Surgical Treatments of Lymphedema

Medicare Advantage Medical Policy # MA-159
Original Effective Date: 02/01/2026
Current Effective Date: 02/01/2026

Applies to all products administered or underwritten by the Health Plan, unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Health Plan considers lymphatic physiologic microsurgery to treat lymphedema (including, but not limited to, lymphatico-lymphatic bypass, lymphovenous bypass, lymphaticovenous anastomosis, autologous lymph node transplantation, and vascularized lymph node transfer) in individuals who have been treated for breast cancer to be **investigational.***

Based on review of available data, the Health Plan considers lymphatic physiologic microsurgery performed during nodal dissection or breast reconstruction to prevent lymphedema (including, but not limited to, the Lymphatic Microsurgical Preventing Healing Approach [LYMPHA]) in individuals who are being treated for breast cancer to be **investigational.***

Background/Overview

Lymphedema

Lymphedema is an accumulation of fluid due to disruption of lymphatic drainage. Lymphedema can be caused by congenital or inherited abnormalities in the lymphatic system (primary lymphedema) but is most often caused by acquired damage to the lymphatic system (secondary lymphedema).

Diagnosis and Staging

A diagnosis of secondary lymphedema is based on history (eg, cancer treatment, trauma) and physical examination (localized, progressive edema and asymmetric limb measurements) when other causes of edema can be excluded. Imaging, such as magnetic resonance imaging, computed tomography, ultrasound, or lymphoscintigraphy, may be used to differentiate lymphedema from other causes of edema in diagnostically challenging cases.

Table 1 lists International Society of Lymphology guidance for staging lymphedema based on "softness" or "firmness" of the limb and the changes with an elevation of the limb.

Table 1. Recommendations for Staging Lymphedema

Stage	Description
Stage 0 (subclinical)	Swelling is not evident and most patients are asymptomatic despite impaired lymphatic transport

Stage I (mild)	Accumulation of fluid that subsides (usually within 24 hours) with limb elevation; soft edema that may pit, without evidence of dermal fibrosis
Stage II (moderate)	Does not resolve with limb elevation alone; limb may no longer pit on examination
Stage III (severe)	Lymphostatic elephantiasis; pitting can be absent; skin has trophic changes

Breast Cancer-Related Lymphedema
Breast cancer treatment is one of the most common causes of secondary lymphedema. Both the surgical removal of lymph nodes and radiotherapy are associated with development of lymphedema in patients with breast cancer.

In a systematic review of 72 studies (N=29,612 women), DiSipio et al (2013) reported that approximately 1 in 5 women who survive breast cancer will develop arm lymphedema. Reviewers reported that risk factors for development of lymphedema that had a strong level of evidence were extensive surgery (ie, axillary-lymph-node dissection, greater number of lymph nodes dissected, mastectomy) and being overweight or obese. The incidence of breast cancer-related lymphedema (BCRL) was found by DiSipio et al as well as other authors to be up to 30% at 3 years after treatment.

Studies have also suggested that Black breast cancer survivors are nearly 2.2 times more likely to develop breast cancer-related lymphedema compared to White breast cancer survivors. These observations may be linked to racial disparities with regards to access to treatment and the types of treatments received. Black women are more likely than White women to undergo axillary lymph node dissection, which is associated with greater morbidity than the less invasive sentinel lymph node biopsy. While this may be explained in part by Black individuals having a higher likelihood of being diagnosed with more aggressive tumors, there is evidence that even when adjusting for stage and grade of tumors, Black women are more likely to undergo axillary lymph node dissection, putting Black women at greater risk of breast cancer-related lymphedema. Additionally, Black breast cancer survivors, on average, have higher body mass indexes than White breast cancer survivors, which could contribute to development of lymphedema in this setting as well.

Management and Treatment
Early and ongoing treatment of lymphedema is necessary. Conservative therapy may consist of several features depending on the severity of the lymphedema. Patients are educated on the importance of self-care including hygiene practices to prevent infection, maintaining ideal body weight through diet and exercise, and limb elevation. Compression therapy consists of repeatedly applying padding and bandages or compression garments. Manual lymphatic drainage is a light pressure massage performed by trained physical therapists or by patients designed to move fluid from obstructed areas into functioning lymph vessels and lymph nodes. Complete decongestive therapy is a multiphase treatment program involving all of the previously mentioned conservative treatment components at different intensities. Pneumatic compression pumps may also be considered as an adjunct to conservative therapy or as an alternative to self-manual lymphatic drainage in

patients who have difficulty performing self-manual lymphatic drainage. In patients with more advanced lymphedema after fat deposition and tissue fibrosis has occurred, palliative surgery using reductive techniques such as liposuction may be performed.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Physiologic microsurgery for lymphedema is a surgical procedure and, as such, is not subject to regulation by the U.S. Food and Drug Administration.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Description

Surgery and radiotherapy for breast cancer can lead to lymphedema and are some of the most common causes of secondary lymphedema. There is no cure for lymphedema. However, physiologic microsurgical techniques such as lymphaticovenular anastomosis or vascularized lymph node transfer have been developed that may improve lymphatic circulation, thereby decreasing symptoms and risk of infection. This review focuses on physiologic microsurgical interventions and will not consider reductive (also known as excisional or ablative) surgical interventions such as liposuction.

Summary of Evidence

For individuals who have breast cancer-related secondary lymphedema who receive physiologic microsurgery to treat lymphedema along with continued conservative therapy, the evidence includes randomized controlled trials (RCTs), observational studies, and systematic reviews. Relevant outcomes are symptoms, morbid events, functional outcomes, health status measures, quality of life, resource utilization, and treatment-related morbidity. Several physiologic microsurgeries have been developed; examples include lymphaticovenular anastomosis (LVA) and vascularized lymph node transfer (VLNT). Two recent systematic reviews have examined microsurgical interventions for lymphedema, especially LVA and VLNT. Both reviews emphasize the need for higher-quality, standardized research to better assess surgical efficacy in lymphedema treatment. An ongoing RCT of LVA was identified, but analyses of comparative outcomes between groups are limited at this time. One RCT of VLNT with 36 participants has been conducted. However, these studies are not adequate for determining the comparative efficacy of physiologic microsurgery versus conservative treatment or decongestive therapy, or the comparative efficacy of different microsurgery techniques. An ongoing multi-center international RCT and the upcoming Cochrane Review address the need for high-quality evidence to compare the efficacy of microsurgery compared to complex physical decongestive therapy for chronic BCRL. This trial is expected to provide robust evidence on the

benefits of combining microsurgery with CDT compared to CDT alone. The Cochrane Review will synthesize existing and future research to offer a comprehensive understanding of the current evidence, informing clinical practice and guiding future research directions in this field. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are undergoing lymphadenectomy for breast cancer who receive physiologic microsurgery to prevent lymphedema, the evidence includes a RCT, an ongoing RCT, observational studies, and systematic reviews. Relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. Lymphatic Microsurgical Preventing Healing Approach (LYMPHA) is a preventive lymphaticovenular anastomosis performed during nodal dissection. Two recent systematic reviews have examined microsurgical interventions for lymphedema prevention. These reviews show that immediate lymphatic reconstruction has a protective effect on breast cancer-related lymphedema rates in patients undergoing autologous lymph node transplantation. However, a notable absence of rigorous clinical trials and studies with extended follow-up limits the strength of these findings. The risk of bias assessment underscores this concern; selection and reporting bias remain prevalent across much of the current literature. One RCT including 46 women has been conducted. The trial reported that lymphedema developed in 4% of women in the LYMPHA group and 30% in the control group by 18 months of follow-up. However, because the cumulative incidence of lymphedema after breast cancer treatment approximates 30% at 3 years, longer follow-up is needed to assess the durability of the procedure. The trial methods of randomization and allocation concealment were not described and there was no blinding, potentially introducing bias. The remaining evidence consists of uncontrolled studies and systematic reviews of these studies. An ongoing RCT indicated improved lymphedema at 24 months (n=40) with immediate lymphatic reconstruction compared with controls (9.5% vs. 32%; p=.014), but conclusions based on this RCT are pending final analysis. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in ‘Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Association of Plastic Surgeons

The American Association of Plastic Surgeons sponsored a conference to create consensus statements and recommendations for surgical treatment and prevention of upper and lower extremity lymphedema. The recommendations were based on the results of a systematic review and meta-analysis. The relevant recommendations include:

"There is evidence to support that lymphovenous anastomosis can be effective in reducing severity of lymphedema (grade 1C). There is evidence to support that vascular lymph node transplantation can be effective in reducing severity of lymphedema (grade 1B). Currently, there is no consensus on which procedure (lymphovenous bypass versus vascular lymph node transplantation) is more effective (grade 2C). A few studies show that prophylactic lymphovenous bypass in patients undergoing extremity lymphadenectomy may reduce the incidence of lymphedema (grade 1B). More studies with longer follow-up are required to confirm this benefit."

American Society of Breast Surgeons
The American Society of Breast Surgeons (ASBrS) published recommendations from an expert panel on preventive and therapeutic options for breast cancer-related lymphedema in 2017. The document stated that "the Panel agrees that LVA [lymphaticovenular anastomosis] and VLNT [vascularized lymph node transfer] may be effective for early secondary breast cancer-related lymphedema."

In a 2022 consensus statement the ASBrS stated that "newer surgical techniques, such as axillary reverse mapping, lymphatic transfer, and lympho-venous anastomosis are promising both for prevention and for treatment of established lymphedema. However, well-designed prospective studies with uniform criteria for patient selection, procedure, and outcome assessment are needed. In institutions where these techniques are available, they should be considered whenever ALND is required."

International Society of Lymphology
The International Society of Lymphology published an updated consensus document on the diagnosis and treatment of peripheral lymphedema in 2023.

The document stated the following on lymphaticovenous (or lymphovenous) anastomoses (LVA) and vascularized lymph node transplantation (VLNT):

- " Lymphaticvenous (or lymphovenous) anastomoses (LVA) are currently in use at many centers around the world. These procedures have undergone confirmation of long-term patency (in some cases more than 25 years) and demonstration of improved lymphatic transport (by objective physiologic measurements of long-term efficacy). Multiple lymphatic-venous anastomoses in a single surgical site, with both the superficial and deep lymphatics, allow the creation of a positive pressure gradient (lymphatic-venous) and evade the phenomenon of gravitational reflux without interrupting the distal peripheral superficial lymphatic pathways. Some centers particularly in areas of endemic filariasis also practice lymph nodal-venous shunts as a derivative method. Multiple centers are using LVA (LYMPHA technique) as a preventative measure in high-risk patients with good results although there has been one report concluding no long-term (4-year) effect."
- "Vascularized Lymph Node Transplantation. Transplantation of superficial lymph nodes (often using microsurgical techniques) from an uninvolved area together with the vascular

> supply (VLNT) to the site of lymphadenectomy is performed in multiple centers. Studies have been performed in these centers to generally support the efficacy of these operations...VLNT procedures have been shown to improve patient outcomes in several studies, but the effect may also depend on pronounced scar release in the axilla increasing the venous outflow in patients with breast cancer-related lymphedema as well as using postoperative compression garments. More work is needed in this area with increased standardization of procedures to develop a stronger experience and there is further documentation to clearly depict changes in the lymphatic system and potential increase in transport of lymph to and through these nodes/flaps. These studies need to include volume decrease as well as QOL investigations."

National Comprehensive Cancer Network
The National Comprehensive Cancer Network (NCCN) published recommendations on management of lymphedema as part of its guideline on survivorship (Version 2: 2025); however, it does not discuss physiologic microsurgical techniques. The guideline states that high-level evidence in support of treatments for lymphedema are lacking. In addition, the NCCN guideline on breast cancer does not give recommendations on use of physiological microsurgical techniques for preventing or treating lymphedema (Version 4.2025).

National Lymphedema Network
The National Lymphedema Network (NLN) published a position paper on the diagnosis and treatment of lymphedema in 2011. The paper provided the following statements, although notably, the document has been retracted and the Network is currently in the process of drafting a new position statement:

"Microsurgical and supramicrosurgical (much smaller vessels) techniques have been developed to move lymph vessels to congested areas to try to improve lymphatic drainage. Surgeries involve connecting lymph vessels and veins, lymph nodes and veins, or lymph vessels to lymph vessels. Reductions in limb volume have been reported and a number of preliminary studies have been done, but there are no long-term studies of the effectiveness of these techniques."

According to their website, the NLN identifies four surgical approaches for treatment: lymphatic debulking procedures, excisional surgeries, VLNT, and LVA.

U.S. Preventive Services Task Force Recommendations
No U.S. Preventive Services Task Force recommendations for lymphedema have been identified.

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
Some currently ongoing and unpublished trials that might influence this review are listed in Table 2.

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT05890677	The LYMPH Trial - Comparing Microsurgical With Conservative Treatment of Chronic Breast Cancer Associated Lymphedema: Study Protocol of a Pragmatic Randomized International Multicentre Superiority Trial	280	Jun 2036
NCT04687956	Effect of Lymphatic Microsurgical Preventing Healing Approach (LYMPHA) for Primary Surgical Prevention of Breast Cancer-related Lymphedema	72	Dec 2027 (last update posted: Oct 2023)
NCT05064176	Comparison of Reconstructive Lymphatic Surgery Versus no Surgery, Additional to Decongestive Lymphatic Therapy (Usual Care), for the Treatment of lymphoedema, Through a Multicentre Randomised Controlled Trial	180	Dec 2026
NCT03428581	Preventing Lymphedema in Patients Undergoing Axillary Lymph Node Dissection Via Axillary Reverse Mapping and Lympho-venous Bypass	264	Feb 2026
NCT04241341	A Randomized Controlled Trial: Does Immediate Lymphatic Reconstruction Decrease the Incidence of Lymphedema After Axillary Lymph Node Dissection	180	Jan 2026
NCT03941756	Prophylactic Lymphovenous Bypass Procedure Following Axillary Lymphadenectomy: A Prospective Observational Study	252	Dec 2025
NCT02790021	Improving the Quality of Life of Patients With Breast Cancer-related Lymphedema by Lymphaticovenous Anastomosis (LVA): A Randomized Controlled Trial	100	Jan 2025

NCT04579029	Prospective Randomized Evaluation of Lymphaticovenous Anastomosis Using Dynamic Imaging in Breast Cancer-related Lymphoedema	64	Apr 2024 (last update posted: Jan 2023)

NCT: national clinical trial.

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Policy History

Original Effective Date: 02/01/2026
Current Effective Date: 02/01/2026
11/18/2025 Utilization Management Committee review/approval. New policy.
Next Scheduled Review Date: 11/2026

Coding

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	15756, 35201, 35206, 38308, 38589, 38999, 49906
HCPCS	No codes

ICD-10 Diagnosis	I89.0-I89.9, I97.2, I97.89, Q82.0

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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NOTICE: If the Patient's health insurance contract contains language that differs from the Health Plan's Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Health Plan recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

NOTICE: All codes listed on the Medical Policy require prior authorization. This ensures appropriate utilization and alignment with current clinical guidelines.

Medicare Advantage Members
Established coverage criteria for Medicare Advantage members can be found in Medicare coverage guidelines in statutes, regulations, National Coverage Determinations (NCD)s, and Local Coverage Determinations (LCD)s. To determine if a National or Local Coverage Determination addresses coverage for a specific service, refer to the Medicare Coverage Database at the following link: https://www.cms.gov/medicare-coverage-database/search.aspx. You may wish to review the Guide to the MCD Search here: https://www.cms.gov/medicare-coverage-database/help/mcd-benehelp.aspx.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, internal coverage criteria may be developed. This policy is to serve as the summary of evidence, a list of resources and an explanation of the rationale that supports the adoption of this internal coverage criteria.

InterQual®
Interqual® is utilized as a source of medical evidence to support medical necessity and level of care decisions. InterQual® criteria are intended to be used in connection with the independent professional medical judgment of a qualified health care provider. InterQual® criteria are clinically based on best practice, clinical data, and medical literature. The criteria are updated continually and released annually. InterQual® criteria are a first-level screening tool to assist in determining if the proposed services are clinically indicated and provided in the appropriate level or whether further evaluation is required. The utilization review staff does the first-level screening. If the criteria are met, the case is approved; if the criteria are not met, the case is referred to the medical director.