MEDICAL POLICY – 7.01.567

Surgical Treatments for Lymphedema

BCBSA Ref. Policy: 7.01.162
Effective Date: July 1, 2019
Last Revised: June 11, 2019
Replaces: 7.01.162

RELATED MEDICAL POLICIES:
1.01.18  Pneumatic Compression Pumps for Treatment of Lymphedema and Venous Ulcers

Select a hyperlink below to be directed to that section.

POLICY CRITERIA  |  CODING  |  RELATED INFORMATION
EVIDENCE REVIEW  |  REFERENCES  |  HISTORY

∞  Clicking this icon returns you to the hyperlinks menu above.

Introduction

Lymphatic fluid is a clear fluid that travels throughout the body. Its job is to remove wastes and bacteria from tissue. Lymphedema is swelling when too much lymphatic fluid accumulates in any part of the body. Lymphedema can be a result of certain surgeries or other procedures that remove or affect lymph node drainage. Lymphedema occurs because there are fewer natural channels for the fluid to move through. Typical treatment calls for raising the affected arm, massaging the area, or using pumps that apply light pressure. Certain surgeries are now being studied. These surgeries call for rerouting the flow of lymphatic fluid by connecting lymph vessels to veins, lymph nodes and veins, or lymph vessels to other lymph vessels. Other surgeries try to reduce swelling by moving other tissue into the surgical area or using suction to remove excess fat and proteins. All of these surgeries are investigational (unproven). More studies are needed to see how well they work over the long term.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
Treatment | Investigational
---|---
**Surgical treatments** | The following surgical treatments for lymphedema (eg, upper or lower extremities or genitalia) are considered investigational:
- Lymphatic physiologic microsurgery
  - Lymphatico-lymphatic bypass
  - Lymphovenous bypass
  - Lymphaticovenous anastomosis
  - Autologous lymph node transplantation
  - Vascularized lymph node transfer
  - Tissue transfer (eg, omental or mesenteric flap)
- Excisional procedures
  - Debulking
  - Liposuction (including suction assisted protein lipectomy [SAPL] also known as suction lipectomy)

**Preventive surgical treatment** | 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.

**Reverse lymphatic mapping** | Reverse lymphatic mapping used during lymphatic surgical or liposuction procedures is considered investigational.

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**Coding**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>CPT</td>
<td></td>
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<tr>
<td>38999</td>
<td>Unlisted procedure, hemic or lymphatic system.</td>
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<tr>
<td>76499</td>
<td>Unlisted diagnostic radiographic procedure</td>
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Related Information

N/A

Evidence Review

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.

Background

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 (e.g., 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 others 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.¹
Table 1. Recommendations for Staging Lymphedema

<table>
<thead>
<tr>
<th>Stage</th>
<th>Description</th>
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<tr>
<td>Stage 0 (subclinical)</td>
<td>Swelling is not evident and most patients are asymptomatic despite impaired lymphatic transport</td>
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<tr>
<td>Stage I (mild)</td>
<td>Accumulation of fluid that subsides (usually within 24 hours) with limb elevation; soft edema that may pit, without evidence of dermal fibrosis</td>
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<tr>
<td>Stage II (moderate)</td>
<td>Does not resolve with limb elevation alone; limb may no longer pit on examination</td>
</tr>
<tr>
<td>Stage III (severe)</td>
<td>Lymphostatic elephantiasis; pitting can be absent; skin has trophic changes</td>
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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.

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.

Table 2. Physiologic Microsurgical Interventions for Lymphedema

<table>
<thead>
<tr>
<th>Purpose</th>
<th>Surgery</th>
<th>Description</th>
<th>Key Features</th>
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</thead>
</table>
| Bypass or reconstruct obstructed lymph vessels to improve drainage | Lymphatic-lymphatic bypass                     | Connects functioning lymphatic vessels directly to affected lymphatic vessels; healthy vessels come from donor site | • Lymphedema can develop in donor extremity  
• Scaring at donor site |
|                                              | Lymphovenous bypass and lymphaticovenular anastomosis | Lymphatic vessels in a affected limb are connected to the venous system                                                                     | • Outpatient procedure or usually discharged within a day  
• Quick return to daily activities |
| Transfer lymph tissue to reestablish lymphatic flow | Autologous lymph node transplantation and vascularized lymph node transfer | Healthy lymph nodes are transferred to the affected limb                                                                                     | • Inpatient procedure; requires 2-3 days of hospitalization  
• Lymphedema can develop in donor extremity |

Reductive (Excisional or Ablative) Surgical Interventions

Reductive techniques remove fibrous, fatty tissue that has developed from sustained lymphatic fluid stasis. Reductive interventions include direct excision and liposuction procedures.

- Direct excision: There are several direct excision procedures for the treatment of extremity and genital lymphedema. Subcutaneous tissue is excised along with the skin and soft tissues to attempt to reduce the volume of the affected area. The resulting defects are then covered with tissue flaps or skin grafts. Wound healing complications and infections have been reported side effects of this type of intervention along with sexual dysfunction, decreased sensation and urethral injury when performed on the genitalia.\(^{35}\)

- Liposuction: Fibrous, fatty issue is removed through multiple small incisions of the affected extremity via a cannula attached to a powered suction device. Compression garments are worn postoperatively and may be required indefinitely to maintain the adipose tissue volume reduction obtained with this procedure. This technique is intended for patients with
end-stage lymphedema who have not responded to conservative treatments. Minor complications such as occasional paresthesias and wound healing are reported with this technique.\textsuperscript{35}

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. 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.

Randomized controlled trials are needed to prove the benefits of pedicled or laparoscopic free omental lymphatic flap for the management of lymphedema.

Results of the available studies provide limited evidence that suction-assisted protein lipectomy (SAPL) for the treatment of lymphedema that fails to respond to conservative therapy due to overgrowth of adipose tissue is a safe and effective technique. The best available evidence of efficacy was obtained in nonrandomized controlled studies. Liposuction combined with compression therapy reduced lymphedema volume versus compression therapy alone. Additional controlled studies are needed to confirm that liposuction for the treatment of lymphedema is a safe and effective therapy.

Reverse mapping using blue dye as a method for preserving the lymphatic drainage of the arm in breast cancer cases or indo-cyanine green as a technique to identify lymph node drainage patterns to localize lymph nodes in the surgical treatment of lymphedema are being investigated. Further studies are needed to determine the long-term outcomes of these techniques. The evidence is insufficient to determine the effects of the technology on health outcomes.

### Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 3.

### Table 3. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<tr>
<td>NCT02790021</td>
<td>Improving Quality of Survivorship for Breast Cancer-related Lymphedema by Lymphaticovenous Anastomosis: A Randomized Controlled Trial</td>
<td>60</td>
<td>Sep 2019</td>
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<tr>
<td>NCT03428581</td>
<td>Preventing Lymphedema in Patients Undergoing Axillary Lymph Node Dissection Via Axillary Reverse Mapping and Lympho-venous Bypass</td>
<td>264</td>
<td>Feb 2023</td>
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</table>

NCT: national clinical trial.
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 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**

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

**Medicare National Coverage**

There is no national coverage determination.
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.

References


**History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
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<tbody>
<tr>
<td>10/01/18</td>
<td>New policy, approved September 11, 2018, effective January 4, 2019. Policy created with a literature review through May 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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<tr>
<td>12/01/18</td>
<td>Interim Review, approved November 13, 2018, effective January 4, 2019. Title changed from &quot;Surgical Treatments for Breast Cancer Related Lymphedema&quot; to &quot;Surgical Treatments for Lymphedema&quot;. Policy statements added: Excisional procedures (debulking, liposuction including SAPL), tissue transfers (eg, omental flap) and reverse lymphatic mapping are considered investigational. References 24-35 added. Policy renumbered from 7.01.162 to 7.01.567. Added CPT code 76499.</td>
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<tr>
<td>05/01/19</td>
<td>Annual Review, approved April 2, 2019. Policy updated with literature search through December 2018; References 36-37 added. Policy statements unchanged.</td>
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