FEP 7.01.162 Surgical Treatment for Breast-Cancer Related Lymphedema

Effective Date: October 15, 2018

Related Policies:
1.01.18 Pneumatic Compression Pumps for Treatment of Lymphedema and Venous Ulcers
2.01.82 Bioimpedance Devices for Detection and Management of Lymphedema
2.01.56 Low-Level Laser Therapy

Surgical Treatment for Breast-Cancer Related Lymphedema

Description
Surgery and radiotherapy for breast cancer can lead to lymphedema and is one 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
The objective of this evidence review is to determine whether lymphatic physiologic microsurgery for the treatment or prevention of breast cancer-related lymphedema improves the net health outcome.

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.

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

Physiologic microsurgery for lymphedema is a surgical procedure and, as such, is not subject to regulation by the U. 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 an 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. No RCTs of lymphaticovenular anastomosis or similar surgeries involving the venous system were identified. One RCT of vascularized lymph node transfer 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 vs conservative treatment or decongestive therapy, or the comparative efficacy of different microsurgery techniques. RCTs are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who are undergoing lymphadenectomy for breast cancer who receive physiologic microsurgery to prevent lymphedema, the evidence includes an 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 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 Lymphatic Microsurgical Preventing Healing Approach group and 30% in the control group by 18 months of follow-up. Longer follow-up is needed to observe incident lymphedema occurring after 18 months and assess the durability of the procedure. The trial methods of randomization and allocation concealment were not described and there was no sham procedure or blinding, potentially introducing bias. The remaining evidence consists of 2 controlled observational studies with inadequate description of control selection and uncontrolled studies. The evidence is insufficient to determine the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

National Lymphedema Network

The National Lymphedema Network published a position paper on the diagnosis and treatment of lymphedema in 2011. The paper stated the following on microsurgical procedures:

“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
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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.

**International Society of Lymphology**

International Society of Lymphology published a consensus document on the diagnosis and treatment of peripheral lymphedema in 2016. 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 20 years) and some demonstration of improved lymphatic transport (by objective physiologic measurements of long-term efficacy).

**U.S. Preventive Services Task Force Recommendations**

Not applicable.

**Medicare National Coverage**

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

**REFERENCES**


The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.
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POLICY HISTORY

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<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
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<tbody>
<tr>
<td>September 2018</td>
<td>New Policy</td>
<td>Policy created with a 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.</td>
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