

## MEDICAL POLICY – 7.01.567

## Surgical Treatments for Lymphedema and Lipedema

BCBSA Ref. Policy: 7.01.162, 7.01.169, 7.01.173

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Replaces: 7.01.162


## RELATED MEDICAL POLICIES:

1.01.18 Pneumatic Compression Pumps for Treatment of Lymphedema and Venous Ulcers

10.01.514 Cosmetic and Reconstructive Services

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## 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 limb, 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. Many of these surgeries are investigational (unproven). More studies are needed to see how well they work over the long term. This policy explains when lipectomy or liposuction for the treatment of lipedema may be considered medically necessary.

**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.

## Policy Coverage Criteria

Treatment	Medically Necessary
<p><b>Lipectomy or liposuction for the treatment of lipedema</b></p>	<p><b>Lipectomy or liposuction for the treatment of lipedema may be considered medically necessary when ALL the following criteria are met:</b></p> <ul style="list-style-type: none"> <li>• There is documentation of significant physical functional impairment (e.g., difficulty ambulating or performing activities of daily living); and</li> <li>• The individual has not responded to at least 3 consecutive months of optimal medical management (such as conservative treatment with compression garments and manual lymph drainage); and</li> <li>• The plan of care postoperatively is to continue to wear compression garments as instructed to maintain the benefits of treatment; and</li> <li>• For the diagnosis of lipedema, the individual has all of the following clinical exam findings: (see <a href="#">Table 1</a>)               <ul style="list-style-type: none"> <li>○ Bilateral symmetric adiposity in the extremities</li> <li>○ Non-pitting edema</li> <li>○ Tissue in affected areas is soft to palpation</li> <li>○ Tissue in affected areas is tender to palpation</li> <li>○ Evidence of cuff phenomenon (sparing of feet if lower extremities are affected, or sparing of hands if upper extremities are affected) is present</li> <li>○ BMI <math>\leq 35</math> kg/m<sup>2</sup></li> </ul> </li> <li>• The requested surgical intervention will be performed by a plastic surgeon</li> <li>• Submission of photographs document the affected extremities requested for treatment and are consistent with the diagnosis of lipedema</li> </ul> <p><b>Staged liposuction procedures may be considered medically necessary when there is a large total volume (i.e., 5000 cc) of aspirate during the initial procedure, and they are completed within a 12-month period</b></p>



Treatment	Medically Necessary
	<p><b>Liposuction or lipectomy for the treatment of lipedema in the trunk or back is considered investigational</b></p> <p><b>Retreatment of a previously treated area using the same procedure is considered investigational.</b></p>

Treatment	Investigational
<b>Surgical treatments</b>	<p><b>The following surgical treatments to treat lymphedema (eg, upper or lower extremities or genitalia) are considered investigational:</b></p> <ul style="list-style-type: none"> <li>• Lymphatic physiologic microsurgery <ul style="list-style-type: none"> <li>○ Lymphatico-lymphatic bypass</li> <li>○ Lymphovenous bypass</li> <li>○ Lymphaticovenous anastomosis</li> <li>○ Autologous lymph node transplantation</li> <li>○ Vascularized lymph node transfer</li> </ul> </li> <li>• Tissue transfer (e.g., omental or mesenteric flap)</li> <li>• Reductive/ablative techniques <ul style="list-style-type: none"> <li>○ Direct excision</li> </ul> </li> </ul>
<b>Preventive surgical treatment</b>	<p><b>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 is considered investigational.</b></p>
<b>Reverse lymphatic mapping</b>	<p><b>Reverse lymphatic mapping used during lymphatic surgical or liposuction procedures is considered investigational.</b></p>

<b>Documentation Requirements</b>
<p><b>The individual’s medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following:</b></p> <ul style="list-style-type: none"> <li>• Office visit notes that contain the relevant history and physical (with the specific surgical procedure requested, any physical functional impairment noted, medical management tried, post-op plan of care for use of compression garments)</li> </ul>



## Documentation Requirements

- If request is for the treatment of lipedema all of the following clinical exam findings are documented: bilateral symmetric adiposity in the extremities, non-pitting edema, tissue in affected areas is soft to palpation, tissue in affected areas is tender to palpation, evidence of cuff phenomenon is present, and BMI  $\leq 35$  kg/m<sup>2</sup>
- The requested surgical intervention will be performed by a plastic surgeon.
- Photographs document the affected extremities requested for treatment and are consistent with the diagnosis of lipedema

## Coding

Code	Description
<b>CPT</b>	
15832	Excision, excessive skin and subcutaneous tissue (includes lipectomy); thigh
15833	Excision, excessive skin and subcutaneous tissue (includes lipectomy); leg
15836	Excision, excessive skin and subcutaneous tissue (includes lipectomy); arm
15839	Excision, excessive skin and subcutaneous tissue (includes lipectomy); other area
15877	Suction assisted lipectomy; trunk
15878	Suction assisted lipectomy; upper extremity
15879	Suction assisted lipectomy; lower extremity
38999	Unlisted procedure, hemic or lymphatic system
76499	Unlisted diagnostic radiographic procedure

**Note:** CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

## Related Information



## Definition of Terms

When specific definitions are not present in a member’s plan, the following definitions will be applied.

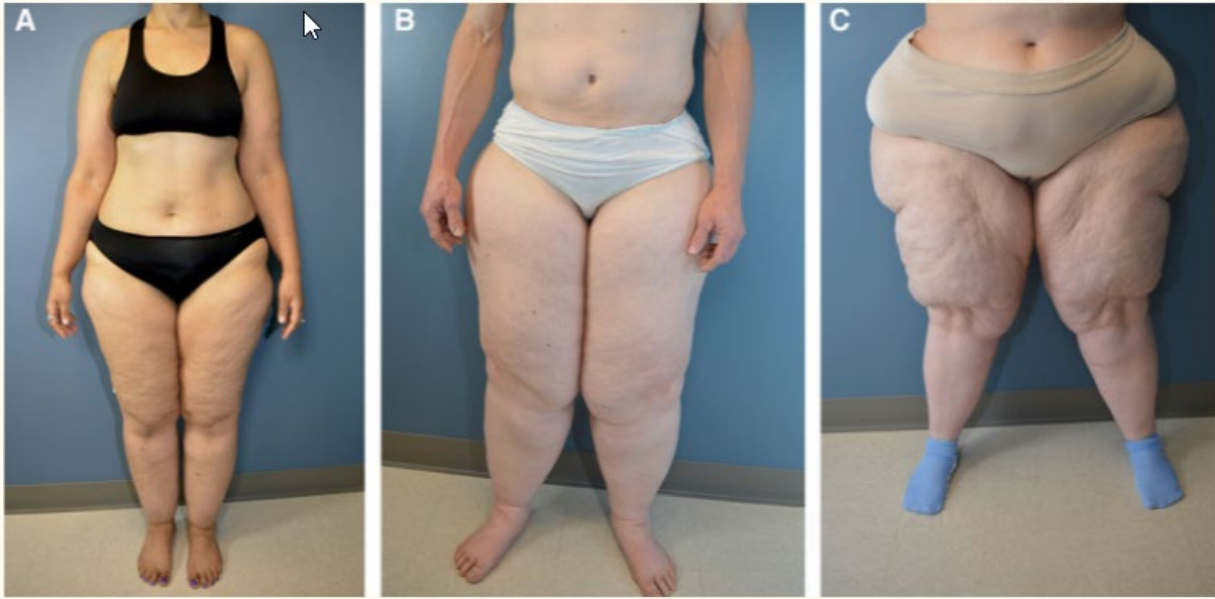
**Physical functional impairment:** In this policy, physical functional impairment means either limitation from normal physical functioning or baseline level of functioning that may include, but is not limited to, problems with ambulation, mobilization, communication, respiration, eating, swallowing, vision, facial expression, skin integrity, distortion of nearby body part(s) or obstruction of an orifice. The physical functional impairment can be due to structure, congenital deformity, pain, or other causes. Physical functional impairment excludes social, emotional and psychological impairments or potential impairments.

**Table 1. Comparison of Findings in Lipedema, Lymphedema, and Lifestyle-induced Obesity**

	Lipedema	Lymphedema	Lifestyle-induced Obesity
Sex	Women	Women and men	Women and men
Adiposity	Bilateral extremities Symmetric	Unilateral or bilateral extremities Asymmetric	Whole body, proportionate Symmetric
Edema	Nonpitting Minimal change with elevation; minimal change with compression	Pitting Reduced by elevation; reduced with compression	None No change with elevation or compression
Tissue turgor	Soft	Firm	Soft
Pain	Tender to palpation	Usually nontender	None
Infection	Rare	Common	Rare

**Source:** <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5055019/> Accessed October 17, 2024.





### ***Types of Lipedema***

Type 1: Pelvis, buttocks and hips (saddle bag phenomenon)

Type 2: Buttocks to knees with formation of folds of fat around the inner side of the knee

Type 3: Buttocks to ankles

Type 4: Arms

Type 5: Isolated lower leg (calves)

### ***Stages of Lipedema***

Stage 1: Even and smooth skin surface with enlarged subcutaneous fat tissue

Stage 2: Uneven skin surface with nodular elevations and indentations of subcutaneous fat and lipomas

Stage 3: Large deforming growths of nodular fat or hanging flaps of the thighs and around the knees

Stage 4: Large overhangs of tissue, dysfunctional lymphatics with lipedema and lipolyphedema

Source: Buck DW 2nd, Herbst KL. Lipedema: A Relatively Common Disease with Extremely Common Misconceptions. *Plast Reconstr Surg Glob Open.* 2016;4(9): e1043. PMID: 27757353. Accessed October 17, 2024.

### 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.

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).

Lipedema is a disorder characterized by a large amount of subcutaneous fat in the extremities, typically the legs and thighs. The adipose tissue may be painful. In contrast, lymphedema is the accumulation of interstitial fluid due to impaired lymphatic flow. This increase in interstitial fluid may lead to the accumulation and hypertrophy of fat cells. Liposuction, consisting of the removal of fat cells with a cannula and tumescent anesthesia, is being investigated as a treatment option for both lipedema and lymphedema.

Axillary reverse mapping, also called reverse lymphatic mapping, has been developed with the intent of sparing axillary lymph nodes and lymphatics during surgery, minimizing disruption and potentially reducing the risk of subsequent lymphedema development.

### Background

#### Lymphedema

Lymphedema is an abnormal accumulation of interstitial fluid and fibroadipose tissue in subcutaneous tissues or body cavities. In the extremities, capillaries in the superficial lymphatic system drain the lymph in the skin and subcutaneous tissue, which then flows into the deep system and then the lymph nodes, finally draining into the venous circulation. Accumulation of interstitial lymph fluid occurs when the accumulation of lymph exceeds the capacity of the system to drain. The excessive fluid may cause the accumulation and hypertrophy of fat cells.

Primary lymphedema may occur due to congenital anomalies or an inherited condition. Secondary lymphedema has a variety of causes that reduce lymph drainage including surgical removal of lymph nodes, post-radiation fibrosis, scarring of lymphatic channels, obesity, and chronic lymphatic overload. Cancer-associated lymphedema can occur due to obstruction, infiltration, removal of lymph nodes, irradiation, or medications. Nearly all cases of lymphedema in the US are secondary to cancer or cancer treatment.

The most common cancer-associated lymphedema occurs in women who have undergone axillary surgery and/or axillary radiation therapy for breast cancer. The risk of developing arm lymphedema is associated with the extent of axillary lymph node dissection, and there is a greater risk of lymphedema in breast cancer patients who undergo dissection compared to those who undergo biopsy.

### 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 other causes of edema in diagnostically challenging cases.

**Table 2** 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.<sup>1</sup>

**Table 2. Recommendations for Staging Lymphedema**

Stage	Description
Stage 0 (subclinical)	Swelling is not evident and most individuals 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 individuals 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.<sup>2</sup> Reviewers reported that risk factors for development of lymphedema that had a strong level of evidence were extensive surgery (i.e., axillary-lymph-node dissection, greater number of lymph nodes dissected, mastectomy) and being overweight or obese. The incidence of breast cancer-related lymphedema was found by DiSipio et al as well as other authors to be up to 30% at 3 years after treatment.<sup>2,3,4</sup>

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.<sup>5</sup> 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. Individuals 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 individuals, 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 individuals who have difficulty performing self-manual lymphatic drainage. In individuals with more advanced lymphedema after fat deposition and tissue fibrosis has occurred, palliative surgery using reductive techniques such as liposuction may be performed.

**Table 3. Physiologic Microsurgical Interventions for Lymphedema**

Purpose	Surgery	Description	Key Features
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	<ul style="list-style-type: none"> <li>•Lymphedema can develop in donor extremity</li> <li>•Scarring at donor site</li> </ul>
	Lymphovenous bypass and lymphaticovenular anastomosis	Lymphatic vessels in an affected limb are connected to the venous system	<ul style="list-style-type: none"> <li>•Outpatient procedure or usually discharged within a day</li> <li>•Quick return to daily activities</li> </ul>
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	<ul style="list-style-type: none"> <li>•Inpatient procedure; requires 2-3 days of hospitalization</li> <li>•Lymphedema can develop in donor extremity</li> </ul>

### **Axillary Reverse Mapping**

Axillary reverse mapping (ARM), involves subcutaneous administration of blue dye, fluorescence (i.e., indocyanine green), or radioisotopes to allow for visualization of the lymphatic drainage pathways of the arm and breast. This visualization is intended to distinguish and enable preservation of axillary lymph nodes and lymphatics in individuals undergoing sentinel lymph node biopsy and/or axillary lymph node dissection. It is believed that because the axilla and breast have mostly separate drainage pathways, the risk of lymphedema is reduced by avoiding the removal of lymph nodes and lymphatics that only drain the axilla identified through ARM. In the event that ARM reveals that the axillary nodes cannot be spared, for example due to crossover of sentinel and axillary nodes, lymphatic physiologic microsurgery has been explored as a method to preserve the axillary nodes, though evidence is limited



## **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.<sup>82</sup>
- 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 individuals 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.<sup>82</sup>

## **Liposuction for the Treatment of Lipedema**

Lipedema is a chronic disorder in which increased adipose (fat) tissue builds up under the skin causing non-pitting, symmetric, bilateral swelling of the lower extremities; in about 30% of cases, the upper extremities may be affected. Hands and feet characteristically do not swell, and the trunk and back are generally spared. Lipedema is often misdiagnosed as obesity or lymphedema. However, the excessive fat deposits are typically unresponsive to traditional weight loss interventions, exercise, or limb elevation. It primarily affects women. The cause of lipedema is unknown and there is currently no curative treatment for this condition. Signs and symptoms typically present at puberty, pregnancy, or menopause. Because of this, it is theorized that there is a hormonal influence on the disorder. Hereditary factors are also thought to play a role in its etiology. Lipedema is often painful and may present with bruising along with sensitivity to touch. This condition gradually worsens over time and may progress to a lipo-lymphedema due to the lymphatic load exceeding the lymphatic transport capacity. Lipedema is often misdiagnosed as obesity or lymphedema but does not generally respond to weight loss, exercise, or elevation of the limbs as do those disorders. Over time, the weight of the excessive fat build-up can impair the ability to walk and lead to reduced mobility.



Initial conservative therapy includes exercise and weight loss, compression garments, and manual lymphatic drainage. Complete decongestive therapy involves health professionals who address skin and nail care, therapeutic exercise, manual lymphatic drainage, and limb compression, which is performed daily for 5 days per week. The maintenance phase is intended to conserve the benefit in the first phase, and is self-administered. For those who have failed conservative measures, pneumatic compression pumps, and, occasionally, surgery are used as treatment options.

Treatment is aimed at relieving the symptoms. Conservative care with combined decongestive therapy (manual lymphatic drainage and compression garments) is the mainstay treatment of choice. If there is an inadequate response to conservative or supportive measures, tumescent liposuction has been proposed as the next line of treatment. Tumescent liposuction is a technique whereby local anesthetic, such as diluted lidocaine and epinephrine, is injected into subcutaneous fat and a vibrating cannula associated with power-assisted liposuction removes the fat. Waterjet assisted liposuction is another method of liposuction that may be used to treat lipedema. This method uses a pressurized stream of saline to dislodge the fat and more gently loosen and remove the fat cells.

## 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 and vascularized lymph node transfer (VLNT). An ongoing RCT of lymphaticovenular anastomosis was identified, but analyses of comparative outcomes between groups are limited at this time. 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 vs conservative treatment or decongestive therapy, or the comparative efficacy of different microsurgery techniques. RCTs 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, 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. 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.

For individuals with lipedema who receive liposuction, the evidence includes case series with over 100 individuals. Relevant outcomes are symptoms, change in disease status, functional outcomes, and quality of life. Baseline to post-treatment comparisons provide low quality evidence that liposuction reduces limb circumference and may reduce pain and improve mobility in individuals with advanced lipedema who have failed conservative therapy. The durability of the procedure is uncertain, and no studies were identified that compared liposuction to continued decongestive therapy. One such trial is currently in progress and will provide needed information on the benefits and harms of this procedure. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with lymphedema who receive liposuction, the evidence includes a few small, controlled trials and an uncontrolled observational study with 5 year follow-up. Relevant outcomes are symptoms, change in disease status, functional outcomes, and quality of life. The available studies suggest that arm volume can be reduced by the procedure, but follow-up is limited, and the trials have a number of other limitations that include lack of blinding, subjective outcome measures, lack of a physiotherapy control, and small sample size. The most rigorous evidence to date is a consecutive series of over 100 individuals with detailed methodology. This



series indicates that individuals who have failed conservative therapy can have complete reversal of excess volume in the short term and that gains can persist through 5 years of follow-up when compression therapy is continued after surgery. However, no studies were identified that compared liposuction to a decongestive therapy protocol with continued compression. Further study is needed to evaluate the impact of liposuction when compared to a decongestive therapy protocol. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome

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

For individuals with breast cancer undergoing sentinel lymph node biopsy (SLNB) who receive axillary reverse mapping (ARM), the evidence includes nonrandomized studies and systematic reviews of those studies. Relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. Evidence from 2 systematic reviews found ARM identified axillary lymphatics in about 38% of individuals undergoing SLNB, with lymphedema rates of 2% to 3% in individuals who underwent ARM during SLNB. Other outcomes such as quality of life were not reported. The systematic reviews had numerous limitations, including unclear mean duration of follow-up and inclusion of only single-arm, uncontrolled studies. Evidence from well-designed RCTs or controlled cohort studies is needed to determine the net health benefit of ARM in SLNB. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with breast cancer undergoing axillary lymph node dissection (ALND) who receive ARM, the evidence includes randomized controlled trials (RCTs), nonrandomized studies, and systematic reviews of those studies. Relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. Pooled evidence from a systematic review of 5 RCTs showed a lower risk of lymphedema with ARM compared with no ARM (odds ratio [OR], 0.20; 95% confidence interval [CI], 0.13 to 0.29), and another systematic review of RCTs and nonrandomized studies found a pooled lymphedema prevalence of 14% and lower risk of lymphedema with ARM and preserved axillary lymph nodes compared with resected lymph nodes (OR, 0.27; 95% CI, 0.20 to 0.36). In the same review, ARM was associated with an 82% identification rate of axillary lymph nodes and lymphatics, and a crossover rate between ARM and sentinel lymph nodes of 12%. Other health outcomes, including quality of life, were not reported. The safety of ARM in ALND has not been established, and the rate of metastatic ARM nodes was 13% based on pooled analysis of 27 studies in one systematic review. ARM in ALND was associated with a lower risk of lymphedema in the largest RCT conducted to date, which was also included in the systematic reviews, but oncological safety could not be determined and the trial also had important study relevance and design limitations.



The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Despite the lack of strong evidence, clinical guidelines recommend liposuction in individuals with advanced lipedema and for chronic lymphedema as there is limited treatment available when conservative measures have failed.

## Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in [Table 4](#).

**Table 4. Summary of Key Trials**

NCT No.	Trial Name	Planned Enrollment	Completion Date
<b>Ongoing</b>			
<a href="#">NCT03428581</a>	Preventing Lymphedema in Patients Undergoing Axillary Lymph Node Dissection Via Axillary Reverse Mapping and Lympho-venous Bypass	264	Feb 2026
<a href="#">NCT04272827</a>	Multicenter, Controlled, Randomized, Investigator-blinded Clinical Study on Efficacy and Safety of Surgical Therapy of Lipedema Compared to Complex Physical Decongestive Therapy Alone (LIPLEG)	450	Sep 2026
<a href="#">NCT04687956</a>	Effect of Lymphatic Microsurgical Preventing Healing Approach (LYMPHA) for Primary Surgical Prevention of Breast Cancer-related Lymphedema	72	Dec 2027
<a href="#">NCT02790021</a>	Improving the Quality of Life of Patients With Breast Cancer-related Lymphedema by Lymphaticovenous Anastomosis (LVA): A Randomized Controlled Trial	100	Dec 2024
<a href="#">NCT04579029</a>	Prospective Randomized Evaluation of Lymphaticovenous Anastomosis Using Dynamic Imaging in Breast Cancer-related Lymphoedema	64	Apr 2024
<a href="#">NCT04328610</a>	A Randomized Controlled Trial to Assess the Efficacy of the Lymphatic Microsurgical Preventive Healing Approach (LYMPHA) to Prevent Lymphedema After Axillary Dissection for Breast Cancer	34	Feb 2022 (status unknown)



NCT No.	Trial Name	Planned Enrollment	Completion Date
<a href="#">NCT04241341</a>	A Randomized Controlled Trial: Does Immediate Lymphatic Reconstruction Decrease the Incidence of Lymphedema After Axillary Lymph Node Dissection	180	Jan 2026
<a href="#">NCT03428581</a>	Preventing Lymphedema in Patients Undergoing Axillary Lymph Node Dissection Via Axillary Reverse Mapping and Lympho-venous Bypass	264	Feb 2026
<a href="#">NCT03927027</a>	ARM: Axillary Reverse Mapping - A Prospective Trial to Study Rates of Lymphedema and Regional Recurrence After Sentinel Lymph Node Biopsy and Sentinel Lymph Node Biopsy Followed by Axillary Lymph Node Dissection	534	Jan 2024
<a href="#">NCT04446494</a>	Identification and Preservation of Arm Lymphatics (DEPART) in Axillary Dissection for Breast Cancer to Reduce Arm Lymphedema Events: A Multicenter Randomized Clinical Trial	1200	Sep 2025
<b>Unpublished</b>			
<a href="#">NCT05040685</a>	Axillary Reverse Mapping (ARM): Validation of Surgical Technique in Breast Cancer Surgery	30	Dec 2023
<a href="#">NCT05094102</a>	Intraoperative Evaluation of Axillary Lymphatics for Breast Cancer Patients Undergoing Axillary Surgery	9 (actual)	Apr 2023

NCT: national clinical trial.

## Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion 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.<sup>12</sup> 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."

A 2021 consensus document sponsored by the American Association of Plastic Surgeons evaluated the evidence on surgical treatment of lymphedema.<sup>12</sup> The conference recommended, based on grade 1C (very low quality) evidence, that there is a role for debulking procedures such as liposuction and for liposuction combined with physiologic procedures in reducing the nonfluid component in lymphedema.<sup>12</sup>

The 2021 publication of the consensus recommendations did not include any recommendations specific to the use of ARM, but the following general statement was included within the text of the publication: "mapping of the lymphatics is encouraged when harvesting lymph nodes adjacent to the limbs such as reverse lymphatic mapping to avoid lymphatics draining the limb and to minimize the risk of donor-site lymphedema."<sup>12</sup>

## 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.<sup>32</sup> The document stated that "the Panel agrees that LVA and VLNT may be effective for early secondary breast cancer-related lymphedema."

The 2022 American Society of Breast Surgeons consensus guideline on axillary management of patients with in-situ and invasive breast cancer indicates that axillary reverse mapping (ARM) is one of several promising techniques for prevention of lymphedema, but also states "well-designed prospective studies with uniform criteria for patient selection, procedure, and outcome



assessment are needed." The guideline recommends considering ARM if it is readily available when axillary lymph node dissection (ALND) is required.<sup>76</sup>

The American Society of Breast Surgeons also published recommendations from an expert panel in 2017 that included prevention of breast cancer-related lymphedema<sup>32</sup>. The panel stated that "emerging data on preventive surgical strategies with ARM and LYMPHA are promising and should be explored further with appropriate patients."

## **International Consensus Conference on Lipedema**

A 2017 international consensus conference on lipedema identified studies from Germany that reported long-term benefits for up to 8 years following liposuction, concluding that lymph-sparing liposuction is the only effective treatment for lipedema.<sup>48</sup>

## **International Society of Lymphology**

The International Society of Lymphology published an updated consensus document on the diagnosis and treatment of peripheral lymphedema in 2020.<sup>1</sup> 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 (LYMPHA) as a preventative measure in high risk patients.

In 2020, the International Society of Lymphology published a consensus document on the diagnosis and treatment of peripheral lymphedema.<sup>1</sup> The consensus of the panel was that liposuction has been shown to completely reduce non-pitting lymphedema due to excess fat deposition, but long-term management requires strict patient adherence to compression garments.



## 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.<sup>33</sup> 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.<sup>33</sup>

## National Institute for Health and Care Excellence (NICE)

The NICE issued clinical guidance addressing the use of liposuction for chronic lymphedema in 2022.<sup>49</sup> The guidance reviewed the evidence and concluded that current evidence on the safety and efficacy of liposuction for chronic lymphedema is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent, and audit. The evidence on safety shows that the potential risks include venous thromboembolism, fat embolism, and fluid overload. Individual selection should only be done by a multidisciplinary team with expertise in managing lymphedema. The procedure should only be done in specialist centers by clinicians with training and expertise in liposuction for lymphedema following agreed perioperative protocols.

The NICE also issued guidance for liposuction in lipedema in 2022.<sup>50</sup> They recommend liposuction for lipedema should be used only in the research setting because the safety data for liposuction in lipedema is inadequate but concerning.

## National Lymphedema Network

The National Lymphedema Network published a position paper on the diagnosis and treatment of lymphedema in 2011.<sup>34</sup> 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 2024.

## **Austrian Academy of Cosmetic Surgery and Aesthetic Medicine and the International Society for Dermatologic Surgery**

Austrian Academy of Cosmetic Surgery and Aesthetic Medicine and the International Society for Dermatologic Surgery: *Prevention of Progression of Lipedema with Liposuction Using Tumescant Local Anesthesia: Results of an International Consensus Conference*. 2020.<sup>103</sup> This consensus statement concludes: "Lymph-sparing liposuction using tumescant local anesthesia is currently the only effective treatment for lipedema."

## **Canadian Agency for Drugs and Technologies in Health (CADTH)**

In 2019 CADTH published A Review of Clinical Effectiveness and Guidelines for Liposuction for the Treatment of Lipedema.<sup>38</sup> The guideline recommends that tumescant liposuction be considered the treatment of choice for individuals with an inadequate response to conservative measures.

## **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 US Food and Drug Administration (FDA).

Liposuction is a surgical procedure and, as such, is not subject to regulation by the FDA.

Axillary reverse mapping for lymphedema is adjunctive to a surgical procedure and, as such, is not subject to regulation by the FDA. Mapping agents used to visualize lymphatic pathways (e.g. isosulfan blue,<sup>53</sup> indocyanine green<sup>54</sup>) may be subject to FDA regulation.



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## History

Date	Comments
10/01/18	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.
12/01/18	Interim Review, approved November 13, 2018, effective January 4, 2019. Title changed from "Surgical Treatments for Breast Cancer Related Lymphedema" to "Surgical Treatments for Lymphedema". 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.
05/01/19	Annual Review, approved April 2, 2019. Policy updated with literature search through December 2018; References 36-37 added. Policy statements unchanged.
07/01/19	Interim Review, approved June 11, 2019. Added genitalia to investigational statement for surgical treatment of lymphedema. References 38-41 added. Policy reformatted for greater clarity.



Date	Comments
10/01/19	Interim Review, approved September 10, 2019. Policy updated with literature review through May 2019; References 42-56 added. Policy statement added indicating liposuction for the treatment of lipedema is investigational Title changed from "Surgical Treatments for Lymphedema" to "Surgical Treatments for Lymphedema and Lipedema". Added CPT codes 15832, 15833, 15836, 15839, 15877, 15878, and 15879.
05/01/20	Interim Review, approved April 14, 2020. References added. Lipectomy or liposuction for the treatment of lymphedema or lipedema changed from investigational to may be considered medically necessary when criteria are met.
07/27/20	Correct minor error in formatting with no impact on policy statements or intent.
12/01/20	Annual Review, approved November 3, 2020. Policy updated with literature review through July 2020; references added. Policy statements unchanged.
01/01/22	Annual Review, approved December 2, 2021. Policy updated with literature review through August 5, 2021; references added. Policy statements unchanged.
12/01/22	Annual Review, approved November 7, 2022. Policy updated with literature review through July 22, 2022; references added. Minor editorial refinements to policy statements; intent unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
02/01/23	Interim Review, approved January 9, 2023. BCBSA reference policy added. References added, Clinical trials added. Policy statements unchanged.
01/01/24	Annual Review, approved December 11, 2023. Policy updated with literature review through October 20, 2023. References added. Policy statement unchanged.
12/01/24	Annual Review, approved November 12, 2024. effective March 5, 2025, after a 90 day hold for provider notification. Policy updated with literature review through July 24, 2024. References added. Added the following medical necessity criteria: evidence of cuff phenomenon (sparing of feet if lower extremities are affected, or sparing of hands if upper extremities are affected) is present, BMI $\leq 35$ kg/m <sup>2</sup> the requested surgical intervention will be performed by a plastic surgeon, and staged liposuction procedures may be considered medically necessary when there is a large total volume of aspirate (i.e. 5000 cc) during the initial procedure, and they are completed within a 12-month period. Added the following investigational criteria: liposuction or lipectomy for the treatment of lipedema in the trunk or back is considered investigational, and retreatment of a previously treated area using the same procedure is considered investigational.

**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply.



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**Scope:** Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.

