



**BlueCross BlueShield
of Alabama**

Name of Blue Advantage Policy:
Surgical Treatments for Lymphedema and Lipedema

Policy #:719
Category: Medical/Surgical

Latest Review Date: September 2020
Policy Grade: B

BACKGROUND:

Blue Advantage medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
 - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
 - *Furnished in a setting appropriate to the patient's medical needs and condition;*
 - *Ordered and furnished by qualified personnel;*
 - *One that meets, but does not exceed, the patient's medical need; and*
 - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill **Original Medicare for covered services that are related to **clinical trials** that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Effective for dates of service on and after November 15, 2019:

Blue Advantage will treat **lymphatic physiologic microsurgery** (including, but not limited to, lymphatico-lymphatic bypass, lymphovenous bypass, lymphaticovenous anastomosis, autologous lymph node transplantation, and vascularized lymph node transfer), as a **non-covered benefit** and as **investigational** for all indications.

Blue Advantage will treat **liposuction (lipectomy)** for the treatment of lipedema as a **non-covered benefit** and as **investigational**.

Effective for dates of service prior to November 15, 2019:

Blue Advantage will treat **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), as a **non-covered benefit** and as **investigational**.

Blue Advantage will treat **lymphatic physiologic microsurgery** performed during nodal dissection or breast reconstruction to prevent lymphedema (including, but not limited to, the Lymphatic Microsurgical Preventing Healing Approach), as a **non-covered benefit** and as **investigational**.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OF SERVICE:

Lymphedema is an abnormal accumulation of lymph fluid in subcutaneous tissues or body cavities resulting from obstruction of lymphatic flow. Lymphedema can be subdivided into primary and secondary categories. Primary lymphedema has no recognizable etiology, while secondary lymphedema is related to a variety of causes including surgical removal of lymph nodes, post-radiation fibrosis, scarring of lymphatic channels, or congenital anomalies.

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.

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 (MRI), computed tomography (CT), 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 (ISL) guidance for staging lymphedema based on "softness" or "firmness" of the limb and the changes with 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 (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.

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 (MLD) 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 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-MLD in patients who have difficulty performing self-MLD. In patients with more advanced lymphedema after fat deposition and tissue fibrosis has occurred, palliative surgery using reductive techniques may be performed.

Lipedema

Lipedema is a rare disorder in which increased adipose tissue builds up under the skin causing non-pitting, symmetric, bilateral swelling of the lower extremities; the upper extremities can also be affected. Hands and feet characteristically do not swell. 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

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. Water-jet 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.

KEY POINTS:

This evidence review was created with a literature search of the MEDLINE database performed through July 30, 2020.

Summary of Evidence:

For individuals who have secondary lymphedema who receive physiologic microsurgery to treat lymphedema along with continued conservative therapy, the evidence includes a randomized

controlled trial, 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 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. However, because the cumulative incidence of lymphedema after breast cancer treatment approximates 30% at 3 years, longer follow-up is needed to 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.

Lipedema

The available published, peer-reviewed literature addressing liposuction for the treatment of lipedema is sparse and mainly includes case series with no comparator group. Consistent criteria to identify the ideal timing or patient characteristics for liposuction are lacking and further research with longer-term outcomes are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

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 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."

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)."

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. The document stated that "the Panel agrees that LVA and VLNT may be effective for early secondary breast cancer-related lymphedema."

U.S. Preventive Services Task Force Recommendations

Not applicable.

KEY WORDS:

Lymphedema, microsurgery, lymphatico-lymphatic bypass, lymphovenous bypass, lymphaticovenous anastomosis, autologous lymph node transplantation, vascularized lymph node transfer, VLNT, LVA, lipedema, lipectomy, liposuction

APPROVED BY GOVERNING BODIES:

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

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT codes:

There is no specific CPT code for this procedure.

15876	Suction assisted lipectomy; head and neck
15877	Suction assisted lipectomy; trunk
15878	Suction assisted lipectomy; upper extremity
15879	Suction assisted lipectomy; lower extremity
38999	Unlisted procedure, hemic or lymphatic system

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POLICY HISTORY:

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Medical Policy Group, March 2019

Medical Policy Group, July 2019

Medical Policy Group, November 2019. Available for comment November 19, 2019, through January 3, 2020.

Medical Policy Group, November 2019.

Medical Policy Group, April 2020: Updated coding to include 15878, 15879.

Medical Policy Group, September 2020

Medical Policy Group, November 2020: Updates to coding; added 15876-15877.

Medical Policy Group, January 2021

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.