



FEP Medical Policy Manual

FEP 7.01.162 Surgical Treatments for Breast Cancer-Related Lymphedema

Annual Effective Policy Date: January 1, 2024

Original Policy Date: September 2018

Related Policies:

- 1.01.18 - Pneumatic Compression Pumps for Treatment of Lymphedema and Venous Ulcers
- 2.01.56 - Low Level Laser Therapy

Surgical Treatments for Breast Cancer-Related Lymphedema

Description

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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.

OBJECTIVE

This evidence review addresses 2 uses of physiologic microsurgery for breast cancer related lymphedema.

1. Does the use of physiologic microsurgery as an adjunct to conservative treatment for individuals who have breast cancer treatment related lymphedema improve the net health outcome as measured by improved symptoms, function, and quality of life?
2. Does the use of physiologic microsurgery for individuals who are undergoing treatment for breast cancer improve the net health outcome as measured by reduction in the incidence of lymphedema?

POLICY STATEMENT

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 is considered **investigational**.

Lymphatic physiologic microsurgery performed during nodal dissection or breast reconstruction to prevent lymphedema (including, but not limited to, the Lymphatic Microsurgical Preventing Healing Approach) in individuals who are being treated for breast cancer is considered **investigational**.

POLICY GUIDELINES

None

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA REGULATORY STATUS

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

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 a randomized controlled trial (RCT), 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 and vascularized lymph node transfer (VLNT). No RCTs of lymphaticovenular anastomosis or similar surgeries involving the venous system were identified. One RCT of VLNT with 36 participants has been conducted. Systematic reviews have indicated that the preponderance of the available evidence comes from single-arm clinical series from individual institutions. Surgical technique, outcomes metrics, and follow-up time have varied across these studies. These types of studies might be used for preliminary estimates of the amount of volume reduction expected from surgery, the durability of the reduction in volume, and the rates of adverse events. 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. Randomized controlled trials are needed. 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, 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. One RCT including 46 patients 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. 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.¹² 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 published recommendations from an expert panel on preventive and therapeutic options for breast cancer-related lymphedema in 2017.³⁰ 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."

International Society of Lymphology

The International Society of Lymphology published an updated consensus document on the diagnosis and treatment of peripheral lymphedema in 2020.³¹ The document stated the following on lymphaticovenous (or lymphovenous) anastomoses (LVA):

"LVA are currently in use at multiple centers around the world. These procedures have undergone confirmation of long-term patency (in some cases more than 25 years) and some 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 (Lymphatic Microsurgical Preventing Healing Approach [LYMPHA]) as a preventative measure in high risk patients."

National Comprehensive Cancer Network

The National Comprehensive Cancer Network (NCCN) published recommendations on management of lymphedema as part of its guideline on survivorship; however, it does not discuss physiologic microsurgical techniques.³² 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.³²

National Lymphedema Network

The National Lymphedema Network published a position paper on the diagnosis and treatment of lymphedema in 2011.³³ 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."

An update of this position paper is in development as of July 2023.

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.

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
September 2018	New policy	Policy updated with literature review through May 17, 2018. Lymphatic physiologic microsurgery to treat lymphedema in individuals who have been treated for breast cancer is considered investigational. Lymphatic physiologic microsurgery performed during nodal dissection or breast reconstruction to prevent lymphedema in individuals who are being treated for breast cancer is considered investigational.
June 2019	Replace policy	Policy updated with literature review through December 6, 2018; no references added. Policy statements unchanged.
September 2019	Replace policy	Policy updated with literature review through May 29, 2019; no references added. Policy statements unchanged.
December 2020	Replace policy	Policy updated with literature review through July 30, 2020; references added. Policy statements unchanged.
December 2021	Replace policy	Policy updated with literature review through August 5, 2021; references added. Policy statements unchanged.
December 2022	Replace policy	Policy updated with literature review through July 22, 2022; references added. Minor editorial refinements to policy statements; intent unchanged.
December 2023	Replace policy	Policy updated with literature review through July 17, 2023; no references added. Policy statements unchanged.

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