

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria Lymphedema Therapy/ Lymphedema Therapy Training

- Complete Decongestive Therapy
- Lymphatic Venous Anastomosis (LVA) for the Treatment of Lymphedema

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Criteria

Complete Decongestive Therapy (CDT) is comprised of four components: Manual lymph drainage (MLD), compression bandaging, exercises and skin care. The goals of CDT are to reduce lymphedema, increase mobility and range of motion (ROM), decrease the risk of cellulitis, and ultimately providing for a better quality of life. The goal of CDT training is to educate the patient and/or the caregiver to be successful in performing decongestive techniques. In the process of learning lymphedema therapy techniques, the patient's lymphedema may improve and stabilize. However, the goal of therapy and training is to transfer the knowledge and skills to the patient, or their caregiver so ongoing decongestive techniques can be performed by the patient or their caregiver, not to necessarily completely decongest the affected limb. Ongoing responsibility for completion and maintenance of decongestion is with the patient and/or the caregiver.

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	Lymphedema Decongestive Treatment (A52959)

For Non-Medicare Members

* CDT training is not routinely covered prophylactically, but patients at risk (such as having recent surgical removal of lymph nodes) who are "Stage 0" can be approved for up to 2 visits for patient education on future management

Complete Decongestive therapy is considered medically necessary if ALL of the following are met:

- 1. The treating or consulting practitioner (within the scope of their practice) documents a diagnosis of primary or secondary lymphedema and specifically orders CDT training **and**
- The patient or patient's caregiver has the ability to understand and provide home-based exercise and management, as the patient and/or caregiver will need to be able to manage the condition on their own after discharge *and*
- 3. CDT training services must be performed by a licensed PT or OT that has received specific training for this service **and**
- 4. The frequency and duration of services must be necessary and reasonable. CDT services are comprised of up to 15 sessions over a 2-12-week period **and**

A CDT course of training is generally expected to occur no more than once per lifetime. However, if medically
necessary, refresher training will be approved for 1-2 sessions to review CDT techniques and measure for
compression garments

Continued therapy may be indicated if ONE of the following are met:

- 1. 15 visits can extend beyond 12 weeks, if treatment is interrupted by chemotherapy or radiation therapy or
- 2. Severe lymphedema that is showing progress with decreasing limb girth, more appointments may be approved if **ALL of the following** are met:
 - a. Documentation of the patient's condition before, during and after therapy supports that progress was measurably sustainable **and**
 - b. Documentation indicates clear objective evidence of improvement, generally within the first week or 10 days of therapy (changes in weight, extremity circumference, etc.) **and**
 - c. Member or their caregiver has not yet mastered and demonstrated understanding of complex decongestive therapy techniques. For continued training to be approved, there must be documentation of the amount of further training required and an assessment if the patient or caregiver will be able to learn these techniques in a reasonable period of time.
 - d. The goal of lymphedema therapy is not to fully decongest the affected limb, rather it is to transfer the skills and knowledge of lymphedema therapy techniques to the member or their caregiver.

Complete Decongestive Therapy is NOT covered when:

- 1. Therapy is limited to exercise or elevation of the affected area and is not CDT
- 2. Therapy does not include ongoing patient education
- 3. Therapy treatment is designed principally for temporary benefit
- 4. The patient or patient caregiver do not have the capacity to learn and perform CDT techniques within a reasonable amount of time

Covered Diagnosis

- 1. Primary lymphedema
- 2. Secondary lymphedema caused by:
 - a. destruction of lymph nodes by radiation therapy or surgery for treatment of cancer.
 - b. destruction of lymph system by:
 - trauma or
 - · recurrent episodes of cellulitis in the affected limb (two episodes of cellulitis requiring antibiotic or
 - the result of severe chronic venous insufficiency

Lymphatic Venous Anastomosis (LVA) for the Treatment of Lymphedema:

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

Lipectomy for Lipedema is addressed on a separate policy: Restorative and Cosmetic Procedures

If requesting these services, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist
- Last 6 months of radiology if applicable

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Primary lymphedema refers to lymphedema that is caused by the imperfect or abnormal development/lymphatic dysplasia of the lymph vascular system. Primary lymphedema may be due to such causes as Milroy's Disease, Meige's Disease, Turner Syndrome Noonan Syndrome, Klippe-Trenaunay Syndrome, Parks Weber Syndrome, Prader-Willi Syndrome, Emberger Syndrome and other genetic and non- genetic syndromes (also known as hereditary and sporadic lymphedema). Secondary lymphedema is caused by known factors that damage the

lymphatic system. Causes of secondary lymphedema include Filariasis, surgery and/or radiation for cancer, cancer, trauma, infection, and chronic venous insufficiency. Obesity is an independent risk factor for lymphedema. The most common cause of secondary lymphedema in developed countries is treatment for cancer, especially breast cancer, due primarily to the removal and/or damage of lymph nodes, and damage to lymph vessels. Complete decongestive therapy can be effective for both primary and secondary lymphedema.

Differential diagnosis must include medical conditions which cause swelling which are *not* considered lymphedema and should be treated medically. These conditions include hepatic/renal disorders, congestive heart failure, venous obstruction (DVT) and in some cases, immobility of the limb where the muscle pump is not active, hypoproteinemia, malnutrition, malabsorption syndromes, sepsis, allergic reactions, lipedema, myxedema (disorder of the thyroid), fluid retention syndrome, neurological conditions which can cause weakness or paralysis resulting in immobility of the limbs and even as a side-effect of certain medications and self-inflicted swelling.

Lymphedema can co-occur with other conditions and may be amenable to CDT treatment, especially if the condition is chronic and medical treatment has not completely resolved the edema. **Chronic venous insufficiency** can lead to lymphedema because as the increased amount of fluid in the interstitium which is filtered from the capillaries begins to overwhelm the lymphatic system and can cause damage to the lymphatics, this usually occurs in Stage 2 of CVI. If the conditions are chronic and swelling continues, they may be amenable to a course of CDT.

Evidence and Source Documents

Medicare B Issues Notice 177, Page 14, 15, 16

Lymphatic Venous Anastomosis (LVA) for the Treatment of Lymphedema BACKGROUND

Lymphedema is the accumulation of fluid in the lymphatic system. Lymphedema is an imbalance between interstitial fluid production and the transport capacity of the lymphatic system ("The diagnosis and treatment of peripheral lymphedema: 2013 Consensus Document of the International Society of Lymphology," 2013). It is caused by congenital anomalies of the lymphatic vessels or any factors that damage the lymphatic system. Lymphedema is classified as primary or secondary depending on etiology. Primary lymphedema is due to a congenital malformation of the lymphatic vessels. It manifests, more commonly, by edema of the lower limbs at birth which can be present up to two years after birth. Secondary lymphedema is due to infection, injury/trauma, inflammation, obesity, cancer and cancer treatment, and chronic venous insufficiency.

Patients may experience swelling, pain, discomfort, heaviness, limited range of motion, and skin lesions. The diagnosis is made by history, physical exam, and measurements (Mehrara, B. et al., 2019).

The treatment of lymphedema can be difficult. However, the foundation of treatment is conservative and multimodal. Multimodal treatment consists of general measures along with compression therapy and physiotherapy. General measures include self-monitoring, limb elevation, maintenance of adequate body weight through diet and exercise, avoidance of skin infection or injury, avoidance of limb constriction. Compression therapy includes bandaging, compression garments, and intermittent pneumatic compression. Physiotherapy is comprised of manual lymphatic drainage and complete decongestive therapy (Mehrara, B. et al., 2019).

Complete decongestive therapy, also called complex decongestive therapy, complex decongestive physiotherapy, or decongestive lymphatic therapy is comprised of two phases: the first phase which is the treatment phase involves manual lymphatic drainage, limb compression, skin care, and exercise. This occurs every day five days per week and lasts two to four weeks. The second phase also called the maintenance phase entails compression garments, self-compression bandaging at night, skin care, exercise, and, if necessary, self-manual lymphatic drainage (Mehrara, B. et al., 2019). The treatment is provided by a health care professional. However, patients or caregivers can treat themselves especially in the second phase of the treatment after being trained.

Medical Technology Assessment Committee (MTAC)

Lymphatic Venous Anastomosis

06/20/2011: MTAC REVIEW

Evidence Conclusion: There is insufficient published evidence to determine the efficacy and safety of lymphatic venous anastomosis in the treatment breast cancer-related lymphedema.

<u>Articles</u>: The literature on the on lymphatic venous anastomosis (LVA) for the treatment of breast cancer-related lymphedema (BCRL) is very limited; the search did not reveal any meta-analyses or randomized controlled trials

that evaluated efficacy or safety of the procedure. The empirical study published on the LVA for the treatment (BCRL) was a small case series with ten patients.

The use of lymphatic venous anastomosis (LVA) for the treatment of post-breast cancer lymphedema does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Complete decongestive therapy for the treatment of lymphedema 04/08/2019: MTAC REVIEW

- Evidence Conclusion:
- Low evidence indicates no difference between complete decongestive therapy and compression bandaging or garments in terms of reduction in limb volume, edema volume, limb-related volume change, QOL, and arm function in patients with secondary lymphedema due to breast cancer treatment on the short and mid-terms (≤1 year).
- There is insufficient evidence for or against the effectiveness of complete decongestive therapy training in term of lymphedema reduction.
- Moderate quality study suggests that decongestive lymphedema therapy may be safe.

<u>Articles</u>: PubMed was searched from 2012 to March 20, 2019 with the search terms Complete decongestive therapy OR complex decongestive physiotherapy OR decongestive lymphatic therapy. The search was limited to English language publications and human populations. The reference lists of relevant studies were reviewed to identify additional publications. RCTs and observational studies were included as filters. See Evidence Table.

The use of Complete decongestive therapy for the treatment of lymphedema does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Hayes Technology Brief

Hayes, Inc. Hayes Technology Brief. Microsurgical Treatment of Lymphedema Following Breast Cancer Surgery. Lansdale, PA: Hayes, Inc.; 7/2013

Interregional New Technologies Committee (INTC) Review

02/02/2021: SCPMG Evidenced-Based Medicine

Overall Conclusion:

- The body of literature on LYMPHA for prevention of secondary extremity lymphedema consists of six comparative studies (including 2 RCTs) and eight non-comparative studies and involved a total of 1,067 participants (range: N=10 to N=380). Follow-up periods ranged from 3 months to 4 years. Most studies involved breast cancer patients, but several studies included patients with other types of cancer.
- The included studies were at high risk of bias and most had small sample sizes. There was also
 heterogeneity in terms of cancer type, lymphedema classification, treatment courses, and follow-up times.
 However, the studies consistently demonstrated substantial reductions in risk of lymphedema occurrence with
 the LYMPHA, compared with standard care.
- Incidence of lymphedema in the included studies ranged from 0% to 12.5%, with lymphedema occurring transiently in some patients and persisting in others. The highest rate of persistent lymphedema was 9% (in a retrospective case series, N=27). The overall quality of the evidence on the efficacy of LYMPHA was found to be low.
- Four studies (1 small RCT; 1 small prospective case series; 2 retrospective) reporting safety outcomes did not indicate any serious concerns regarding safety or complications associated with LYMPHA for prevention of secondary lymphedema. The overall quality of the evidence on the safety of LYMPHA is very low.
- We applied the ROBIS (i.e., risk of bias in systematic reviews) tool to the Hayes, Inc. assessment and found risk of bias in their review to be low.
- Given the overall low quality of the body evidence on LYMPHA, there remains a need for large, high-quality comparative studies or RCTs to draw a conclusion regarding the efficacy and safety of LYMPHA for prevention of secondary lymphedema, compared with standard care.

Applicable Codes

Complete Decongestive Therapy (CDT) - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

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CPT [®] or HCPC	Description
Codes	
97140	Manual therapy techniques (eg, mobilization/ manipulation, manual lymphatic drainage, manual traction), 1 or more regions, each 15 minutes
97535	Self-care/home management training (eg, 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
S8950	Complex lymphedema therapy, each 15 minutes

Lymphatic Venous Anastomosis (LVA) - Considered not medically necessary:

CPT [®] or	Description
HCPC	
Codes	
No specific codes – often submitted as 38999 Unlisted procedure, hemic or lymphatic system	

*Note: Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

**To verify authorization requirements for a specific code by plan type, please use the Pre-authorization Code Check.

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Date Created	Date Reviewed	Date Last Revised
01/1996	06/01/2010 MDCRPC, 04/05/2011 MDCRPC, 02/07/2012 MDCRPC, 12/04/2012 MDCRPC, 10/01/2013 MPC, 08/05/2014 MPC, 05/05/2015 MPC, 03/01/2016 MPC, 05/03/2016 MPC, 03/7/2017 MPC, 01/09/2018 MPC, 12/04/2018 MPC, 12/03/2019 MPC, 12/01/2020 MPC, 12/07/2021 MPC, 12/06/2022 MPC, 12/09/2023 MPC, 04/02/2024 MPC, 04/01/2025 MPC	05/11/2023

MDCRPC Medical Director Clinical Review and Policy Committee MPC Medical Policy Committee

Revision History	Description
05/05/2015	The criteria were completely revised to mirror Medicare guidelines to support payment for comprehensive decongestive therapy only.
05/03/2016	Merged CDT & LVA criteria into one document under Lymphedema Therapy
04/13/2017	Added Hayes Technology Brief Review
03/05/2019	MPC approved to expand criteria to treat members with lymphedema caused by other diagnosis
04/08/2019	other than cancer MTAC review for Complete Decongestive Therapy for the treatment of lymphedema was added
09/12/2022	INTO Review for Lymphovenous Anastomosis (LVA) (LYMPHA) for Prevention of Lymphedema from
	02/01/2021 was added
05/11/2023	Updated format for clarity