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## Liposuction for Lipedema and Lymphedema

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<b>Related Policies (if applicable)</b>
MED201.036 Bioimpedance Devices for Detection and Management of Lymphedema
SUR701.024: Surgical Treatments for Breast Cancer-Related Lymphedema
SUR708.002: Axillary Reverse Mapping for Prevention of Breast Cancer-Related Lymphedema

### Disclaimer

#### **Carefully check state regulations and/or the member contract.**

Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

### Legislative Mandates

**EXCEPTION: For Illinois only:** Illinois Public Act 103-0123 (IL HB 1384) Coverage for Reconstructive Services requires the following policies amended, delivered, issued, or renewed on or after January 1, 2025 (Individual and family PPO/HMO/POS; Student; Group [Small Group; Mid-Market; Large Group Fully Insured PPO/HMO/POS] or Medicaid), to provide coverage for medically necessary services that are intended to restore physical appearance on structures of the body damaged by trauma.

**EXCEPTION: For HCSC members residing in the state of Arkansas, § 23-99-405** related to coverage of mastectomy and reconstruction services, should an enrollee elect reconstruction after a mastectomy, requires coverage for surgery and reconstruction of the breast on which the mastectomy has been performed, surgery and reconstruction of the other breast to produce a symmetrical appearance, and prostheses and coverage for physical complications at all stages of a mastectomy, including lymphedema. This applies to the following: Fully Insured Group, Student, Small Group, Mid-Market, Large Group, HMO, EPO, PPO, POS. Unless indicated by the group, this mandate or coverage will not apply to ASO groups.

### Coverage

### **Lipedema**

Suction assisted protein lipectomy (also known as suction lipectomy and liposuction) for the treatment of lipedema, including any subsequent revisions, **may be considered medically necessary** when **ALL** the following criteria are met:

1. There is documentation of significant physical functional impairment (e.g., difficulty ambulating or difficulty performing activities of daily living) or medical complication, such as recurrent cellulitis; and
2. 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
3. The plan of care postoperatively is to continue to wear compression garments as instructed to maintain the benefits of treatment; and
4. For the diagnosis of lipedema, the individual has ALL the following clinical exam findings:
  - a. Bilateral symmetric adiposity in the extremities;
  - b. Non-pitting edema;
  - c. Negative Stemmer sign, unless the individual has coexisting lymphedema (Stemmer sign is negative when a fold of skin can be pinched and lifted at the base of the second toe or at the base of the middle finger);
  - d. Tissue in affected areas is soft to palpation;
  - e. Tissue in affected areas is tender to palpation; and
5. Submission of photographs document the affected extremities requested for treatment.

### **Lymphedema**

Suction assisted protein lipectomy (also known as suction lipectomy and liposuction) **may be considered medically necessary** in individuals with documented lymphedema when **ALL** of the following criteria are met:

1. There is documentation of significant physical functional impairment (e.g., difficulty ambulating or difficulty performing activities of daily living) or medical complication, such as recurrent cellulitis; and
2. 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
3. The plan of care postoperatively is to continue to wear compression garments as instructed to maintain the benefits of treatment; and
4. Submission of photographs document the affected extremities requested for treatment.

### **Policy Guidelines**

None.

### **Description**

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.

### **Lipedema**

Lipedema, also known as lipoedema, is a rare disorder characterized by a large amount of subcutaneous fat in the extremities. The cause is unknown but is most frequently seen in women with a family history. The exact prevalence is uncertain as it does not have a diagnosis in the International Classification of Diseases (ICD-10). Lipedema is often misdiagnosed as obesity or lymphedema.

Lipedema is typically observed in the legs and thighs without affecting the feet, and the adipose tissue is painful. The arms may also be affected without edema of the hands. Symptoms include heaviness, pain (particularly with pressure), loss of strength, easy bruising, and a reduction in daily activity levels that affects the health and quality of life of the individual. The excessive fat deposits are typically unresponsive to traditional weight loss interventions and there is no cure.

Untreated lipedema may result in secondary problems including osteoarthritis and reduced mobility. Over time, the weight of the excessive fat build-up can impair the ability to walk. Initially, the lymphatic system can cope with the increased amount of interstitial fluid, but in the later stages, secondary lymphedema (lipolymphoedema) can occur if the fatty deposits compromise the lymphatic system.

### **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 U.S. 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.

Notable differences between lipedema and lymphedema are described in Table 1.

**Table 1. Characteristics of Lipedema and Lymphedema**

Characteristics	Lipedema	Lymphedema
Pathophysiology	Genetic, primary	Defects in lymph vessels, primary or secondary
Age of onset	Puberty	Any age
Sex	Female	Both sexes
Involvement	Bilateral, mainly legs	Unilateral or bilateral, mainly arms and legs
Symmetry	Symmetric	May be asymmetric
Disproportion	Yes	No
Involvement of feet or hands	No	Yes
Easy Bruising	Yes	No

Adapted from Schavit et al. (2018) (1)

### Treatment

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.

Liposuction has been proposed as a treatment option for both lipedema and lymphedema.

### **Regulatory Status**

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

### **Rationale**

Medical policies assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

## **Lipedema**

### Clinical Context and Therapy Purpose

There is no cure for lipedema. The goal of therapy is to reduce symptoms, disability, and functional limitations, and prevent disease progression. Conservative treatment includes manual lymphatic drainage, compression stockings, intermittent pneumatic compression, skin care, and exercise. Individuals with lipedema may have obesity as a comorbidity, and diet is frequently prescribed. Conservative care may alleviate symptoms, but treatments are short-lived and may require repeat treatment within days. For individuals who do not respond to conservative treatment, liposuction may be recommended.

The purpose of liposuction in individuals who have lipedema is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this policy.

### *Populations*

The relevant population of interest is individuals with lipedema/lipoedema or lipolymphedema who have failed to respond to conservative therapy.

In stage I lipedema the skin is smooth, and the subcutaneous layer is thickened, soft, and with an even structure. In stage II lipedema the skin becomes uneven and subcutaneous nodules develop. In stage III lipedema there are bulging protrusions of fat along with tender subcutaneous tissue. In an advanced stage, sometimes referred to as stage IV lipedema, the excess fat can impair lymphatic vessel function leading to secondary lymphedema (lipolymphedema).

### *Interventions*

The therapy being considered is liposuction using specialized techniques. Tumescent infused in the subcutaneous tissues causes the fat cells to swell and vessels to constrict; micro-cannulas are then used to suction the fat. Procedures use local anesthetics in the tumescent fluid and do

not require general anesthesia. Specialized techniques for liposuction may include power-assisted, which uses a variable speed motor for reciprocating motion, laser-assisted, ultrasound-assisted, radiofrequency-assisted, and water-assisted. (2) Water-assisted liposuction (WAL) is a technique that uses pulsating jets of tumescent solution to dislodge fatty tissue with simultaneous suction of the fat and tumescent fluid. A small, randomized trial from 2007 on cosmetic indications suggests a reduction in pain and ecchymosis with WAL compared to traditional liposuction. (3)

Liposuction reduces the amount of fatty tissue but does not eliminate it, and multiple sessions may be needed.

#### *Comparators*

Conservative treatment (decongestive therapy) consists of manual lymphatic drainage, compression garments, intermittent pneumatic compression, skin care, and exercise. Diet is also used to prevent or treat obesity associated with lipedema.

#### *Outcomes*

The general outcomes of interest are symptoms, change in disease status, functional outcomes, and quality of life.

Reported outcomes for lipedema are reduction in size of extremities, circumferential measurement, restriction of movement, spontaneous pain or discomfort, sensitivity to pressure, edema/swelling, bruising, trophic skin changes, and quality of life.

#### Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies;
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought;
- Studies with duplicative or overlapping populations were excluded.

#### Systematic Reviews

The Canadian Agency for Drugs and Technologies in Health (2019) conducted a qualitative systematic review of liposuction for the treatment of lipedema. (4) The authors identified 5 uncontrolled before-and-after studies in the English language that suggested that liposuction may be effective in reducing the size of the extremities, symptoms, and functional limitations of lipedema.

The case series with over 100 patients are described in greater detail below (Tables 2 and 3).

#### Observational Studies

Schmeller et al. (2012) reported a case series of patients with lipedema who were treated between 2003 and 2009. (5) Over multiple procedures that averaged 2 hours each, a mean of 9846 mL of fatty tissue was removed, resulting in a reduction in thigh circumference of 8 cm. Out of 165 patients who had at least 6 months of follow-up and received standardized questionnaires, 112 patients (68%) returned the questionnaires, and the data could be analyzed. The patients who returned the questionnaires reported significant improvements in spontaneous pain and pain with pressure, movement, and quality of life. The need for decongestive therapy was reduced or eliminated in a majority of these patients. The authors concluded that tumescent liposuction was a highly effective treatment for lipedema with good morphological and functional long-term results.

Follow-up out to 12 years from this series was reported by Baumgartner et al. (2021). (6) Sixty patients (36%) had returned questionnaires at 4, 8, and 12 years. All of the patients who were included in the follow-up had stage I or stage II lipedema; no patients with stage III lipedema had returned questionnaires at all follow-up times. In those who returned questionnaires, improvements were maintained over the 12 years of follow-up.

Wollina and Heinig (2019) reported a consecutive series of 111 patients with advanced lipedema with pain and/or leg volume who had been treated with liposuction. (7) They reported that 7 patients had stage I lipedema, 50 patients had stage II, and 48 patients had stage III lipedema (n=105). All of the patients had either not responded to decongestive therapy for at least 6 months or had progressed. The mean reduction in fatty tissue with liposuction was 4700 mL (range, 950 to 14,250 mL), with an improvement in thigh circumference of 6 cm. Serious adverse events from treatment were noted in 1.2% of patients. At a median follow-up of 2 years, patients reported a significant reduction in pain and improvement in mobility; 16% of patients no longer needed decongestive therapy.

A prospective cohort of WAL for liposuction was reported by Witte et al. (2020). (8) The 130 patients enrolled in the study had stage I or II lipedema diagnosed by 2 specialists. No patients with advanced lipedema were included. Patients underwent weight loss, exercise, and treatment of varicose veins in addition to WAL. Manual lymphatic drainage and compression garments were worn for 8 weeks after the procedure. At a mean of 22 months after the procedure all symptoms decreased in severity, and use of conservative therapy (compression garments or manual lymphatic drainage) was reduced in these patients from 100% pre-treatment to 44% after liposuction.

Kruppa et al. (2022) completed a 10-year retrospective before-and-after study of 106 patients who underwent a total of 298 liposuctions for treatment of lipedema. (9) The authors reported that 11 patients had stage I lipedema, 61 patients had stage II, and 34 had stage III disease. A total of 65 (61.3%) patients had upper extremity involvement and the majority of patients (58.5%) had onset of lipedema symptoms occurring during puberty. Preoperative body mass index was higher in stage III patients compared to stage I and II patients. Liposuction was shown to reduce symptom severity and the need for conservative treatment, especially among patients with a body mass index  $<35 \text{ kg/m}^2$  at an early stage of disease. Thirty-seven patients

did not need to wear compression garments and 27 patients did not require any conservative treatment postoperatively.

The publication by Wollina and Heinig (2019) notes a German language study by Munch (2017) that reported an improvement of pain, bruising, mobility, and quality of life using WAL in 141 patients. (10) An English language abstract of the study indicates that out of 141 patients treated between 2010 and 2016, 71 were re-evaluated after a mean of 35.9 months. The 50% of patients who had follow-up reported improvement in the 10 complaints from 6.1 to 3.1 on a visual analog scale (VAS) and in 38.3% of cases conservative therapy was reduced or found to be more effective.

**Table 2. Summary of Key Case Series Characteristics**

<b>Study</b>	<b>Country</b>	<b>Years</b>	<b>Participants</b>	<b>Treatment Delivery</b>	<b>Follow-Up</b>
Schmeller et al. (2012), Baumgartner et al. (2021) (5, 6)	Germany	2003-2009	Patients had undergone conservative therapy for a period of years. 165 patients received standardized questionnaires. 112 patients returned the questionnaires and could be analyzed.	Liposuction under tumescent local anesthesia with a vibrating microcannula. The average time of surgery was 2 hours. The number of treatments ranged from 1 to 7 times spaced from 1 month to 1 year.	3, 4, 8, and 12 years 5 step Likert scale.
Wollina and Heinig (2019) (7)	Germany	2007-2018	111 patients with advanced lipedema with pain and/or leg volume not responding to decongestive therapy for at least 6 months.	Inpatient liposuction under tumescent local anesthesia or laser-assisted liposuction, followed by compression garments for at least 6 months.	Median of 2.0 (2.1 SD) years. Pain was measured on a 10-point VAS. Improvement in mobility and bruising was assessed with a 3 point scale.
Witte et al. (2020) (8)	Germany	2016-2019	130 patients with stage I or II lipedema diagnosed by 2 specialists were enrolled, 63 patients had follow-up.	One to 3 treatments with WAL under tumescent anesthesia following weight loss, exercise, and treatment of varicose veins when appropriate. Decongestive therapy	Median of 22 months with a standardized questionnaire with 11 items scored with a VAS.

				was performed for 8 weeks after liposuction.	
Kruppa et al. (2022) (9)	Germany	2009-2019	106 patients with lipedema who had received preoperative complex decongestive therapy for at least 6 months.	Power-assisted liposuction or WAL was utilized; the surgical goal of fat removal equivalent to approximately 6% of the patient's body weight often required megaliposuction (defined as large volume liposuction with a minimum of 4 L of pure fat or 5 L of total aspirate; 69.1% of all liposuctions met the definition of megaliposuction).	Minimum of 6 months since last liposuction (median 20 months; range, 6 to 115 months); assessed with a nonvalidated disease-related questionnaire to evaluate pre- and postoperative lipedema-associated complaints.

SD: standard deviation; VAS: visual analog scale; WAL: water-assisted liposuction.

**Table 3a. Summary of Key Case Series Results**

Study	Mean Reduction in Fatty Tissue	Mean Reduction in Limb Circumference (SD)	Spontaneous Pain (SD)	Pain with Pressure (SD)	Restriction of Movement (SD)
Schmeller et al. (2012) (5)	9846 mL	8 cm in thighs	Before: 1.88 (1.33) After: 0.37 (0.60) Effect size: 1.36 p<.001	Before: 2.91 (1.33) After: 0.91 (0.92) Effect size: 2.01 p<.001	Before: 2.03 (1.06) After: 0.91 (0.60) Effect size: 1.58 p<.001
Wollina and Heinig (2019) (7)	4700 mL (range, 950 to 14,250 mL)	6 (1.6) cm	Before: 7.8 (2.1) median After: 2.2 (1.3) p<.03		All patients reported an improvement in mobility
Witte et al. (2020) (8)	12,922 mL (2922 mL SD)		Before: 6.47±2.05 After:	Before: 7.14±1.9 After:	Before: 5.28±3.04

			1.39±1.66 p<.001	1.55±1.79 p<.001	After: 0.6±1.1 p<.001
Kruppa et al. (2022) (9)			Before (median, IQR): 80.0; 70 to 90 After: 30; 10 to 50* p<.0001	Before (median, IQR): 80; 70 to 90 After: 30; 20 to 55* p<.0001	

IQR: interquartile range; SD: standard deviation.

\*Visual analog scale of symptom severity ranging from 0 to 100 in increments of 5, with 100 indicating the greatest severity.

**Table 3b. Summary of Key Case Series Results**

Study	Quality of Life (SD)	Use of Physical Decongestive Therapy	Adverse Events	General Impairment
Schmeller et al. (2012) (5)	Before: 1.88 (1.33) After: 0.37 (0.60) Effect size: 2.95 p<.001	Before: 67 patients After: 13 of 67 had no improvement	Wound infection rate of 1.4%	
Wollina and Heinig (2019) (7)		16.4% no longer needed decongestive therapy	1.2% serious adverse events	
Witte et al. (2020) (8)		Before: 84% After: 39.7% p<.001	NR	
Kruppa et al. (2022) (9)	Before (median, IQR): 75; 40 to 82.5 After: 30; 10 to 50* p<.0001 (impairment of sexual quality of life specifically)	Reduction in the complex decongestive therapy score with a median of 37.5% (IQR, 0% to 88.8%) seen for all stages of lipedema p<.001		Before (median, IQR): 90; 80 to 100 After: 60; 30 to 82.5* p<.0001

IQR: interquartile range; NR: not reported.

\*Visual analog scale of symptom severity ranging from 0 to 100 in increments of 5, with 100 indicating the greatest severity.

### Section Summary: Lipedema

While no controlled trials were identified, the evidence on liposuction for lipedema includes various case series with over 100 patients. Studies with follow-up out to 12 years have reported improvements in pain, function, and decreased need for decongestive therapy following liposuction.

### **Lymphedema**

#### Clinical Context and Therapy Purpose

Lymphedema is a chronic condition that is managed with lifelong care. Care is aimed at improving comfort, reducing limb volume, and slowing the rate of progression. For the relatively few individuals who fail conservative treatment, surgical options may be recommended. Surgical approaches include lymphatic surgery and soft tissue reduction.

The purpose of liposuction in individuals who have lymphedema is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this policy.

#### *Populations*

The relevant population of interest is individuals with lymphedema who have failed to respond to conservative therapy or present with more advanced lymphedema with fat deposition and tissue fibrosis.

#### *Interventions*

The therapy being considered is liposuction using specialized techniques to remove the deposited fibrofatty tissue with cannulas. Tumescent infused in the subcutaneous tissues causes the fat cells to swell and vessels to constrict; micro-cannulas are then used to suction the fat. Procedures use local anesthetics in the tumescent fluid and do not require general anesthesia. Specialized techniques for liposuction may include power-assisted, which uses a variable speed motor for reciprocating motion, laser-assisted, ultrasound-assisted, radiofrequency-assisted, and water-assisted. (2) WAL is a popular technique that uses pulsating jets of tumescent solution to dislodge fatty tissue with simultaneous suction of the fat and tumescent fluid. Compression garments must be worn following liposuction to prevent the rapid reaccumulation of fibrofatty tissue.

Liposuction reduces the amount of fatty tissue but does not eliminate it, and multiple sessions may be needed.

#### *Comparators*

Conservative treatment consists of skin care, exercise and weight reduction, compression garments, manual lymphatic drainage, and in more severe cases intermittent pneumatic compression. Decongestive therapy involves intensive treatment by a health care professional for 5 days a week.

### *Outcomes*

The general outcomes of interest are symptoms, change in disease status, functional outcomes, and quality of life.

Reported outcomes for lymphedema are reduction in size of extremities, direct circumferential measurement, restriction of movement, spontaneous pain or discomfort, edema/swelling, trophic skin changes, and quality of life. Assessment of the fat layer with magnetic resonance imaging, bioimpedance spectroscopy, and perometry have also been reported.

### Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies;
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought;
- Studies with duplicative or overlapping populations were excluded.

### Systematic Reviews

A 2021 meta-analysis sponsored by the American Association of Plastic Surgeons evaluated the evidence on surgical treatment of lymphedema. (11) Pooled analysis of 2 studies (n=48) showed a 63.95% greater reduction in volume and pooled analysis of 2 studies (n=69) showed a greater reduction in volume by 895 mL for liposuction compared to compression therapy alone.

A qualitative systematic review of liposuction for lymphedema of the lower limb was published by Forte et al. (2019). (12) The authors identified 8 articles with 191 patients (4 were case reports) that met the inclusion criteria of the review. The mean duration of lymphedema ranged from 10 to 20 years. Volume reduction of greater than 50% was reported following liposuction and compression therapy, with a greater volume reduction for secondary lymphedema compared to primary lymphedema. One study reported improvement in function, quality of life, and rate of infection.

### Randomized Controlled Trials

Alamoudi et al. (2018) reported a non-blinded RCT on submental liposuction for cervical lymphedema following head and neck cancer treatment. (13) Twenty patients with cervical lymphedema were randomized into treatment with liposuction or to no treatment control. Patients filled out 2 surveys after consenting for the trial and at 6 months. Compared to the no-treatment group, patients in the liposuction group showed statistically significant improvement in patient's self-perception and subjective scoring of appearance.

### Observational Studies

Hoffner et al. (2018) reported on a series of 105 consecutive patients with secondary non-pitting lymphedema who had been treated with liposuction and compression garments at their institution between 1993 and 2012. (14) Lymphedema began at a mean of 2.9 (5.0) years after the breast cancer operation and persisted for a mean of 10 (7.4) years at the time of treatment. Criteria for liposuction included excess volume measured by plethysmography with concomitant subjective discomfort, failure of conservative treatment, no or minimal pitting as a sign of adipose tissue hypertrophy and customized to the use of compression garments preoperatively. Standardized forms were used to collect pre-, peri-, and postoperative data and measurements were conducted by the same physiotherapist and occupational therapist. The surgical procedure and post-operative management with gradual alterations in the sizing and changing of compression garments was reported in detail. Patients were followed at 0.5, 1, 2, 6, 9, and 12 months after surgery, and then annually. The preoperative excess volume was 1573 mL (range, 570 to 33,520 mL) with a ratio between the affected arm and the healthy arm of 1.5 (range, 1.2 to 2.1). The mean aspirate volume was 1831 mL (range, 650 to 3780 mL) and contained 94% fat (range, 58 to 100), resulting in a reduction in excess volume at 6 months of 107% (range, 73 to 179). The reduction in excess volume was maintained for 5 years, with a mean reduction in excess volume of 117% (range, 25 to 191) and a ratio of 0.9 (range, 0.8 to 1.4) compared to the healthy arm. The authors concluded that as long as post-operative conservative therapy is maintained, liposuction is effective for treating chronic, non-pitting arm lymphedema.

In a cohort study, Hoffner et al. (2017) assessed liposuction plus controlled compression therapy in patients with lymphedema of an arm secondary to breast cancer treatment. (15) The aim of the study is to test the hypothesis that liposuction improves health-related quality of life (HRQoL). Sixty female patients with arm lymphedema were followed for a one-year period after surgery. The 36-item short-form health survey (SF-36) was used to assess HRQoL. Patients completed the SF-36 questionnaire before liposuction, and after one, three, six, and 12 months. They reported a mean difference between affected and unaffected limbs of 1365 mL (standard error of the mean [SEM] 73) at baseline, which declined to 75 mL (SEM 35) at one month, -26 mL (SEM 40) at three months, -133 mL (SEM 40) at six months, and -213 mL (SEM 35) at one year, indicating > 100% reduction in excess volume on average. They reported that 82% (49 of 60) patients had complete resolution of their lymphedema. The adipose tissue volume removed at surgery was 1373 – 56 mL. One month after liposuction, better scores were found in mental health. After three months, an increase in physical functioning, bodily pain, and vitality was detected. After one year, an increase was also seen for social functioning. The physical component score was higher at three months and thereafter, while the mental component score was improved at three and 12 months.

In a cohort study, Lamprou et al. (2017) reported the long-term results of circumferential suction-assisted lipectomy (CSAL) in end-stage primary and secondary lymphedema of the leg. (16) Patients were treated with CSAL for unilateral chronic irreversible lymphedema of the leg (n=88). Compression therapy was resumed after surgery. Leg volumes were measured before surgery, and at one, six, 12 and 24 months after the procedure. A total of 47 patients with primary lymphedema had a median preoperative volume difference between affected and

unaffected legs of 3686 (interquartile range [IQR]), 2851 to 5121) mL. Two years after surgery, this volume difference was reduced to 761 ml, a 79% reduction. In the 41 patients treated for secondary lymphedema, the median preoperative volume difference was 3320 (IQR 2533-4783) ml, decreasing after two years to -38 ml indicating a 100% reduction in excess volume on average. The preoperative volume difference and the sex of the patient significantly influenced the final outcome after two years. The outcome was not related to body mass index (BMI) or other patient characteristics. Subsequent continuous compression, weight control, physical exercise, and lifestyle alterations are still needed to achieve the maximum effect.

Karlsson et al. (2023) presented the long-term outcomes of all patients treated with liposuction and controlled compression therapy (CCT) for lower extremity lymphedema (LEL) who were followed up for 5 years. (17) Sixty-seven LEL patients underwent liposuction and CCT. Thirty-six patients had primary lymphedema and 31 patients had secondary lymphedema. The outcomes included excess leg volume over a follow-up period of 5 years. Any association between patient characteristics and treatment outcomes was analyzed. The preoperative excess volume prior was 3515 mL (interquartile range [IQR]: 2225-5455 mL), and the volume ratio to the unaffected leg was 1.35 (IQR: 1.25-1.53). One year after treatment, the excess volume decreased by 101% (IQR: 84-116). The decrease in excess volume continued during the 5-year follow-up, and at the end of the study, the excess volume had decreased by 115% (IQR: 98-124). No major complications were noted. Authors concluded that liposuction and CCT are safe and effective procedures for removing excess adipose tissue and normalizing the leg volume in patients with late-stage LEL. When no satisfactory results are obtained with conservative methods, such as complex decongestive therapy, and there is no or minimal pitting on limb examination, excess adipose tissue is present, and liposuction can be considered.

#### Section Summary: Lymphedema

Lymphedema can be associated with hypertrophy of fat cells due to the excessive fluid buildup with non-pitting of the skin. The evidence identified on liposuction for lymphedema includes case reports and case series, a few small, controlled trials, and uncontrolled observational studies. Although durability was not assessed, a systematic review of the controlled trials for arm lymphedema suggests a greater reduction in volume compared to compression alone. Observational studies with follow-up out to 5 years have found that liposuction, combined with postoperative compression therapy, effectively reduces excess limb volume in patients with lymphedema resistant to conservative treatment.

#### **Summary of Evidence**

For individuals with lipedema who receive liposuction, the evidence includes case series and several before- and after-treatment studies that suggest that liposuction may reduce pain and improve quality of life (QOL) at up to 12-year follow-up. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with lymphedema who receive liposuction, the evidence includes small, controlled trials and uncontrolled observational studies that suggest that liposuction, combined with postoperative compression therapy, effectively reduces excess limb volume in patients

with lymphedema resistant to conservative treatment. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

### **Practice Guidelines and Position Statements**

#### American Association of Plastic Surgeons

A 2021 consensus document sponsored by the American Association of Plastic Surgeons evaluated the evidence on surgical treatment of lymphedema. (11) 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.

#### International Society of Lymphology

In 2020, the International Society of Lymphology published a consensus document on the diagnosis and treatment of peripheral lymphedema. (18) 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.

#### 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. (19)

#### National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence (NICE) issued clinical guidance addressing the use of liposuction for chronic lymphedema in 2022. (20) 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. Patient 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. (21) They recommend liposuction for lipedema should be used only in the research setting because the efficacy and safety data for liposuction in lipedema is inadequate.

### **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 Number	Trial Name	Planned Enrollment	Completion Date
<b><i>Ongoing</i></b>			
NCT04272827	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 2025

NCT: national clinical trial.

## Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	15876, 15877, 15878, 15879
HCPCS Codes	None

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## **Centers for Medicare and Medicaid Services (CMS)**

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <<https://www.cms.hhs.gov>>.

## **Policy History/Revision**

<b>Date</b>	<b>Description of Change</b>
05/15/2025	<p>New medical document originating from SUR701.024. Coverage for lipedema was updated to include criteria on Stemmer sign: "Suction assisted protein lipectomy (also known as suction lipectomy and liposuction) for the treatment of lipedema, including any subsequent revisions, may be considered medically necessary when ALL the following criteria are met:</p> <ol style="list-style-type: none"><li>1. There is documentation of significant physical functional impairment (e.g., difficulty ambulating or difficulty performing activities of daily living) or medical complication, such as recurrent cellulitis; and</li><li>2. 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>3. The plan of care postoperatively is to continue to wear compression garments as instructed to maintain the benefits of treatment; and</li><li>4. For the diagnosis of lipedema, the individual has <u>ALL</u> the following clinical exam findings:<ol style="list-style-type: none"><li>a. Bilateral symmetric adiposity in the extremities;</li><li>b. Non-pitting edema;</li><li>c. Negative Stemmer sign, unless the individual has coexisting lymphedema (Stemmer sign is negative when a fold of skin can be pinched and lifted at the base of the second toe or at the base of the middle finger);</li><li>d. Tissue in affected areas is soft to palpation;</li><li>e. Tissue in affected areas is tender to palpation; and</li></ol></li><li>5. Submission of photographs document the affected extremities requested for treatment."</li></ol>

	<p>Coverage for lymphedema was updated from experimental, investigational and/or unproven to: "Suction assisted protein lipectomy (also known as suction lipectomy and liposuction) may be considered medically necessary in individuals with documented lymphedema when ALL of the following criteria are met:</p> <ol style="list-style-type: none"><li>1. There is documentation of significant physical functional impairment (e.g., difficulty ambulating or difficulty performing activities of daily living) or medical complication, such as recurrent cellulitis; and</li><li>2. 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>3. The plan of care postoperatively is to continue to wear compression garments as instructed to maintain the benefits of treatment; and</li><li>4. Submission of photographs document the affected extremities requested for treatment."</li></ol>
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