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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).

Lipedema is a rare and progressive disease of subcutaneous lipodystrophy resulting in an overgrowth of fat deposits in the buttocks, hips and limbs. In some patients, overgrowth of fat deposits can compromise the lymphatic system, resulting in co-occurrence of lymphedema with lipedema (lipolymphedema).

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MEDICAL CRITERIA

Medicare Advantage Plans and Commercial Products

TREATMENT OF LYMPHEDEMA

The following procedures may be considered medically necessary as treatment for Lymphedema when filed with the appropriate ICD-10 diagnosis codes for Lymphedema or Postmastectomy lymphedema syndrome (see Coding section), AND when medical criteria are met:

- **Lymph Node Transplant**
- **Lymphovenous Bypass**
- **Debulking of a Limb**

Lymph Node Transplant

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

1. Individual 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. 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. Individual meets **ALL** of the following lymph node transplant eligibility criteria:
 - a. Individual has BMI $\leq 35\text{kg}/\text{m}^2$
 - b. Individual has completed a course of conservative treatment defined as lymphedema therapy for a minimum of 20 hours/week for 6 months.
 - i. Lymphedema therapy 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
 - c. Individual has demonstrated the ability to tolerate post-surgical compression therapy and physical therapy sessions per treating lymphedema provider.
3. Individual 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. Surgical treatment is performed by a hospital credentialed, board certified plastic surgeon.

Lymphovenous Bypass

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

1. Individual 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. Individual meets **ALL** of the following lymph node transplant eligibility criteria
 - a. Individual has BMI \leq 35kg/m²
 - b. Indocyanine green (ICG) lymphangiography findings demonstrate the presence of lymphatic channels
 - c. Individual has completed a course of conservative treatment defined as lymphedema therapy for a minimum of 20 hours/week for 6 months.
 - i. Lymphedema therapy 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. Individual has demonstrated the ability to tolerate post-surgical compression therapy and physical therapy sessions per treating lymphedema provider.
3. Individual 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. Surgical treatment is performed by a hospital credentialed, board certified plastic surgeon.

Debulking of a Limb

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

1. Individual 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. Individual has BMI \leq 35kg/m²
 - b. Individual has MRI imaging findings consistent with moderate to severe fat hypertrophy
 - c. Individual must have completed a course of conservative treatment defined as lymphedema therapy or a minimum of 20 hours/week for 6 months.
 - i. Lymphedema 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. Individual has demonstrated the ability to tolerate post-surgical compression therapy and physical therapy sessions per treating lymphedema provider.
3. Individual 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. 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
 - c. Pregnancy
 - d. Dye anaphylaxis
 - e. Active infection of the affected extremity (cellulitis/erysipelas).
4. Surgical treatment is performed by a hospital credentialed, board certified plastic surgeon.

*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 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

TREATMENT OF LIPEDEMA

Liposuction/excision/debulking for the treatment of lipedema may be considered medically necessary when all of the following criteria are met, and clinical documentation in medical record is available, including photographs:

1. Diagnosis of lipedema in the limbs, hips or buttocks as evidenced by all of the following:
 - Bilateral, symmetrical, disproportionate fatty tissue hypertrophy on the limbs based as evidenced by clinical documentation and photographs, AND
 - Evidence of cuff phenomenon (sparing of feet (if lower extremities are affected) and hands (if upper extremities are affected), AND
 - Pain and/or hypersensitivity to touch in lipedema affected areas; AND
 - Absence of pitting edema (no “pitting” when finger or thumb pressure is applied to the area of fat) (unless there is comorbid lymphedema), AND
 - Negative stemmer sign, AND
 - Documented significant physical functional impairment, e.g., difficulty ambulating or performing activities of daily living, or medical complications such as recurrent cellulitis or skin ulcerations; AND
 - Failure of limb adipose hypertrophy to respond to recommended bariatric surgery or other medically supervised weight loss measure, if class II or III obesity, AND
2. Refractory to 6 or more months of conservative medical management such as medical grade compression garments as recommended by a compression specialist, complex decongestive lymphatic therapy (also referred to as manual lymph drainage), intermittent sequential pneumatic compression, AND
3. Evaluation by the referring primary care provider or a vascular/endocrine specialist confirms that lipedema is an independent cause of functional impairment and surgery is expected to restore or improve function impairment, AND
4. Surgical treatment is performed by a hospital credentialed, board certified plastic surgeon.

Liposuction for Lipedema Completed in Stages

Liposuction for lipedema may need to be completed in stages when the total volume of liposuction exceeds clinical standards of 5000cc total aspirate during the initial procedure and may be considered medically necessary when expected to be completed within a 12 month period.

PRIOR AUTHORIZATION

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

POLICY STATEMENT

TREATMENT OF LYMPHEDEMA

Medicare Advantage Plans and Commercial Products

The following procedures may be considered medically necessary as treatment for Lymphedema when filed with the appropriate ICD-10 diagnosis codes for Lymphedema or Postmastectomy lymphedema syndrome (see Coding section), AND when medical criteria above are met:

- Lymph node transplant
- Lymphovenous bypass

- Debulking of a limb

The above procedures **may** be considered not covered for Medicare Advantage Plans and not medically necessary for Commercial Products when the above criteria are not met and when not filed with the specified diagnosis codes. Refer to the Related Policies section below.

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)

TREATMENT OF LIPEDEMA

Medicare Advantage Plans and Commercial Products

Liposuction/excision/debulking for the treatment of lipedema may be considered medically necessary when filed with the appropriate ICD-10 diagnosis codes for Adiposity or Lipomatosis (see Coding Section), AND when all of the medical criteria for lipedema, above, are met.

Liposuction for lipedema that may need to be completed in stages is medically necessary when all of the medical criteria for lipedema, above, are met.

Repeat treatment of lipedema with liposuction in areas that have been fully treated is considered 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.

Liposuction for lipedema when the medical criteria above are not met is considered not covered for Medicare Advantage Plans and Commercial Products. Refer to the Coverage section, below.

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

TREATMENT OF LYMPHEDEMA

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 individual quality of life, and even malignant transformation. Recurrent episodes of infection (cellulitis) can cause further lymphatic damage and are associated with increased individual 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. Individual 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. Individuals 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 effected 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 individuals 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 individuals 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, individuals must wear a garment, which often is custom-fitted to the extremity. Individuals 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 individuals 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 individual-population. The systematic review and meta-analysis by Carl et al. include 105 individuals 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). Individuals were told to adhere to a post-operative compression regimen. ISL staging was used in two studies and individuals 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 individual 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 individuals 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, individuals who underwent liposuction and used post-operative compression were compared to individuals receiving compression only (control). Individuals 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 individuals 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 individuals, 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 individuals, respectively, were able to discontinue therapy after undergoing VLNT. Subjective improvement was observed in 84%-100% of all individuals 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 individuals 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, individual quality of life was exclusively assessed in the study by Salgarello et al. which utilized a validated tool, the LYMQOL in individuals at multiple time points after LVA. The study supports that LVA improved health-related quality of life in individuals 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 individuals reported symptomatic reduction; however, only one study used a validated tool (SF-36). The study by Leung et al. consisted exclusively of a BCRL individual 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 individuals reported post-operatively. Furthermore, 56.3% to 85% of individuals 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 individuals 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, individual-reported quality of life, and complications. The current available evidence in conjunction with expert opinion demonstrates improved clinical outcomes for individuals who are appropriately diagnosed with lymphatic disease and who do not respond to conservative treatments.

TREATMENT OF LIPEDEMA

Lipedema is a rare and progressive disease of subcutaneous lipodystrophy resulting in an overgrowth of fat deposits in the buttocks, hips and limbs. In some patients, overgrowth of fat deposits can compromise the lymphatic system, resulting in co-occurrence of lymphedema with lipedema (lipolymphedema). Lipedema primarily affects females and is typically found to affect extremities bilaterally, lower extremities much more often than upper. Diagnosis of lipedema is based on physical characteristics including bilaterally symmetrical overgrowth in the extremities, distinction between normal and abnormal tissue at the ankle (“cuff” syndrome) and lack of overgrowth typically in the hands, feet, and trunk. Patients often report pain when pressure is applied to area of overgrowth and fat deposits as well as easy bruising in these areas. Lipedema can also affect mobility. Magnetic Resonance Imaging studies demonstrated that the subcutaneous fat appears normal but is disproportionately larger compared to other bodily areas.

Lipedema is classified into four stages by the lipedema foundation:

1. Stage 1 characterized by smooth skin with an increase of enlarged subcutaneous fat tissue
2. Stage 2 characterized by uneven skin with indentations in the fat tissue and larger mounds of fat tissue (lipomas) able to be seen and felt
3. Stage 3 characterized by large extrusion of fat tissue causing deformations especially on the thighs and around the knees
4. Stage 4 characterized by development of lipolymphedema, a condition where both lipedema and lymphedema are present in the same body region with large overhangs of tissue on legs and/or arms.

Lipedema does not respond to normal weight loss interventions and treatment consists of conservative measures to reduce lower extremity symptoms, disability, and functional limitations, to improve quality of life and prevent disease progression. The primary focus of treatment is weight normalization (if coexisting obesity is present), exercise, and decongestive lymphatic therapy. Liposuction has been proposed as a surgical treatment option for lipedema. Lipedema is often misdiagnosed as obesity or lymphedema. The pathophysiology of lipedema is unknown. Diagnosis is determined by clinical and physical findings alone, as there is no diagnostic test available.

Liposuction for lipedema in an extremity or the trunk may need to be completed in stages when the liposuction volume exceeds clinical standards for one surgery (>5000 cc total aspirate).

For individuals who are undergoing suction lipectomy for lipedema of the extremities, the evidence includes single-arm studies, case studies, consensus articles, and review articles. Additional publications not in the English language were identified but not reviewed. All studies used patients as their own controls and none of the studies compared outcomes with patients treated with decongestive therapy alone. Studies reported improvements in pain, function, and decreased need for decongestive therapy following liposuction.

In 2016, Baumgartner et al., published success rates for 85 patients who underwent liposuction treatment for lipedema at 4 and 8 years which demonstrated improvements in pain, sensitivity to pressure, bruising and functional impairments. Most patients showed similar results at the 8 year follow up compared to the initial 4 year outcome data. Most patients who had recurrence of bruising or restricted movement were between 50-60 during the initial surgery demonstrating the importance of surgical intervention in earlier stages of lipedema and in younger populations. In a follow up study at 12 years, 60 patients reported sustained improvements and overall positive outcomes similar to the 4 and 8 year measures. The study demonstrated permanent reductions in symptom severity and continued improvements in quality of life for most patients evaluated.

Wollina and Heinig (2019) reported a consecutive series of patients who had failed conservative therapy for at least 6 months. In this series, 43% of patients had stage III lipedema and follow-up by clinician interview was provided for all patients at a median of 2 years. The range of follow-up was wide. Patients reported a substantial improvement in pain on a 10 point VAS and minor to marked improvement in mobility and bruising using a 3 point scale. A strength of this study is the inclusion of consecutive patients with advanced lipedema who had previously failed conservative therapy. Limitations of this study include the potential for bias in responses to clinician interview, lack of a control group treated by continued decongestive therapy, and the limited duration of follow-up.

A 10 year retrospective, before and after study for multistage liposuction for lipedema by Kruppa et al, (2022) found that liposuction was an effective surgical option for reducing symptoms and reducing the need for potential future surgeries especially when performed in patients with lower body mass index scores or early stage diseases. A 35.7% reduction in complex decongestive therapy score was found in 106 patients who underwent large volume liposuction (mean lipoaspirate, 6355 ± 2797 ml) after 20 months. Patients reported improvement in lipedema associated symptoms including pain and functional impairments.

Given the study limitations described above, the policy is based primarily on clinical practice guidelines and recommendations as well as national standards of care. Randomized controlled trials looking at outcomes of patients undergoing Liposuction as primary method versus decongestive therapy are ongoing.

Clinical Practice and Professional Society Guidelines

The American Society of Plastic Surgeons (ASPS) has not published clinical practice guidelines for treatment of lipedema. However, they state that certain measures should be taken to ensure proper patient care and quality and safety with use of liposuction. To ensure only providers with appropriate training and expertise are credentialed, the ASPS recommends the following:

- Plastic surgery training or other formal training in liposuction methods that is recognized as sufficient by a governing medical body (e.g., American Board of Medical Specialties)
- Liposuction training as part of board-specific requirements and maintenance of certification activities
- Hospital admitting privileges

The 2003 Practice Advisory indicated that large volume liposuction (greater than 5,000 cc total aspirate) should be performed in an acute-care hospital or in a facility that is either accredited or licensed. Large volume procedures should be done in stages if the total volume is greater than 5,000 per procedure and patients should wear compression garments and stockings for several weeks postoperatively as recommended by surgical team and compression specialists.

In 2021, a consensus standard of care guideline was published by a U.S. committee of lipedema experts (Herbst, 2021). The standard of care guideline indicates that conservative (non-surgical) therapies for lipedema may help slow progression and possibly relieve symptoms but are not curative. These include nutritional guidance and weight loss programs. Long term outcomes of non-surgical and surgical treatments demonstrated improvement in quality of life and overall symptoms including reducing pain, increasing mobility and ambulation, and improving gait. Reduction surgery for lipedema is the only approach that can restore functional impairments and should be done before complications and disabilities occur. In the case of lipolymphedema, compression garments, decongestive lymphatic therapy (also referred to as manual lymph drainage) and intermittent sequential pneumatic compression may also provide a benefit to improve mobility, stance, and gait, and reduce pain. The evidence is sufficient to improve overall net health outcomes for liposuction for the treatment of lipedema in the extremities.

CODING

TREATMENT OF LYMPHEDEMA

Medicare Advantage Plans and Commercial Products

The following code(s) for lipectomy are medically necessary when the criteria above have been met and must be filed with one of the ICD-10 CM Diagnosis Codes* listed below. Claims filed with all other diagnosis

code(s) **may** deny as not covered. Please see Related Policies below when service is being performed for Gender Affirming Care.

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

I89.0 Lymphedema, not elsewhere classified

I97.2 Postmastectomy lymphedema syndrome

CPT Codes that may be used for Debulking of a Limb

15878 Suction assisted lipectomy; upper extremity

15879 Suction assisted lipectomy; lower extremity

There are no specific CPT code(s) for **Lymph Node Transplant and Lymphovenous Bypass**. Therefore, for these procedures, the following Unlisted CPT code should be reported:

38999 Unlisted procedure, hemic or lymphatic system

There are no specific CPT code(s) for the following procedures. Please use the 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)

TREATMENT OF LIPEDEMA

Medicare Advantage Plans and Commercial Products

The following CPT code(s) are medically necessary when the medical criteria above have been met and must be filed with one of the ICD-10-CM Diagnosis Codes** in the primary position listed below. Claims filed with all other diagnosis code(s) **may** deny as not covered. Please see Related Policies below when service is being performed for Gender Affirming Care.

15832 Excision, excessive skin and subcutaneous tissue (includes lipectomy); thigh

15833 Excision, excessive skin and subcutaneous tissue (includes lipectomy); leg

15834 Excision, excessive skin and subcutaneous tissue (includes lipectomy); hip

15835 Excision, excessive skin and subcutaneous tissue (includes lipectomy); buttock

15836 Excision, excessive skin and subcutaneous tissue (includes lipectomy); arm

15878 Suction assisted lipectomy; upper extremity

15879 Suction assisted lipectomy; lower extremity

**ICD-10-CM Diagnosis Codes – must be filed as primary diagnosis

E65 Localized adiposity

E88.2 Lipomatosis, not elsewhere classified

RELATED POLICIES

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Gender Affirming Care

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Unlisted Procedures

PUBLISHED

Provider Update, July 2024

Provider Update, October 2023

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