Based on accumulating evidence, authors suggest less emphasis on manual lymph drainage and more on early diagnosis, compression, weight control and exercise for improvement of strength and circulation. Bakar and Tuğral (2017) reviewed the current management strategies for lower extremity management of lymphedema after gynecologic cancer surgery. Studies indicated that the incidence of lower extremity lymphedema ranges between 2.4% and 41% after pelvic lymph node dissection in patients with gynecologic malignancies. Thus, management of lower extremity lymphedema in patients after gynecologic cancer surgery is an important issue. Complex decongestive therapy method is still the gold standard of lymphedema management.

Nelson (2017) summarizes the results of recent randomized controlled trials (RCTs) investigating the effect of resistance exercise in those with, or at risk for, BCRL. He also wanted to determine whether breast cancer survivors can perform RET at sufficient intensities to elicit gains in strength without causing BCRL flare-up or incidence. A total of 6 RCTs, involving 805 breast cancer survivors, met the inclusion criteria and corresponded to the aims of this review. The results of this review indicated that breast cancer survivors can perform RET at high-enough intensities to elicit strength gains without triggering changes to lymphedema status. There is strong evidence indicating that RET produces significant gains in muscular strength without provoking BCRL. Do et al. (2017) investigated the effects of a complex rehabilitation (CR) program and complex decongestive therapy (CDT) on edema status, physical function, and quality of life in patients with unilateral lower-limb lymphedema after gynecologic cancer surgery. CR comprised of stretching, strengthening, and aerobic exercises was performed for 40min, five times a week for 4weeks. Intensive CDT was administered by a physical therapist during weeks 0-2 and by the patients themselves during weeks 2-4. Results demonstrated that the edema status, fatigue, pain, and GCLQ-K scores were significantly improved in both groups after the 4-week intervention. Physical function and fatigue and the 30-s chair stand test and quadriceps muscle strength were significantly improved in the CRCDT group compared with the CDT alone group. Authors concluded that CR improves physical function, fatigue, and muscular strength without increasing edema status in patients with unilateral lower-limb lymphedema after gynecologic cancer surgery. Yeung et al.

(2018) conducted a systematic review and meta-analysis on aquatic therapy compared to other lymphedema interventions. Four RCTs of moderate quality were included. There was moderate level evidence of no significant short-term differences in lymphedema status (relative volume) between patients receiving aquatic lymphatic therapy compared to land based standard care. There was low level evidence that no significant difference between aquatic lymphatic therapy and standard care for improving upper limb physical function. Authors conclude that current evidence indicates no significant benefit of aquatic lymphatic therapy over standard land-based care for treatment of lymphedema. Further research is needed to strengthen the evidence. Baumann et al. (2018) assessed the effect of different types of exercise on breast cancer-related lymphedema (BCRL) in order to understand the role of exercise in this patient group. Eleven randomized controlled trials that included 458 women with breast cancer in aftercare were included. The different types of exercise consisted of aqua lymph training, swimming, resistance exercise, yoga, aerobic, and gravity-resistive exercise. Four of the studies measured a significant reduction in BCRL status based on arm volume and seven studies reported significant subjective improvements. No study showed adverse effects of exercise on BCRL. Authors concluded that the evidence indicates that exercise can improve subjective and objective parameters in BCRL patients, with dynamic, moderate, and high-frequency exercise appearing to provide the most positive effects. Hasenoehrl et al. (2020) performed a systematic review analyzing resistance exercise (RE) intervention trials in breast cancer survivors (BCS) regarding their effect on breast cancer-related lymphedema (BCRL) status. Authors concluded that RE seems to be a safe exercise intervention for BCS and not to be harmful concerning the risk of lymphedema. Lymphedema assessment methods that allow for a qualitative analysis of arm tissue composition should be favored. At the current time breast cancer related lymphedema is incurable but well manageable by a number of physical therapy modalities, especially complete decongestive therapy (CDT). One of the encouraging treatment methods is resistance exercise.

#### Measurement of Lymphedema

Hidding et al. (2016) attempted to provide best evidence of which measurement instruments are most appropriate in measuring lymphedema in its different stages. Authors concluded that measurement instruments with evidence for good reliability and validity are Bioelectrical Impedance Spectroscopy (BIS), water volumetry, tape measurement and perometry, where BIS can detect alterations in extracellular fluid in stage 1 lymphedema and the other measurement instruments alterations in volume starting from stage 2. In research water volumetry is indicated as reference test for measuring lymphedema in upper extremities. Limitations included the following: no uniform definition of lymphedema was available and a gold standard as reference test was lacking. Items concerning risk of bias were study design, patient selection, description of lymphedema, blinding of test outcomes and number of included patients.

## Coding/Billing Information

**Note:** 1) This list of codes may not be all-inclusive.

2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

**Considered Medically Necessary when criteria in the applicable policy statements listed above are met:**

CPT®*	Description
97140	Manual therapy techniques (eg, mobilization/manipulation, manual lymphatic drainage, manual traction), 1 or more regions, each 15 minutes

HCPCS Codes	Description
S8950	Complex lymphedema therapy, each 15 minutes

\*Current Procedural Terminology (CPT®) ©2020 American Medical Association: Chicago, IL.

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