

EFFECTIVE DATE: 10|01|2021

POLICY LAST UPDATED: 06|16|2021

OVERVIEW

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).

MEDICAL CRITERIA

- **Lymph node transplant**

Lymph node transplant may be considered **medically necessary** when criteria 1-4 are met:

1. Patient meets **ALL** of the following diagnostic criteria:
 - a. Signs and symptoms consistent with lymphedema as determined by a certified lymphedema therapist **AND** a diagnosis of stage \geq II lymphedema (International Society of Lymphology) (ISL)*
 - b. At least **one** of the following positive quantitative measurements:
 - i. For unilateral disease
 1. Volumetry differential (circumferential measurements and/or perometry differential) $>10\%$ (if affected extremity dominant extremity) or $>7\%$ (affected extremity is non-dominant extremity), **OR**
 2. Bioimpedance (L-Dex) differential of at least 10 units, **OR**
 3. Lymphoscintigraphy findings must show a minimum of a one-hour delayed transit time to first-level lymph nodes, axillary lymph nodes (upper extremity lymphedema) or inguinal lymph nodes (lower extremity lymphedema), **OR** a dermal back flow pattern
 - ii. For bilateral disease
 1. lymphoscintigraphy findings must show a minimum of a one-hour delayed transit time to first-level lymph nodes, axillary lymph nodes (upper extremity lymphedema) or inguinal lymph nodes (lower extremity lymphedema), **OR** dermal back flow.
2. Patient meets **ALL** of the following lymph node transplant eligibility criteria:
 - a. Patient has BMI $\leq 35\text{kg/m}^2$
 - b. Patient has completed a course of conservative treatment defined as lymphedema therapy for a minimum of 20 hours/week for 6 months. Lymphedema therapy includes:
 - i. compression therapy (bandaging/garment/gauntlet)
AND any of the following treatment modalities:
manual lymphatic drainage,
complete decongestive therapy,
use of pneumatic compression pump,
targeted exercises for lymphedema treatment
 - c. Patient has demonstrated the ability to tolerate post-surgical compression therapy and physical therapy sessions per treating lymphedema provider.
3. Patient has **NONE** of the following:
 - a. Transient lymphedema: any swelling that meets threshold for lymphedema criteria and occurs up to six months post last oncologic treatment
 - b. Lipidema without lymphatic dysfunction
 - c. Any of the following uncontrolled comorbidities:
 - i. Venous disease (DVT, superior vena cava syndrome)

- ii. Congestive heart failure (CHF)
 - iii. Medication-induced swelling
 - iv. Liver disease including but not limited to cirrhosis, hypoproteinemia
 - v. Nephropathy including end-stage renal disease
- d. Pregnancy
 - e. Dye anaphylaxis
 - f. Active infection of the affected extremity (cellulitis/erysipelas).
4. Surgery must be performed by a certified lymphedema center of excellence.
Lymph node transplant is considered **not medically necessary** if the above criteria are not met.

- **Lymphovenous bypass**

Lymphovenous bypass may be considered **medically necessary** when criteria 1-4 are met:

1. Patient meets **ALL** of the following diagnostic criteria:
 - a. Signs and symptoms consistent with lymphedema as determined by a certified lymphedema therapist **AND** a diagnosis of stage \geq I lymphedema (International Society of Lymphology (ISL))*
 - b. At least one of the following positive quantitative measurements:
 - i. For unilateral disease
 1. Volumetry differential (circumferential measurements and/or perometry differential) $>10\%$ (if affected extremity dominant extremity) or $>7\%$ (affected extremity is non-dominant extremity), **OR**
 2. Bioimpedance (L-Dex) differential of at least 10 units, **OR**
 3. Lymphoscintigraphy findings must show a minimum of a one-hour delayed transit time to first-level lymph nodes, axillary lymph nodes (upper extremity lymphedema) or inguinal lymph nodes (lower extremity lymphedema), **OR** dermal back flow
 - ii. For bilateral disease
 1. lymphoscintigraphy findings must show a minimum of a one-hour delayed transit time to first-level lymph nodes, axillary lymph nodes (upper extremity lymphedema) or inguinal lymph nodes (lower extremity lymphedema), **OR** dermal back flow.
2. Patient meets **ALL** of the following lymph node transplant eligibility criteria
 - a. Patient has BMI \leq 35kg/m²
 - b. Indocyanine green (ICG) lymphangiography findings demonstrate the presence of lymphatic channels
 - c. Patient has completed a course of conservative treatment defined as lymphedema therapy for a minimum of 20 hours/week for 6 months. Lymphedema therapy includes
 - i. includes compression therapy (bandaging/garment/gauntlet) **AND** any of the following treatment modalities:
 - manual lymphatic drainage,
 - complete decongestive therapy,
 - use of pneumatic compression pump,
 - targeted exercises for lymphedema treatment
 - d. Patient has demonstrated the ability to tolerate post-surgical compression therapy and physical therapy sessions per treating lymphedema provider.
3. Patient has **NONE** of the following:
 - a. Transient lymphedema: any swelling that meets threshold for lymphedema criteria and occurs up to six months post last oncologic treatment
 - b. Lipidema without lymphatic dysfunction
 - c. Any of the following uncontrolled comorbidities:
 - i. Venous disease (DVT, superior vena cava syndrome)
 - ii. Congestive heart failure (CHF)
 - iii. Medication-induced swelling
 - iv. Liver disease including but not limited to cirrhosis, hypoproteinemia

- v. Nephropathy including end-stage renal disease
 - d. Pregnancy
 - e. Dye anaphylaxis
 - f. Active infection of the affected extremity (cellulitis/erysipelas).
4. Surgery **must be performed** by a certified lymphedema center of excellence.
Lymphovenous bypass is considered not medically necessary if the above criteria are not met.

- **Debulking of a limb**

Debulking of a limb impacted by lymphedema may be considered medically necessary when criteria 1-4 are met:

1. Patient meets the following diagnostic criteria:
 - a. Signs and symptoms consistent with lymphedema as determined by a certified lymphedema therapist **AND** a diagnosis of stage \geq II lymphedema (International Society of Lymphology (ISL)*)
 - b. At least one of the following positive quantitative measurements:
 - i. For unilateral disease
 1. Volumetry differential (circumferential measurements and/or perometry differential) $>10\%$ (if affected extremity dominant extremity) or $>7\%$ (affected extremity is non-dominant extremity), **OR**
 2. bioimpedance (L-Dex) differential of at least 10 units
 - ii. For bilateral disease
 1. lymphoscintigraphy findings must show a minimum of a one-hour delayed transit time to first-level lymph nodes, axillary lymph nodes (upper extremity lymphedema) or inguinal lymph nodes (lower extremity lymphedema), **OR** dermal back flow.
2. Debulking eligibility criteria
 - a. Patient has BMI \leq 35kg/m²
 - b. Patient has MRI imaging findings consistent with moderate to severe fat hypertrophy
 - c. Patient must have completed a course of conservative treatment defined as lymphedema therapy or a minimum of 20 hours/week for 6 months. Lymphedema therapy includes:
 - i. compression therapy (bandaging/garment/gauntlet)

AND any of the following treatment modalities:

 - manual lymphatic drainage,
 - complete decongestive therapy,
 - use of pneumatic compression pump,
 - targeted exercises for lymphedema treatment
 - d. Patient has demonstrated the ability to tolerate post-surgical compression therapy and physical therapy sessions per treating lymphedema provider.
3. Patient has **NONE** of the following:
 - a. Transient lymphedema: any swelling that meets threshold for lymphedema criteria and occurs up to six months post last oncologic treatment
 - b. Lipidema without lymphatic dysfunction
 - c. Any of the following uncontrolled comorbidities:
 - i. Venous disease (DVT, superior vena cava syndrome)
 - ii. Congestive heart failure (CHF)
 - iii. Medication-induced swelling
 - iv. Liver disease including but not limited to cirrhosis, hypoproteinemia
 - v. Nephropathy including end-stage renal disease
 - d. Pregnancy
 - e. Dye anaphylaxis
 - f. Active infection of the affected extremity (cellulitis/erysipelas).
4. Surgery must be performed by a certified lymphedema center of excellence.
Debulking of a limb is considered not medically necessary if the above criteria are not met.

*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.

| Table 1. Recommendations for Staging Lymphedema Stage Description | 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 |

PRIOR AUTHORIZATION

Prior authorization is required for Medicare Advantage Plans and recommended for Commercial Products.

POLICY STATEMENT

Medicare Advantage Plans and Commercial Products

The following procedures may be considered medically necessary when the medical criteria above are met:

- Lymph node transplant
- Lymphovenous bypass
- Debulking of a limb

All other Lymphatic physiologic microsurgery to treat lymphedema, including, but not limited to the following procedures are not covered for Medicare Advantage Plans and not medically necessary for Commercial products as the evidence is insufficient to determine the effects of the technology on health outcomes:

- Lymphatico-lymphatic bypass
- Lymphaticovenous anastomosis
- Vascularized lymph node transfer
- Lymphatic physiologic microsurgery performed during nodal dissection or breast reconstruction to prevent lymphedema (including, but not limited to, the Lymphatic Microsurgical Preventing Healing Approach)

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate section of the Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for applicable surgery or not medically necessary/not covered benefits/coverage.

BACKGROUND

Lymphedema is a chronic condition caused by accumulation of subcutaneous fluid and fat in body tissue. It can lead to pain, disfigurement, predisposition to infection, decreased patient quality of life, and even malignant transformation. Recurrent episodes of infection (cellulitis) can cause further lymphatic damage and are

associated with increased patient morbidity and mortality. Lymphedema can be either primary or secondary in nature. Primary (congenital) lymphedema is rarer and results from congenital lymphatic dysfunction. Secondary lymphedema is more common and often occurs after injury or insult to the lymphatic system (infection, surgery, removal of lymph nodes). Any part of the body can be affected; however, in the United States, breast cancer-related lymphedema (involving the upper extremities) prevails. The risk of lymphedema is increased by factors such as increased number of nodes removed during axillary lymph node dissection (ALND), radiation, and elevated body mass index (BMI).

Treatment for lymphedema has been largely palliative in nature and aimed towards preventing disease progression. Patient education regarding skin hygiene to prevent infection and the importance of maintaining a healthy body weight (via dieting and exercise) are two central tenets of disease management. Limb elevation is often advised to decrease limb swelling. Conservative therapy includes manual lymphatic drainage (MLD), which involves movement of the lymph away from the affected limb (where there are obstructions of lymph/lymph nodes) by a certified therapist. Compression garments are often used to decrease limb girth. Patients can also be instructed to perform MLD independently. Decongestive therapy is a combination of both MLD, compressive bandaging, skin care, and other conservative management modalities. Pneumatic pumps can also be used. These devices are designed to force excess lymph fluid out of the affected limb and into central body circulation. Pneumatic pumps can be single or multi-chambered and have the potential to be programmed to apply a fixed pressure.

When conservative treatment fails, surgical intervention may be considered. Procedures can be either physiologic or ablative. Physiologic procedures help restore lymphatic flow and include lymphovenous bypass and vascularized lymph node transplant. Although shown to demonstrate physiological changes on lymphoscintigraphy, ablative procedures for treatment of lymphedema include debulking.

Vascularized lymph node transplant is a surgical procedure where autologous healthy tissue and lymph nodes are transferred to the affected limb. Different theories exist regarding the mechanism of action of VLNT. One theory posits that the transplanted lymph nodes produce growth factors to produce and bridge lymphatic pathways. Another theory proposes that the VLNT acts as a pump to move lymphatic fluid away from the affected limb and into central circulation. Thus far, despite its treatment success, no definitive mechanism has been elucidated. This treatment option has been used for patients with BCRL and others with chronic lymphedema of both the upper and lower extremity. There are various donor sites (where the autologous tissue and lymph nodes are harvested) that have been described including the groin, omentum, submental region, supraclavicular region, and thoracic area. Recipient sites (where the autologous tissue and lymph nodes are transferred) also vary and include the axilla, elbow, wrist, ankle, groin, and knee. Complications include donor site lymphedema, seroma, lymphocele, donor-site pain/paresthesia, and infection. These vary depending on area of intervention (harvest), harvest technique, and transfer location.

Lymphovenous anastomosis or lymphovenous bypass is a physiologic surgical procedure for the treatment of primary and/or secondary lymphedema. In this procedure, lymphatic fluid is diverted into the venous system through one or more anastomoses of lymphatic channels to venous drainage. This would create a physiological bypass of lymphatic fluid before it reached an area of obstruction in the affected extremity. In patients with chronic lymphedema, the accumulation of lymphatic fluid increases lymphatic pressure and causes dilation of the vessel. The pressure differential promotes flow from the lymphatic vessel to the recipient vein. There have been multiple techniques described. Compared to vascularized lymph node transplant, this surgical option has been associated with fewer risks and is considered less invasive.

Liposuction for lymphedema is usually performed under general anesthesia. Small incisions in the affected extremity(ies) are made and excess tissue is removed by vacuum aspiration. Liposuction is generally performed around the entire circumference of the limb and compression bandaging is applied post-operatively to control bleeding and limit post-operative swelling. Antibiotics are commonly prescribed. To achieve ultimate volume reduction, patients must wear a garment, which often is custom-fitted to the extremity. Patients may need to return for new garment fitting throughout the first year until a stable limb volume is achieved. The Lymphatic Education & Research Network (LE&RN) is a non-profit organization dedicated to education, research and advocacy related to lymphatic diseases (LD). LE&RN has designed an international standard for best practice multi-disciplinary care in the management of LD and has a certification process to designate LD Centers of Excellence. The criteria include diagnostic capabilities, imaging capabilities, conservative management services, assessment tools and surgical capabilities.

For patients with lymphedema who undergo debulking procedures, the evidence includes one systematic review and meta-analysis, one prospective cohort study, one retrospective review, and two case series. Three studies involve a BCRL patient-population. The systematic review and meta-analysis by Carl et al. include 105 patients with both upper extremity (n=99) and lower extremity (n=9) lymphedema. Liposuction is the technique used in three studies and suction-assisted lipectomy is used in one study. All four studies report on volume reduction (using circumferential measurements and water displacement) compared to the contralateral side. On meta-analysis, the weighted excess volume reduction in the study by Carl et al. was 96.6% (95%CI: 86.2-107). Patients were told to adhere to a post-operative compression regimen. ISL staging was used in two studies and patients undergoing debulking procedures were at least stage II. Three studies reported on quality of life measures and showed improvement in the personally important activities index, reduced anxiety and improved sense of wellbeing. The SF-36 was also used to evaluate physical function improvement in one study. Follow up time ranged from a minimum of 12 months to 38.4 months. In a study by Lee et al. in an exclusive breast cancer patient population (122/130 receiving adjuvant radiation), a 97% decrease was found in upper extremity girth. Although there was an overall decreased incidence of infection (erysipelas) observed in this cohort, de novo infection did occur in 6 of 56 patients who had never had a prior occurrence. Decrease in infection was observed across all studies assessing this outcome. In the study by Lamprou et al, cellulitis incidence decreased from a mean of 6 attacks/year to 0.3 attacks/year after surgical intervention. The overall incidence of complications was low. In one study by Brorson et al, patients who underwent liposuction and used post-operative compression were compared to patients receiving compression only (control). Patients receiving compression had decreased volume changes compared to the intervention group and scored comparatively worse on all quality of life and functional indices used (VAS, HAD, NHP, PSG).

Available literature for VLNT includes 3 systematic reviews and meta-analyses, 1 systematic review, 1 randomized control trial, and one cross-sectional study. Studies report on patients with both upper and lower extremity lymphedema. Varying types of flaps and flap harvesting techniques were described. Mean overall reduction in limb volume was observed in all studies assessing this outcome. We acknowledge that there was heterogeneity in measurement modality. Notable findings included reduction in infection incidence, functional improvement, and improved quality of life measures. In the largest study by Ozturk et al including 305 patients, there was no incidence of donor-site lymphedema. In the RCT conducted by Dionyssiou et al., the authors conclude that improvement in the abovementioned 3 parameters suggest clear superiority of surgical intervention over conservative management. In three studies, the authors reported on reduction in hours of therapy. In these studies, 78%, 60%, and 53% of patients, respectively, were able to discontinue therapy after

undergoing VLNT. Subjective improvement was observed in 84%-100% of all patients undergoing this procedure.

Available literature evaluating lymphovenous bypass as a surgical intervention for the treatment of chronic lymphedema includes three systematic reviews, two literature reviews, and one prospective cohort study. A total of 6066 patients were included in analysis; with some existing overlap between systematic and literature reviews. Studies demonstrated a consistent trend in reduction of limb volume and circumferential measurements. Furthermore, patient quality of life was exclusively assessed in the study by Salgarello et al. which utilized a validated tool, the LYMQOL in patients at multiple time points after LVA. The study supports that LVA improved health-related quality of life in patients with both UE and LE lymphedema across all four LYMQOL domains, and overall quality of life. In the systematic review by Scaglioni et al, 50-100% of all patients reported symptomatic reduction; however, only one study used a validated tool (SF-36). The study by Leung et al. consisted exclusively of a BCRL patient population and found an overall 26% mean volumetric reduction at one year. The excess volume reduction ranged from 2% to 61%. Infection was a commonly reported outcome and all studies reported a mean decrease in the number of infections patients reported post-operatively. Furthermore, 56.3% to 85% of patients were able to discontinue or decrease the class of compression post-operatively. One study by Chang et al. supports that volumetric reduction may be more robust in patients with earlier staged lymphedema (MD I-II) who had a 61% overall reduction compared to those with later-stage lymphedema (MD III-IV) who had a mean 17% reduction. Differences in assessment modality compromised the ability to compare results across studies. However, consistent modes of limb assessments were used pre-operatively and post-operatively in all studies and often consisted of either circumferential measurements or water displacement. In studies where LVA with compression was compared to compression only, more pronounced objective and subjective improvement was seen in the LVA+compression group. Complications were infrequently reported across studies. Basta et al. reported an overall rate of infection of 3.9% and lymphorrhea of 4.1%.

Primary outcomes for the above surgical procedures include change in limb circumference (compared to the contralateral extremity), symptom reduction, patient-reported quality of life, and complications. The current available evidence in conjunction with expert opinion demonstrates improved clinical outcomes for patients who are appropriately diagnosed with lymphatic disease and who do not respond to conservative treatments.

CODING

Medicare Advantage Plans and Commercial Products

Lymph node transplant and Lymphovenous bypass

There are no specific CPT codes for these procedures; report the following unlisted CPT code:

38999 Unlisted procedure, hemic or lymphatic system

Debulking of a limb:

The following codes are medically necessary when the criteria are met:

15878 Suction assisted lipectomy; upper extremity

15879 Suction assisted lipectomy; lower extremity

ICD-10 CM Diagnosis Codes for Debulking of a limb:

When medical criteria are met, claims must be filed with one of the diagnosis codes listed below.

Claims filed with all other diagnosis codes will deny as not covered.

I89.0 Lymphedema, not elsewhere classified

I97.2 Postmastectomy lymphedema syndrome

There are no specific CPT codes for the following procedures report unlisted CPT code 38999 (Unlisted procedure, hemic or lymphatic system):

Lymphatico-lymphatic bypass

Lymphaticovenous anastomosis

Vascularized lymph node transfer

Lymphatic physiologic microsurgery performed during nodal dissection or breast reconstruction to prevent lymphedema (including, but not limited to, the Lymphatic Microsurgical Preventing Healing Approach)

RELATED POLICIES

Not applicable

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Provider Update, August 2021

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DRAFT

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