<b>Clinical Practice Guideline:</b>	Lymphedema
Date of Implementation:	October 18, 2012
Product:	Specialty
GUIDELINES	
Medically Necessary	
	SH) considers complex lymphedema therapy (complete necessary for the treatment of intractable lymphedema net:
	reasonable course of conservative medical management ises, limb elevation, and compression garments.
• The lymphedema is directlimb.	ctly responsible for impaired functioning in the affected
• The complex lymphedem appropriate healthcare pro-	ha therapy is prescribed by or under the supervision of an ovider.
Not Medically Necessary	
· ·	evice use as part of complex lymphedema therapy is
considered not medically necessa	
Considered Medically Necessary	y when criteria in the applicable policy statements listed

<b>CPT<sup>®</sup>Code</b>	CPT <sup>®</sup> Code Description
97140	Manual therapy techniques (e.g., mobilization/manipulation, manual
	lymphatic drainage, manual traction), 1 or more regions, each 15 minutes
97535	Self-care/home management training (e.g., activities of daily living
	(ADL) and compensatory training, meal preparation, safety procedures,
	and instructions in use of assistive technology devices/adaptive
	equipment) direct one-on-one contact, each 15 minutes
29581	Application of multi-layer compression system; leg (below knee),
	including ankle and foot
25984	Application of multi-layer compression system; upper arm, forearm,
	hand, and fingers

HCPCS Code	HCPCS Code Description
S8430	Padding for compression bandage, roll
S8431	Compression bandage, roll
S8950	Complex lymphedema therapy, each 15 minutes

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2 Multi-layered, sustained, graduated, high compression bandage systems (CPT code 29581-

3 Application of multi-layer compression system; leg (below knee), including ankle and foot

and CPT code 29584 - Application of multi-layer compression system; upper arm, forearm,
hand, and fingers) are used primarily to treat lymphedema and venous or stasis ulcers. A
number of graduated, high-compression bandage systems products have been developed,

7 including Profore<sup>®</sup>, Dyna-Flex<sup>®</sup>, Surepress<sup>®</sup>, Setopress<sup>®</sup>, and other similar product 8 systems.

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10 Providers should note that the treatment of lymphedema with the application of high compression bandage systems continues to be non-covered by Medicare. However, a brief 11 period, i.e., three or fewer sessions if no new specific issues are identified, of patient and/or 12 caregiver education for home management of lymphedema with compression wrap 13 applications may be medically necessary and reimbursable. Medical necessity for the 14 education must be clearly indicated in the patient's record and must meet the code 15 descriptor requirements for CPT 97535, supporting home management training. S8430 -16 padding for compression bandage, roll and S8431 – compression bandage, roll may be 17 appropriate and allowable per health plan benefit. 18

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#### 20 **DESCRIPTION**

Complex lymphedema therapy (CLT) is a non-invasive treatment for lymphedema with the 21 aim to reduce and control the amount of swelling in the affected limb and restore function. 22 Complex lymphedema therapy (CLT) is a noninvasive treatment that is a considered a 23 24 standard of care for lymphedema. This method has also been referred to as complete decongestive physiotherapy (CDP), and complex decongestive therapy (CDT). The 25 treatment aim is to reduce and control the amount of swelling in the affected limb and 26 restore function. The objective of the technique is to redirect and enhance the flow of lymph 27 28 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 29 Boris, 2002; MacDonald et al., 2003). The typical CLT program consists of two phases of 30 treatment: a treatment phase and a maintenance phase. Phase I, the treatment phase, usually 31 last 2 to 4 weeks. This phase consists of four components (Lawenda et al., 2009): 32

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.

9 Most patients will be able to progress to a home-based, self-managed program after an 10 initial in-office program of 1–2 weeks. Instruction in self-management should begin in the 11 first week of therapy. Both patients and family are taught bandaging and exercise 12 techniques, as well as the essentials of skin and nail care. After the initial one- to two-week 13 program, patients should be re-evaluated to determine whether continued in-office therapy 14 is necessary or if treatment can be provided in the home.

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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).

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# 21 **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 fourweek period are generally considered not medically necessary.

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# 27 **Contraindications**

28 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
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34 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
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# 39 GENERAL BACKGROUND

- 40 Lymphedema is defined as the excessive and persistent accumulation of protein rich fluid 41 that collects in the interstitial spaces, due to an inefficiency of the lymphatic system (Szuba
- 42 et al., 2002; Leal et al., 2009). Lymphedema occurs primarily as a result of malformation,

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underdevelopment, or acquired disruption of the lymphatic circulation (Szuba et al., 2002). 1 Primary lymphedema is due to congenital defects of the lymphatic system, which can affect 2 from one to as many as four limbs or other parts of the body and is considered rare (National 3 Lymphedema Network, 2011). Secondary lymphedema is acquired and is due to an 4 obstruction or interruption in the lymphatic circulation. Secondary lymphedema can 5 develop as a result of surgery, radiation, infection or trauma. It is a common treatment-6 related side effect experienced by cancer patients. Patients that undergo surgery for breast 7 cancer that includes node dissection or axillary radiation therapy are at high risk of 8 developing lymphedema. 9

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11 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 12 of Lymphedema is recognizing a Stage 0 in patients, which refers to a latent or sub-clinical 13 condition where swelling is not evident despite impaired lymph circulation. Patients often 14 report a feeling of heaviness in the limb; however, many patients are asymptomatic in the 15 latency stage. Stage 0 may be present for months or years prior to a patient exhibiting signs 16 and symptoms of edema. Stage I lymphedema is referred to as spontaneously reversible 17 lymphedema (Lawenda et al., 2009; Bicego et al., 2006) and typically involves pitting 18 edema, an increase in limb girth (usually upper extremity), and heaviness. Stage II is also 19 20 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 21 beginning of hardening of the limbs and increased girth of extremity and is often found in 22 Stage II (Bicego et al., 2006). Stage III is the most advanced stage and is often referred to 23 as lymphostatic elephantiasis. During Stage III the swelling is irreversible with tissue being 24 fibrotic and unresponsive including patients who present with very large limb(s) size. It is 25 associated with a significant increase in the severity of the fibrotic response, tissue volume, 26 and other skin changes such as papillomas, cysts, fistulas, and hyperkeratosis (Lawenda et 27 al., 2009; Zuther, 2005). With regards to Stage 0, the literature is insufficient to conclude 28 that the use of CDT is either clinically effective or ineffective in the treatment of subclinical 29 or latent stage of breast cancer related lymphedema. 30

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The best practice or gold standard for lymphedema treatment is considered CDT, 32 33 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 34 (MLD), followed by bandaging/compression, education, and exercise. The goal of CDT is 35 to reduce and control the amount of swelling in the affected limb and restore function. 36 A treatment option that may be used to manage secondary lymphedema is intermittent 37 pneumatic compressions (IPC) (vasopneumatic compression) which is often added to 38 39 CDT. However, evidence does not support the addition of IPC to CDT or within any treatment plan. Low-level laser therapy (LLLT) is another treatment option that has 40 been studied as a treatment when used in conjunction with other standard lymphedema 41 treatments. However, low-level laser is currently considered experimental, investigational 42

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and/or unproven. Exercise demonstrates improvements in function and quality of life (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.

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#### 5 EVIDENCE REVIEW

Lymphedema is a common sequela of cancer or its treatment that affects the lymphatic 6 transport system that results in failure of lymph node drainage. Secondary lymphedema is 7 often a debilitating, chronic, progressive condition that commonly occurs after treatment 8 of breast cancer. A number of health professional and patient instigated conservative 9 therapies have been developed to help treat this condition. A systematic review 10 conducted by Moseley et al. (2007) reviewed the common conservative therapies used 11 for management of secondary arm lymphedema as follows: complex physical 12 therapy, manual lymphatic drainage, pneumatic pumps, oral pharmaceuticals, low level 13 laser therapy, compression bandaging and garments, limb exercises and limb 14 elevation. This study found that the more intensive and health care professional driven 15 therapies, such as complex physical therapy (skin and nail care, manual lymphatic 16 drainage, a multilayer compression bandage and therapeutic exercises), manual lymphatic 17 drainage, pneumatic pump and laser level light therapy generally yielded the greater 18 volume reductions, compared to self-instigated therapies such as compression garment 19 20 wear, exercises and limb elevation. These self-care methods showed reductions, however in lesser volumes. All conservative therapies reviewed in this study produced 21 improvements in subjective arm symptoms and OoL issues, where these were measured. 22

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Stout et al. (2008) completed a study on Stage 0 lymphedema. They used infrared 24 optoelectronic technology to identify those at risk for edema based on volume 25 measurements. This technology allows for changes to be noted before they are actually 26 visible to the eye. When these changes are noted, treatment initiated immediately may 27 prevent the development of further stages of lymphedema. However, there is no standard 28 for the treatment of early-stage, subclinical lymphedema. When the diagnosis of breast 29 cancer related lymphedema is delayed, therapeutic management requires intensive 30 decongestive therapy and life-long maintenance. This study suggested that an early 31 intervention protocol with 20- to 30-mm Hg compression garments, significantly reduced 32 33 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 34 is warranted to confirm the long-term clinical and cost effectiveness of this early 35 intervention model compared with a traditional model in treating breast cancer related 36 37 lymphedema.

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# 39 <u>Complete Decongestive Therapy (CDT), Manual Lymphatic Drainage (MLD), and</u> 40 <u>Compression Methods</u>

- 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)
- breast cancer was reviewed by Mondry et al. (2004). Patients completed two to four (2

weeks (median, 2 weeks) of treatment; including skin and nail care, manual 1 lymphatic drainage, a multilayer compression bandage and therapeutic exercises. Edema 2 of the affected limb was reassessed on a weekly basis. Authors concluded that decreasing 3 girth correlated significantly with decreasing visual analogue scale scores for pain, but 4 not with increasing OoL. Data gathered showed median girth reduced 1.5 cm and median 5 volume reduced 138mL. This study concluded that compliance with the treatment regimen 6 at home decreased with duration of the program and girth reductions contributed to less 7 pain. Increased frequency of treatment sessions provides marked improvement in girth, 8 volume, and weight but resulted in poorer compliance. Longer latency more 9 successfully reduces girth, volume, and pain and increases QoL. Pain and QoL are 10 11 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 12 drainage to compression therapy for managing breast cancer-related lymphedema. The 13 authors of this study compared the reduction in arm lymphedema volume achieved from 14 manual lymph drainage massage in combination with multi-layered compression 15 bandaging to that achieved by compression bandaging alone. Treatment group one 16 received manual lymph drainage (MLD)/compress ion bandaging (CB). This group 17 received 45 minutes of daily MLD and CB, Monday-Friday for four (4) weeks. The second 18 treatment group received short stretch bandaging, Monday-Friday for four (4) weeks. 19 20 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 21 compression bandaging alone groups. No significant differences existed between 22 groups (McNeely et al., 2004). 23

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Koul et al. (2007) assessed the results of combined decongestive therapy and manual 25 lymphatic drainage in patients with breast cancer-related lymphedema over a two-year 26 period. This study was a non-randomized clinical trial that reviewed data from 250 patients 27 with a final analysis reviewed from 138 patients. The pre- and post-treatment volumetric 28 measurements were compared and correlated with age, body mass index, and type of 29 surgery, chemotherapy, and radiotherapy. One group was treated with all four (4) parts of 30 combined decongestive therapy for one (1) hour daily for up to several weeks, depending 31 on the severity and response. Combined decongestive therapy consisted of manual 32 33 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-34 made garments to be worn daily while awake and removed at bedtime. Self-lymph drainage 35 at least once daily was also recommended. A second treatment group received MLD 36 alone. They were also fitted for custom compression garments. Self-lymph drainage was 37 also recommended. A third treatment group received one hour of home instruction and 38 39 counseling, including simple self-drainage techniques, skin care, and exercise. They also received custom compression garments. Results noted a significant reduction in arm 40 volumes at one (1) year after the beginning of treatment with some or all components of 41 combined decongestive therapy in patients with lymphedema after breast cancer treatment. 42

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Patients with moderate to severe lymphedema had a maximal response after combined 1 decongestive therapy, and patients enrolled in the home program had mild lymphedema 2 and less dramatic responses to treatment. Authors concluded that combined 3 decongestive therapy and manual lymphatic drainage with exercises were associated with 4 a significant reduction in the lymphedema volume in all groups assessed. Long-term 5 management of breast cancer-related lymphedema after intensive decongestive therapy 6 was studied by Vignes et al. (2007). The authors' aim was to describe the effect of the 7 maintenance therapy on lymphedema volume reduction and to analyze the impact of the 8 different components of treatment in women with upper limb lymphedema after breast 9 cancer treatment. The treatment consisted of an intensive phase of CDT, including manual 10 lymph drainage (30 minutes, five [5] times a week), low stretch compression bandaging 11 (24 hours daily), exercises after bandages were applied to enhance lymphatic flow from 12 peripheral to central compartments and skin care. Maintenance therapy consisted 13 of education (3 bandages per week). Authors concluded that bandaging and elastic 14 sleeves are a key component to maintenance therapy after intensive CDT. 15

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A systematic review was conducted by Karki et al. (2009) on the effects and harms of 17 physiotherapy methods of lymphedema therapy in breast cancer patients. Fourteen 18 randomized controlled studies were included, two of which had moderate risk of bias and 19 20 the remainder had high risk. There was moderate evidence that compression bandages alone decreased lymphedema, and that pneumatic pumps had no effect on 21 lymphedema compared to no treatment. With the remainder of the studies that had high 22 risk of bias, the interventions and comparisons varied across all trials. This review found 23 moderate evidence to support that compression bandages decreased lymphedema. 24 There was no evidence regarding volume reduction outcomes in any other body part 25 except the upper limb. Evidence on other physiotherapy methods and combinations is 26 limited due to poor quality of the studies. Devoogdt et al. (2010) conducted a systematic 27 review of combined physical therapy, intermittent compression and arm elevation for 28 treatment of lymphedema secondary to axillary dissection for breast cancer. The review 29 included ten randomized controlled trials and non-randomized, experimental trials. The 30 review found that combined physical therapy can be considered as an effective treatment 31 modality for treatment of lymphedema; however, the effectiveness of its different 32 33 components remains uncertain. Szolnoky et al. (2009) compared manual lymphatic drainage with manual lymphatic drainage plus intermittent pneumatic 34 compression for treatment of unilateral arm lymphedema in 27 women previously 35 treated for breast cancer. One treatment group received complex decongestive 36 physiotherapy (CDP), which included manual lymph drainage (MLD) using the Vodder 37 technique. Treatment sessions were for 60 minutes per day for 10 consecutive business 38 39 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 40 complex decongestive physiotherapy plus intermittent pneumatic compression 41 (CDP+IPC). This included the same MLD using the Vodder technique for 30 minutes 42

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per day for 10 days, followed by 30 minutes of IPC with a Lympha Mat device at a pressure 1 of 50 mmHg. Patient also received skin care, bandaging, and exercise. Each treatment 2 method was effective in reducing limb size, but the combination treatment of 3 CDP+IPC showed statistically significant greater reductions in limb size when compared 4 to CDP alone, with no negative side effects noted. No other statistically significant changes 5 were noted in the patients' subjective reports with either treatment method at any time. 6 7 A technology assessment requested by Centers for Medicare and Medicaid Services (CMS) 8 was conducted by McMaster University Evidence-based Practice Center for the Agency 9 for Healthcare Research and Quality (AHRQ) (Oremus et al., 2010) diagnosis and 10 treatment of secondary lymphedema. The review included randomized controlled trials or 11 observation studies with comparison groups (e.g., cohort, case control). The assessment 12

- 13 concluded the following:
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- 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 21 differences between the effects of complex decongestive physiotherapy with and without 22 23 active resistive exercise for the treatment of patients with breast cancer-related lymphedema. Treatment group one received CDT (manual lymphatic 24 drainage, compression therapy, and exercise, including resistance training) five (5) times 25 a week for two weeks followed by self-administered treatment for another six weeks. The 26 control group received the CDT without the resistance training added to the exercise 27 program. Authors concluded that active resistive exercise with CDT did not create 28 additional swelling and assisted with reduction of arm volume. QoL was also improved 29 for this group. The National Lymphedema Network (NLN) published a position statement 30 regarding treatment of lymphedema (NLN, 2011). Included in the document were the 31 following statements regarding CDT: 32

- 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.

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• 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 2020, the International Society of Lymphology (ISL) published an updated consensus
document regarding the diagnosis and treatment of peripheral lymphedema (ISL, 2020).
The document makes the following notes regarding lymphedema treatment:

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.

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Hwang et al. (2013) completed a systematic review and meta-analysis on the effects of 18 MLD on breast cancer-related lymphedema. They investigated whether manual lymphatic 19 drainage (MLD) could prevent or manage limb edema in women after breast-cancer 20 surgery. In total, 10 RCTs with 566 patients were identified. Authors concluded that 21 the current evidence from RCTs does not support the use of MLD in preventing or treating 22 lymphedema. However, clinical and statistical inconsistencies between the various 23 studies confounded our evaluation of the effect of MLD on breast-cancer-related 24 lymphedema. Lasinski (2013) summarized the evidence on the management of lymphedema 25 and provided recommendations. CDT is effective in reducing lymphedema, although the 26 contribution of each individual complete decongestive therapy component has not been 27 determined. In general, levels of evidence for complete decongestive therapy are 28 moderate. Fu et al. (2014) aimed to provide healthcare professionals with evidence-29 based clinical practice guidelines for lymphedema treatment and management through a 30 systematic review. Findings of the systematic review support complete decongestive therapy, 31 compression bandages, and compression garments with highest evidence for best clinical 32 practice. Weight management, full-body exercise, education, prevention, and early 33 intervention protocols are likely to be effective for clinical practice. 34

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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

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lymphoedema in patients with malignancies. Authors concluded that few studies have 1 evaluated the clinical effectiveness and potential side effects of treatments for lower limb 2 lymphoedema. Moreover, symptoms and quality-of-life assessments were inconsistently 3 reported. All included studies report lower limb volume reduction after treatment, which 4 includes complex decongestion therapy, graded compression stockings and lymphovenous 5 microsurgical shunts. Adequately powered randomized controlled trials of these 6 interventions are recommended. Ezzo et al. (2015) assessed the efficacy and safety of MLD 7 in treating BCRL. Six trials were included. Authors concluded that MLD is safe and 8 may offer additional benefit to compression bandaging for swelling reduction. 9 Compared to individuals with moderate-to-severe BCRL, those with mild-to-10 11 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 12 confirmed by randomized data. In trials where MLD and sleeve were compared with a non-13 MLD treatment and sleeve, volumetric outcomes were inconsistent within the same trial. 14 Findings were contradictory for function (range of motion), and inconclusive for quality of 15 life. For symptoms such as pain and heaviness, 60% to 80% of participants reported feeling 16 better regardless of which treatment they received. One-year follow-up suggests that once 17 swelling had been reduced, participants were likely to keep their swelling down if they 18 continued to use a custom-made sleeve. Finnane et al. (2015) sought to summarize efficacy 19 20 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 21 overall, has been poor. Reviews consistently concluded that complex physical therapy is 22 effective at reducing limb volume. Volume reductions were also reported after the use of 23 compression garments, pumps, and manual lymphatic drainage. However, greatest 24 improvements were reported when these treatments formed a combined treatment 25 program. Large, well-designed, evaluated, and reported randomized, controlled trials are 26 needed to evaluate and compare treatments. 27

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Elastic therapeutic taping (e.g., Kinesio taping) has been proposed as a treatment 29 intervention for lymphedema, given its properties and hypothesized mechanism to lift the 30 skin away from the adjacent muscle and allow intercellular fluid to flow more freely. For 31 example, lymph will move more easily out of lymph channels and into larger lymph ducts 32 33 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-34 surgical lymphedema. They were randomized into two (2) groups. One group received 35 taping and the other received standard physiotherapy (lymphatic drainage). Both methods 36 reduced edema significantly pre- and post-treatment (after 10 days); however, the 37 application of the KT produced a significantly faster reduction of edema compared to 38 39 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-40 related lymphedema. The pilot study looked at standard DLT combined with pneumatic 41 compression (PC) or modified DLT using KT combined with PC; both types of treatments 42

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resulted in reduced girth measurements of the upper extremity and other outcomes in forty-1 one (41) patients with breast-cancer-related lymphedema. Results demonstrated no 2 significant differences between the two types of treatments. Thus, use of KT could replace 3 the bandage typically used in DLT. Morris et al. (2013) reported on a systematic review 4 with the purpose of this study was to investigate the effect of Kinesio Tex tape (KTT) from 5 randomized controlled trials (RCTs) in the management of clinical conditions. The review 6 included eight RCTs: six included patients with musculoskeletal conditions; one with 7 breast-cancer-related lymphedema; and, one included stroke patients with muscle 8 spasticity. Six studies included a sham or usual care tape/bandage group. The review found 9 limited to moderate evidence that KTT is no more clinically effective than sham or usual 10 11 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 12 (2013) reported on a systematic review that assessed the effects of therapeutic Kinesio 13 Taping (KT) on pain and disability in participants suffering from musculoskeletal, 14 neurological and lymphatic pathologies. Twelve met inclusion criteria. The final 12 articles 15 were subdivided according to the basic pathological disorders: musculoskeletal (N=9) (four 16 randomized, controlled trials (RCT), three single-blinded RCT, one cross-over trial and 17 one case-control study); neurological (N=1) (RCT); and, lymphatic (N=2) (RCT). 18 Regarding lymphatic disorders, inconclusive evidence was reported. The authors 19 20 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 21 of movement disorders within a wide range of pathologic disabilities. Gatt et al. (2017) 22 aimed to determine the effectiveness and safety of kinesiotaping (KT) in the management 23 of cancer-related lymphoedema (CRL) compared to compression bandaging or hosiery. 24 Five studies were included in the meta-analysis of the primary outcome limb volume (n =25 203, KT n = 91, compression n = 112). No significant difference existed between the 26 interventions. An increased risk of skin complications with KT was reported in five studies 27 affecting between 10% and 21% of patients. Where lymphoedema-related symptoms 28 were reported KT was found to be superior to compression. Paradoxically, 29 patients receiving bandaging reported a higher QoL. Thus, authors concluded that 30 KT was not found to be more comfortable than bandaging and should only be used with 31 caution where bandaging cannot be used. 32

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Torres-Lacomba et al. (2020) compared the effects of four types of bandages and kinesio-34 tape and determine which one is the most effective in women with unilateral breast cancer-35 related lymphoedema. A total of 150 women presenting breast-cancer-related 36 lymphoedema were randomized into five groups (n = 30). All women received an intensive 37 phase of complex decongestive physiotherapy including manual lymphatic drainage, 38 39 pneumatic compression therapy, therapeutic education, active therapeutic exercise and bandaging. The only difference between the groups was the bandage or tape applied 40 (multilayer; simplified multilayer; cohesive; adhesive; kinesio-tape). The main outcome 41 was percentage excess volume change. Other outcomes measured were heaviness and 42

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tightness symptoms, and bandage or tape perceived comfort. Data were collected at 1 baseline and finishing interventions. This study showed significant differences between the 2 bandage groups in absolute value of excess volume. The five groups exhibited a significant 3 decrease in symptoms after interventions, with no differences between groups. In addition, 4 kinesio-tape was perceived as the most comfortable by women and multilayer as the most 5 uncomfortable (P < 0.001). The most effective were the simplified multilayer and the 6 cohesive bandages. The bandages/tape with the least difference were kinesio- and adhesive 7 bandage. 8

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Zasadzka et al. (2018) compared the effectiveness of multi-layer compression 10 bandaging (MCB) and CDT for treating lymphedema in elderly patients. One 11 hundred three patients (85 women and 18 men) aged  $\geq 60$  years, with unilateral lower 12 limb lymphedema. The subjects were divided into two groups: 50 treated with CDT 13 and 53 with MCB. Pre- and post-treatment BMI, and average and maximum 14 circumference of the edematous extremities were analyzed. Results noted a reduction 15 in swelling in both groups was achieved after 15 interventions. Both therapies 16 demonstrated similar efficacy in reducing limb volume and circumference, but MCB 17 showed greater efficacy in reducing the maximum circumference. Authors concluded 18 that compression bandaging is a vital component of CDT. Maximum lymphedema 19 20 reduction during therapy and maintaining its effect cannot be achieved without it. Sezgin Ozcan et al. (2018) evaluated the effects of CDT on upper extremity 21 functions, the severity of pain, and quality of life. A total of 37 women with breast 22 cancer-related lymphedema (BCRL) [age,  $53.6 \pm 11.2$  (28-72)] were included in this 23 study. All patients underwent CDT-phase 1 program, including meticulous skin care, 24 manual lymphatic drainage, remedial exercises, and compression bandages. The 25 mean of the posttreatment volume of the affected limb was lower compared to 26 pretreatment volume. A statistically significant reduction in pain and heaviness VAS 27 scores and improvement of shoulder mobility among upper extremities with 28 lymphedema (p < 0.001) was noted after CDT. The mean of posttreatment DASH 29 score was lower, and all subgroups of the SF-36 parameters were increased after the 30 CDT application. Also, being under 65 years old, having a body mass index above 31 30 and short duration of lymphedema were found to be related to greater 32 33 improvement in upper extremity functions. Authors concluded that CDT provides enhancement of upper extremity functions and quality of life in patients with BCRL. 34 35

Michopoulos et al. (2020) evaluated the effectiveness and safety of CDT of phase I in the Greek population with lymphedema. CDT was implemented in all patients for 20 sessions in a four-week treatment period. The edema's (excess volume (EV) and percent of excess volume (PEV)) measurements were carried out four times in the treatment period, whereas the percent reduction of excess volume (PREV) was calculated at the end of phase I. Every infection, trauma of skin, and pain of limb during the treatment was also recorded. Onehundred five patients with lymphedema were enrolled, of whom 31.4% had upper limb

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lymphedema and 68.6% had lower limb lymphedema. A significant reduction between the 1 pre-treatment and post-treatment values of EV and PEV was found for both upper and 2 lower limb lymphedema. For patients with upper limb lymphedema, the average PREV 3 was 66.5%, whereas for patients with lower limb lymphedema, a 71.5% median value was 4 measured. No side effects from the treatment were recorded during CDT. Authors 5 concluded that the proper treatment of the CDT phase I ensures safety and a great reduction 6 in edema in patients with lymphedema that predispose the success of phase II of CDT. 7

8

Watanabe et al. (2019) authored an article on the development and themes of diagnostic 9 and treatment procedures for secondary leg lymphedema in patients with gynecologic 10 cancers. They note that for the treatment of lymphedema, complex decongestive 11 physiotherapy (CDP) including manual lymphatic drainage (MLD), compression therapy, 12 exercise and skin care, are generally performed. In recent years, CDP has often required 13 effective multi-layer lymph edema bandaging (MLLB) or advanced pneumatic 14 compression devices (APCDs). If CDP is not effective, microsurgical procedures can be 15 performed. They conclude that the most important concern is the prevention of secondary 16 lymphedema, which is achieved through approaches such as skin care, weight control, 17 gentle limb exercises, avoiding sun and heat, and elevation of the affected leg. 18

19

20 In accordance with the most recent Consensus Document of the International Society of Lymphology (2020), CDT should include two phases: 1. Phase I: characterized by skincare, 21 manual lymphatic drainage (MLD), with or without deeper techniques including muscle 22 pumping exercises or hydraulic pressotherapy, followed by multilayer compression 23 bandage, aiming at improving lymphedema volume; 2. Phase II: characterized by skincare 24 and compression garments wearing, including lowstretch elastic stocking or sleeve, aiming 25 at avoiding complications and conserving the results obtained in Phase I. 26

27

Thompson et al. (2021) evaluated the effectiveness of MLD for those at-risk of or living 28 with lymphedema. Seventeen studies with a total of 867 female and two male participants 29 were included. Only studies examining breast cancer-related lymphedema were identified. 30 Some studies reported positive effects of MLD on volume reduction, quality of life and 31 symptom-related outcomes compared with other treatments, while other studies reported 32 33 no additional benefit of MLD as a component of complex decongestive therapy. In patients at-risk, MLD was reported to reduce incidence of lymphedema in some studies, while 34 others reported no such benefits. Authors concluded that reviewed articles reported 35 conflicting findings and were often limited by methodological issues. They suggest the 36 need for further experimental studies on the effectiveness of MLD in lymphedema. There 37 is some evidence that MLD in early stages following breast cancer surgery may help 38 39 prevent progression to clinical lymphedema. MLD may also provide additional benefits in volume reduction for mild lymphedema. However, in moderate to severe lymphedema, 40 MLD may not provide additional benefit when combined with complex decongestive 41 therapy. 42

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Kalemikerakis et al. (2021) authored an article on the diagnosis and management of cancer-1 related lymphedema. They note that early diagnosis and treatment of lymphedema is 2 related with better therapeutic outcomes. Women with breast cancer confront more 3 problems with lymphedema than with mastectomy. Its effect on patients' quality of life is 4 relevant to changes in body image, self-esteem, feelings of weakness, fear and anxiety 5 about disease progression, financial costs, and reduced limb function. Relative to 6 conservative management, authors summarize that CDT remains the treatment of choice 7 and in combination with exercise, weight control programs and self-care training seems to 8 significantly improve patients' quality of life. Forner-Cordero et al. (2021) assessed 9 whether treatment with intermittent pneumatic compression plus multilayer bandages is 10 11 not inferior to classical trimodal therapy with manual lymphatic drainage in the decongestive lymphedema treatment. 194 lymphedema patients, stage II-III with excess 12 volume > 10% were stratified within upper and lower limb and then randomized to one of 13 the three treatment groups. Baseline characteristics were comparable between the groups. 14 For interventions all patients were prescribed 20 sessions of the following regimens: Group 15 A (control group): manual lymphatic drainage + Intermittent Pneumatic Compression + 16 Bandages; Group B: pneumatic lymphatic drainage + Intermittent Pneumatic Compression 17 + Bandages; and Group C: only Intermittent Pneumatic Compression + Bandages. The 18 outcome was the percentage reduction in excess volume (PREV). Results demonstrated 19 20 that all patients improved after treatment. Global mean of PREV was 63.9%, without significant differences between the groups. Most frequent adverse events were discomfort 21 and lymphangitis, without differences between groups. A greater baseline edema, an upper-22 limb lymphedema and a history of dermatolymphangitis were independent predictive 23 factors of worse response in the multivariate analysis. Authors concluded that decongestive 24 lymphatic therapy performed only with intermittent pneumatic compression plus bandages 25 is not inferior to the traditional trimodal therapy with manual lymphatic drainage. This 26 approach did not increase adverse events. 27

28

Corum et al. (2021) compared the effects of CDT accompanied by resistance exercises on 29 extremity circumference, lymphedema volume, grip strength, functional status, and quality 30 of life in the treatment of breast cancer-related lymphedema (BCRL) in patients with and 31 without pain. Fifty patients with unilateral BCRL were divided into groups: with pain 32 33 (Group 1, n = 25) and without pain (Group 2, n = 25). Thirty minutes of manual lymphatic drainage and multilayered short-stretch bandaging were applied to all patients five times a 34 week for 4 weeks. In addition, all patients were informed about skin care and given a 35 supervised resistance exercise program throughout the treatment. During the 1-month 36 follow-up period, patients were asked to use low-tension elastic garments and to continue 37 their home exercise program. Differences in upper extremity circumference and volume; 38 39 grip strength; Quick Disabilities of the Arm, Shoulder, and Hand; and Functional Assessment of Cancer Therapy-Breast scores were evaluated at baseline, after treatment 40 (week 4), and at 1-month follow-up. Moreover, the pain intensity of patients in Group 1 41 was measured using the visual analog scale (VAS). Patients in both Group 1 and Group 2 42

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1 showed a statistical improvement in all outcome measures after treatment and at follow-up

2 (p < 0.05); however, no significant difference was observed between the groups (p > 0.05).

3 In Group 1, a statistically significant decrease was observed in the VAS score both at the

- end of treatment and at 1-month follow-up (p < 0.05). Authors concluded that combined 5 CDT and resistance exercises appear to be effective in BCRL patients both with and
- 6 without pain.
- 7

McNeely et al. (2022) examined the efficacy of nighttime compression as a self-8 management strategy for women with chronic breast cancer-related lymphedema. Authors 9 conducted a parallel 3-arm, multicenter, randomized trial. Women were recruited from 3 10 11 centers in Canada and randomized to group 1 (daytime compression garment alone [standard care]), group 2 (daytime compression garment plus nighttime compression 12 bandaging), or group 3 (daytime compression garment plus the use of a nighttime 13 compression system garment). The primary outcome was the change in excess arm volume 14 from the baseline to 12 weeks. Participants from all groups used a nighttime compression 15 system garment from weeks 13 to 24. One hundred twenty women were enrolled, 118 16 completed the randomized trial, and 114 completed the 24-week follow-up. The rates of 17 adherence to nighttime compression were  $95\% \pm 15\%$  and  $96\% \pm 11\%$  in the compression 18 bandaging and nighttime compression system groups, respectively. After the intervention, 19 20 the addition of nighttime compression was found to be superior to standard care for both absolute milliliter reductions (P = .006) and percentage reductions (P = .002) in excess arm 21 lymphedema volume. Significant within-group changes were seen for quality of life across 22 all groups; however, no between-group differences were found (P > .05). Authors 23 concluded that this study demonstrated a significant improvement in arm lymphedema 24 volume from the addition of nighttime compression whether through the application of 25 compression bandaging or through the use of a nighttime compression system garment. 26

27

De Vrieze et al. (2022) investigated the effect of fluoroscopy-guided manual lymphatic 28 drainage (MLD) versus traditional MLD or placebo MLD for the treatment of breast 29 cancer-related lymphoedema (BCRL) when added to decongestive lymphatic therapy 30 (DLT). All participants received standard DLT (education, skin care, compression therapy 31 and exercises). Participants were randomized to also receive fluoroscopy guided MLD 32 33 (n = 65), traditional MLD (n = 64) or placebo MLD (n = 65). Participants received 14 sessions of physiotherapy during the 3-week intensive phase and 17 sessions during the 34 6-month maintenance phase. Participants performed self-management on the other days. 35 All outcomes were measured: at baseline; after the intensive phase; after 1, 3 and 6 months 36 of maintenance phase; and after 6 months of follow-up. The primary outcomes were 37 reduction in excess volume of the arm/hand and accumulation of excess volume at the 38 39 shoulder/trunk, with the end of the intensive phase as the primary endpoint. Excess lymphoedema volume decreased after 3 weeks of intensive treatment in each group. The 40 effect of fluoroscopy guided MLD was very similar to traditional MLD and placebo MLD. 41

1 Authors concluded that in patients with chronic BCRL, MLD did not provide clinically 2 important additional benefit when added to other components of DLT.

3

Borman et al. (2022) evaluated the effects of CDT in patients with breast cancer-related 4 lymphedema (BCRL), in regard to volume reduction, functional status and OoL. Fifty 5 patients with unilateral BCRL were included. All patients received combined phase 1 CDT 6 including skincare, manual lymphatic drainage, multilayer bandaging and supervised 7 exercises, 5 times a week for 3 weeks, as a total of 15 sessions. Patients were assessed by 8 limb volumes and excess volumes. The functional disability was evaluated by quick 9 disability of arm, shoulder and hand questionnaire (Q-DASH). QoL was assessed by the 10 European Organization for Research and Treatment of Cancer Core Cancer Quality of Life 11 Questionnaire (EORTC QLQ-C30) and its breast-cancer-module (EORTC QLQ-BR23). 12 Fifty females with mean age of  $53.22 \pm 11.2$  years were included. The median duration of 13 lymphedema was 12 months. There were 22 patients in stage1, 26 in stage2 and 2 patients 14 in stage3. The mean baseline limb and excess volumes were significantly decreased at the 15 end of therapies. The Q-DASH and EORTC QLQ-C30 and BR23 scores were also 16 decreased significantly. The improvements in volumes were related negatively with the 17 duration of lymphedema, and the stage of lymphedema. Authors concluded that CDT in a 18 combined manner performed daily for 3 weeks, greatly reduces the volumes as well as 19 20 improves the disability and QoL, especially when performed earlier.

21

De Sire et al. (2022) completed a review to characterize the comprehensive management 22 of lymphedema, providing a broad overview of the potential therapy available in the 23 current literature. They conclude that a multidisciplinary treatment should be truly 24 integrated for lymphedema patients, and rehabilitation should be considered the 25 cornerstone of the multidisciplinary treatment not only for patients not suitable for surgical 26 interventions but also before and after surgical procedures. Rehabilitation should include 27 (CDT), which includes manual lymph drainage (MLD), skin care, specialized exercises, 28 compression garments and self-education. Rangon et al. (2022) investigated the immediate, 29 short-term, and long-term effects of complex physical therapy and multimodal approaches 30 on lymphedema secondary to breast cancer. Fourteen studies were identified for the 31 systematic review and 11 studies for the meta-analysis. The common outcomes involved 32 33 total volume, pain, and physical function of the upper limb. Complex physical therapy has shown a favorable tendency to control outcomes in the short- and long-term. The meta-34 analysis indicated a small effect for volume reduction and a moderate effect for short-term 35 pain reduction. Authors concluded that high-quality evidence suggests a more significant 36 effect of complex physical therapy on multimodal approaches to the control of the upper 37 limb total volume, substantiating the absence of changes in the current clinical practice in 38 39 the management of lymphedema secondary to breast cancer. Future research should aim to identify concrete effect of therapeutic modalities in the immediate-, short-, and long-term. 40

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Lin et al. (2022) analyzed the effectiveness of manual lymphatic drainage (MLD) in breast 1 cancer-related lymphedema (BCRL) patients in a systematic review and meta-analysis. In 2 total, 11 RCTs involving 1564 patients were included, in which 10 trials were deemed 3 viable for inclusion in the meta-analysis. Due to the effects of MLD for BCRL, statistically 4 significant improvements were found on the incidence of lymphedema and pain intensity. 5 Besides, the meta-analysis carried out implied that the effects that MLD had on volumetric 6 changes of lymphedema and quality of life, were not statistically significant. The current 7 evidence based on the RCTs shows that pain of BCRL patients undergoing MLD is 8 significantly improved, while our findings do not support the use of MLD in improving 9 volumetric of lymphedema and quality of life. Torgbenu et al. (2023) aimed to describe 10 11 and compare international guidelines on lymphedema diagnosis, assessment, and management. This systematic review of 1,564 articles and 159 web pages yielded 14 12 guidelines. All guidelines were from high-income countries. Ten focused exclusively on 13 lymphedema, and four on cancer. Most (n = 13) guidelines recommended an integrated 14 medical, psychological assessment, and physical examination, with a limb volume 15 measurement of >10% in the affected limb compared, confirming a lymphedema diagnosis. 16 Recommended management involved Complex Decongestive Therapy (CDT) followed by 17 self-management using skincare, self-lymphatic drainage massage, exercise, and 18 compression. 19

20

#### 21 Other Treatments

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

Carati et al. (2003) performed a double blind, placebo controlled randomized, single 23 crossover trial use of low-level laser therapy (LLLT) for a treatment option for patients 24 with post mastectomy lymphedema (PML). Participants received either one cycle or two 25 cycles of LLLT to the axillary region of their affected arm. The authors monitored for 26 reduction in affected limb volume, upper body extracellular tissue fluid distribution, dermal 27 tonometry and range of motion. The result yielded two cycles of LLLT improved 28 lymphedema; however, limb volume reduction was not immediate and was reported two 29 to three (2-3) months post-treatment (Carati et al., 2003). A study conducted by 30 Dirican et al. (2011) reviewed the authors' short-term experience with low-level laser 31 therapy in the treatment of breast-cancer related lymphedema. Treatment consisted of laser 32 33 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. 34 Two of the patients in the study also had sessions using an intermittent 35 compression device. Authors concluded that patients with breast cancer gain additional 36 benefits in the form of volume reduction from low level laser therapy when used in 37 conjunction with other standard treatments (Dirican et al., 2011). Further studies are needed 38 39 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 40 (BCRL). They concluded that moderate strength evidence supports LLLT in the 41 management of BCRL. The overall review of literature investigated conservative therapies 42

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for secondary arm lymphedema that can be divided into intensive treatments administered 1 by trained healthcare professionals and limb maintenance that are carried out by the patient. 2 Treatments that are predominantly administered by healthcare professionals, such as 3 CDT, MLD, and pneumatic pump therapy generally yielded the larger reduction in limb 4 volume. LLLT may be a potential treatment option, but more well-designed studies are 5 needed. Maintenance therapies generally carried out by the patient in a self-care 6 program (e.g., wearing compression garments, performing limb exercises, limb 7 elevation, and self-massage) yielded smaller limb reduction. 8 9

Kozanoglu et al. (2022) investigated the long-term effectiveness of combined intermittent 10 pneumatic compression (IPC) plus low-level laser therapy (LLLT) versus IPC therapy 11 alone in patients with postmastectomy upper limb lymphedema (PML). The patients were 12 allocated into two groups in this single-blinded, controlled clinical trial. Group I received 13 combined treatment with IPC plus LLLT (n = 21) and group II received only IPC (n = 21). 14 IPC treatment was given 5 sessions per week for 4 weeks (20 sessions). LLLT was also 15 performed 5 sessions per week for 4 weeks (20 sessions). Clinical evaluations were 16 performed before and after the treatment at the 3, 6, and 12-month follow-up visits. 17 According to within-group analysis, statistically significant improvements in the 18 circumference difference and grip strength were observed in both groups. Visual analog 19 20 scale values for arm pain and shoulder pain during motion were decreased only in group I. Authors concluded that interventions have positive effects on lymphedema, grip strength, 21 and pain. Long-term effects of combined therapy, especially on pain, are slightly superior 22 to the pneumatic compression alone. 23

24

Wang et al. (2022) analyzed the evidence from existing systematic reviews investigating 25 the effectiveness and safety of low-level laser therapy (LLLT) in patients with breast 26 cancer-related lymphedema (BCRL). Conflicting results regarding the effectiveness of 27 LLLT were presented by the overview of systematic reviews. The AMSTAR 2 showed that 28 the methodological quality of included systematic reviews was low or critically low quality 29 due to one or more critical weaknesses. The GRADE and GRADE-CEROual showed that 30 the evidence quality was low to very low for most outcomes. The updated systematic 31 review showed that LLLT may offer additional benefits as compared to compression 32 33 therapies (pneumatic compression or compression bandage), placebo laser, or no treatment for patients with BCRL. However, when compared to other types of active interventions, 34 LLLT did not improve outcomes significantly. None of the treatment-related adverse event 35 was reported. Many trials had a high or unclear risk of bias for two or more items, and this 36 updated systematic review showed low quality of evidence per outcome using GRADE 37 approach. Due to insufficient data and poor quality of evidence, there is uncertain evidence 38 39 to reach these conclusions that LLLT is superior to another active or negative intervention and is safe. More RCTs of high methodological quality, with large sample sizes and long-40 term follow-up, are needed to inform clinical guidelines and routine practice. 41

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Qiao et al. (2023) analyzed the efficacy of MLD for BCRL. A total of 457 patients were 1 included in the analysis. There was no significant difference in the amount of upper 2 extremity edema between the MLD treatment and control or no MLD groups. However, 3 when the treatment course was  $\geq 20$  sessions, there was a significant reduction in the upper 4 extremity volume. There was also a significant reduction in the upper extremity volume 5 when treatment duration was >2 weeks. Authors concluded that manual lymphatic drainage 6 treatment statistically did not reduce the upper extremity limb volume of BCRL, but upper 7 extremity volume was reduced at statistically significant levels when treatment number 8 were  $\geq 20$  sessions or the duration of treatment was  $\geq 2$  weeks. 9

10

## 11 **Exercise**

Kwan et al. (2011) conducted a systematic review of the contemporary literature to distill 12 the weight of the evidence and provide recommendations for exercise and lymphedema 13 care in breast cancer survivors. Seven studies were identified addressing resistance 14 exercise, seven studies on aerobic and resistance exercise, and five studies on other exercise 15 modalities. Studies concluded that slowly progressive exercise of varying modalities is not 16 associated with the development or exacerbation of breast cancer-related lymphedema and 17 can be safely pursued with proper supervision. Combined aerobic and resistance exercise 18 appear safe, but confirmation requires larger and more rigorous studies. Authors concluded 19 20 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 21 the effect of progressive resistance- or aerobic-based exercise on breast cancer-related 22 lymphedema extent and severity, as well as participants' muscular strength and endurance, 23 aerobic fitness, body composition, upper-body function and QoL. Authors concluded that 24 participating in resistance- or aerobic-based exercise did not change lymphedema status 25 but led to clinically relevant improvements in function and QoL, with findings suggesting 26 that neither mode is superior with respect to lymphoedema impact. As such, personal 27 preferences, survivorship concerns and functional needs are important and 28 relevant considerations when prescribing exercise mode to those with secondary 29 lymphedema. 30

31

Overall, the consensus of managing lymphedema includes an appropriate diagnosis based 32 33 on the patient's history and physical examination and a determination that there is consistent evidence to indicate that lymphedema can be reliably measured 34 using circumferential measures or volume displacement. Complex decongestive 35 therapy is suggested as the main method of conservative care for lymphedema and is a 36 combination of therapies that includes manual lymphatic drainage (MLD), application of 37 compression low stretch bandages, skin care, education, and exercise. Johansson et al. 38 39 (2015) reported on the evidence-based or traditional treatment of cancer-related lymphedema. Authors concluded that with accumulating evidence and experience, it is 40 time to consider if altering these treatment principles is needed. Based on accumulating 41 evidence, authors suggest less emphasis on manual lymph drainage and more on early 42

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diagnosis, compression, weight control and exercise for improvement of strength and 1 circulation. Bakar and Tuğral (2017) reviewed the current management strategies for lower 2 extremity management of lymphedema after gynecologic cancer surgery. Studies indicated 3 that the incidence of lower extremity lymphedema ranges between 2.4% and 41% after 4 pelvic lymph node dissection in patients with gynecologic malignancies. Thus, 5 management of lower extremity lymphedema in patients after gynecologic cancer surgery 6 is an important issue. Complex decongestive therapy method is still the gold standard of 7 lymphedema management. 8

9

Nelson (2017) summarizes the results of recent randomized controlled trials (RCTs) 10 11 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 12 intensities to elicit gains in strength without causing BCRL flare-up or incidence. A total 13 of 6 RCTs, involving 805 breast cancer survivors, met the inclusion criteria and 14 corresponded to the aims of this review. The results of this review indicated that breast 15 cancer survivors can perform RET at high-enough intensities to elicit strength gains 16 without triggering changes to lymphedema status. There is strong evidence indicating that 17 RET produces significant gains in muscular strength without provoking BCRL. Do et al. 18 (2017) investigated the effects of a complex rehabilitation (CR) program and complex 19 20 decongestive therapy (CDT) on edema status, physical function, and quality of life in patients with unilateral lower-limb lymphedema after gynecologic cancer surgery. CR 21 comprised of stretching, strengthening, and aerobic exercises was performed for 40min, 22 five times a week for 4weeks. Intensive CDT was administered by a physical therapist 23 during weeks 0-2 and by the patients themselves during weeks 2-4. Results demonstrated 24 that the edema status, fatigue, pain, and GCLQ-K scores were significantly improved in 25 both groups after the 4-week intervention. Physical function and fatigue and the 30-s chair 26 stand test and quadriceps muscle strength were significantly improved in the CRCDT 27 group compared with the CDT alone group. Authors concluded that CR improves physical 28 function, fatigue, and muscular strength without increasing edema status in patients with 29 unilateral lower-limb lymphedema after gynecologic cancer surgery. Yeung et al. (2018) 30 conducted a systematic review and meta-analysis on aquatic therapy compared to other 31 lymphedema interventions. Four RCTs of moderate quality were included. There was 32 33 moderate level evidence of no significant short-term differences in lymphedema status (relative volume) between patients receiving aquatic lymphatic therapy compared to land 34 based standard care. There was low level evidence that no significant difference between 35 aquatic lymphatic therapy and standard care for improving upper limb physical function. 36 Authors conclude that current evidence indicates no significant benefit of aquatic 37 lymphatic therapy over standard land-based care for treatment of lymphedema. Further 38 39 research is needed to strengthen the evidence.

40

Baumann et al. (2018) assessed the effect of different types of exercise on breast cancerrelated lymphedema (BCRL) in order to understand the role of exercise in this patient

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group. Eleven randomized controlled trials that included 458 women with breast cancer in 1 aftercare were included. The different types of exercise consisted of aqua lymph training, 2 swimming, resistance exercise, yoga, aerobic, and gravity-resistive exercise. Four of the 3 studies measured a significant reduction in BCRL status based on arm volume and seven 4 studies reported significant subjective improvements. No study showed adverse effects of 5 exercise on BCRL. Authors concluded that the evidence indicates that exercise can 6 improve subjective and objective parameters in BCRL patients, with dynamic, moderate, 7 and high-frequency exercise appearing to provide the most positive effects. Hasenoehrl et 8 al. (2020) performed a systematic review analyzing resistance exercise (RE) intervention 9 trials in breast cancer survivors (BCS) regarding their effect on breast cancer-related 10 11 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. 12 Lymphedema assessment methods that allow for a qualitative analysis of arm tissue 13 composition should be favored..At the current time breast cancer related lymphedema is 14 incurable but well manageable by a number of physical therapy modalities, especially 15 complete decongestive therapy (CDT). One of the encouraging treatment methods is 16 resistance exercise. 17

18

Kilbreath et al. (2020) investigated whether an exercise program reduced breast 19 20 lymphoedema symptoms compared to a non-exercise control group. This single-blinded randomized controlled trial was conducted in which women with stable breast 21 lymphoedema (n = 89) were randomized into an exercise (n = 41) or control (n = 47) group. 22 The intervention comprised a 12-week combined aerobic and resistance training program, 23 supervised weekly by an accredited exercise physiologist. All participants completed a 24 weekly symptoms diary and were assessed monthly to ensure that there was no 25 exacerbation of their lymphoedema. Changes in the breast were captured physically with 26 ultrasound and bioimpedance spectroscopy and changes in symptoms were captured using 27 European Organization for Research and Treatment of Cancer (EORTC) Breast Cancer 28 (BR23) and Lymphoedema Symptom Intensity and Distress questionnaires. The exercise 29 group reported a greater reduction in breast-related symptoms than the control group, 30 assessed by the EORTC BR23 breast symptom questions. Measures of extracellular fluid, 31 assessed with bioimpedance spectroscopy ratio, decreased in the exercise group compared 32 33 to the control group. No significant difference was detected in dermal thickness in the breast, assessed by ultrasound. Session attendance in the exercise sessions was high, with 34 two musculoskeletal adverse events reported, but no exacerbations of lymphoedema 35 observed. Authors concluded that combined resistance and aerobic exercise training is safe 36 for women living with breast lymphoedema. Preliminary data suggest exercise training can 37 reduce breast lymphoedema symptoms to a greater extent than usual care. 38

39

Saraswathi et al. (2021) systematically reviewed the effect of yoga therapy on managing
lymphedema, increasing the range of motion (ROM), and quality of life (QoL) among
breast cancer survivors. Studies which assessed the outcome variables such as QoL and

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management of lymphedema or related physical symptoms as effect of yoga intervention 1 were considered for review. The different styles of yoga employed in the studies were 2 Iyengar yoga (n = 2), Satyananda yoga (n = 2), Hatha yoga (n = 2), and Ashtanga yoga 3 (n = 1). The length of intervention and post intervention analysis ranged from 8 weeks to 4 12 months. Authors concluded that yoga could be a safe and feasible exercise intervention 5 for BCRL patients. Evidence generated from these studies was of moderate strength. 6 Further long-term clinical trials with large sample size are essential for the development 7 and standardization of yoga intervention guidelines for BCRL patients. 8 9

Bruce et al. (2021) evaluated whether a structured exercise programme improved 10 functional and health related quality of life outcomes compared with usual care for women 11 at high risk of upper limb disability after breast cancer surgery. Subjects included 392 12 women undergoing breast cancer surgery, at risk of postoperative upper limb morbidity, 13 randomised (1:1) to usual care with structured exercise (n=196) or usual care alone 14 (n=196). Usual care (information leaflets) only or usual care plus a physiotherapy led 15 exercise programme, incorporating stretching, strengthening, physical activity, and 16 behavioural change techniques to support adherence to exercise, introduced at 7-10 days 17 postoperatively, with two further appointments at one and three months. Main outcome 18 measures included the Disability of Arm, Hand and Shoulder (DASH) questionnaire at 12 19 20 months, analysed by intention to treat. Secondary outcomes included DASH subscales, pain, complications, health related quality of life, and resource use, from a health and 21 personal social services perspective. Upper limb function improved after exercise 22 compared with usual care for exercise. Secondary outcomes favoured exercise over usual 23 care, with lower pain intensity at 12 months and fewer arm disability symptoms at 12 24 months. No increase in complications, lymphoedema, or adverse events was noted in 25 participants allocated to exercise. Exercise accrued lower costs per patient and was cost 26 effective compared with usual care. Authors concluded that the PROSPER exercise 27 programme was clinically effective and cost effective and reduced upper limb disability 28 one year after breast cancer treatment in patients at risk of treatment related postoperative 29 complications. 30

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Corum et al. (2021) compared the effects of complex decongestive therapy (CDT) 32 33 accompanied by resistance exercises on extremity circumference, lymphedema volume, grip strength, functional status, and quality of life in the treatment of breast cancer-related 34 lymphedema (BCRL) in patients with and without pain. Fifty patients with unilateral 35 BCRL were divided into groups: with pain (Group 1, n = 25) and without pain (Group 2, n 36 = 25). Thirty minutes of manual lymphatic drainage and multilayered short-stretch 37 bandaging were applied to all patients five times a week for 4 weeks. In addition, all 38 39 patients were informed about skin care and given a supervised resistance exercise program throughout the treatment. During the 1-month follow-up period, patients were asked to use 40 low-tension elastic garments and to continue their home exercise program. Differences in 41 upper extremity circumference and volume; grip strength; Quick Disabilities of the Arm, 42

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Shoulder, and Hand; and Functional Assessment of Cancer Therapy-Breast scores were 1 evaluated at baseline, after treatment (week 4), and at 1-month follow-up. Moreover, the 2 pain intensity of patients in Group 1 was measured using the visual analog scale (VAS). 3 Patients in both Group 1 and Group 2 showed a statistical improvement in all outcome 4 measures after treatment and at follow-up (p < 0.05); however, no significant difference 5 was observed between the groups (p > 0.05). In Group 1, a statistically significant decrease 6 was observed in the VAS score both at the end of treatment and at 1-month follow-up (p < p7 0.05). Authors concluded that combined CDT and resistance exercises appear to be 8 effective in BCRL patients both with and without pain. 9

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11 Hayes et al. (2022) evaluated the effects of exercise on (i) the prevention of cancer-related lymphedema (CRL), and (ii) the treatment of CRL, lymphedema-associated symptoms, 12 and other health outcomes among individuals with CRL in a systematic review and meta-13 analysis. Twelve studies (n = 1,955; 75% moderate-high quality) and 36 studies (n = 1,741; 14 58% moderate-high quality) were included in the prevention and treatment aim, 15 respectively. Relative risk of developing CRL for those in the exercise group compared 16 with the non-exercise group was 0.90 overall, and 0.49 for those with 5 or more lymph 17 nodes removed. Improvements post-intervention were observed for pain, upper-body 18 function and strength, lower-body strength, fatigue and quality of life for those in the 19 20 exercise group. Authors concluded that findings support the application of exercise guidelines for the wider cancer population to those with or at risk of CRL. This includes 21 promotion of aerobic and resistance exercise, and not just resistance exercise alone, as well 22 as unsupervised exercise guided by symptom response. 23

24

Maccarone et al. (2023) evaluated the effects of water-based exercise on pain, limb motor 25 function, quality of life (QoL), and limb volume among patients affected by primary and 26 secondary upper and lower limb lymphedema. The search produced a total of 88 studies. 27 Eight randomized controlled trials and one clinical study of patients with primary or 28 secondary lymphedema of upper or lower limbs who had undergone water-based treatment 29 were included in the present study. Most trials had focused on breast cancer-related 30 lymphedema. The shoulder range of flexion, external rotation, and abduction have been 31 shown to improve after performing a water-based exercise protocol. Some evidence has 32 33 also demonstrated that the lymphedematous limb strength can improve. Moreover, waterbased exercise seemed to improve pain perception and QoL for patients with upper or lower 34 limb lymphedema. In contrast, in the control groups, the QoL showed a tendency to worsen 35 over time. Although some studies had not reported beneficial effects on the 36 lymphedematous limb volume, most of the studies examined had reported a reduction in 37 volume, especially in the short term. No adverse events were reported in the included 38 39 studies. Authors concluded that these findings from the present review have shown the potential for aquatic exercise in lymphedema management. However, at the same time, the 40 findings underline the multiple limitations resulting from the heterogeneity in the study 41 populations and related physical activity protocols. The role of aquatic exercise in the 42

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1 conservative treatment of lymphedema requires further investigation in the future to define

- 2 specific protocols of application.
- 3

## 4 Measurement of Lymphedema

Hidding et al. (2016) attempted to provide best evidence of which measurement 5 instruments are most appropriate in measuring lymphedema in its different stages. Authors 6 concluded that measurement instruments with evidence for good reliability and validity are 7 Bioelectrical Impedance Spectroscopy (BIS), water volumetry, tape measurement and 8 perometry, where BIS can detect alterations in extracellular fluid in stage 1 lymphedema 9 and the other measurement instruments alterations in volume starting from stage 2. In 10 11 research water volumetry is indicated as reference test for measuring lymphedema in upper extremities. Limitations included the following: no uniform definition of lymphedema was 12 available and a gold standard as reference test was lacking. Items concerning risk of bias 13 were study design, patient selection, description of lymphedema, blinding of test outcomes 14

- 15 and number of included patients.
- 16

## 17 **PRACTITIONER SCOPE AND TRAINING**

Practitioners should practice only in the areas in which they are competent based on their education, training and experience. Levels of education, experience, and proficiency may vary among individual practitioners. It is ethically and legally incumbent on a practitioner to determine where they have the knowledge and skills necessary to perform such services and whether the services are within their scope of practice.

23

It is best practice for the practitioner to appropriately render services to a member only if they are trained, equally skilled, and adequately competent to deliver a service compared to others trained to perform the same procedure. If the service would be most competently delivered by another health care practitioner who has more skill and training, it would be best practice to refer the member to the more expert practitioner.

29

Best practice can be defined as a clinical, scientific, or professional technique, method, or process that is typically evidence-based and consensus driven and is recognized by a majority of professionals in a particular field as more effective at delivering a particular outcome than any other practice (Joint Commission International Accreditation Standards for Hospitals, 2020).

35

Bepending on the practitioner's scope of practice, training, and experience, a member's condition and/or symptoms during examination or the course of treatment may indicate the need for referral to another practitioner or even emergency care. In such cases it is prudent for the practitioner to refer the member for appropriate co-management (e.g., to their primary care physician) or if immediate emergency care is warranted, to contact 911 as appropriate. See the *Managing Medical Emergencies (CPG 159 – S)* clinical practice guideline for information.

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