Medical Policy



Blue Cross Blue Shield Blue Care Network of Michigan

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*Current Policy Effective Date: 3/1/25 (See policy history boxes for previous effective dates)

Title: Lipedema-Surgical Treatments

Description/Background

LIPEDEMA

Lipedema is a rare disorder of adipose tissue of the extremities that primarily affects females. It does not have an ICD-10 designation and may be misdiagnosed as obesity or lymphedema. Clinicians treating patients with this disorder believe it is a distinct entity that can be differentiated from obesity and lymphedema, although it may progress to involve the venous and lymphatic systems, which increases the difficulty of diagnosis. In the majority of the cases, lipedema affects the lower limbs, leaving the ankles and feet unaffected. There is usually minimal pitting edema. The typical presentation is of a woman with bilateral "stovepipe" enlargement of the legs without involvement of the feet, with a sharp demarcation between normal and abnormal tissue at the top of the ankle, referred to as the "cuff sign." There may also be symmetrical involvement of the legs is extremely rare. There is no preventive or curative treatment available.

The diagnosis of lipedema is clinical. Chief symptoms are pain, tenderness, fatigue, and difficulty in ambulation. There are no confirmatory diagnostic tests. The pathogenesis is unknown, but it is thought to have a genetic predisposition. There is a spectrum of severity, arbitrarily divided into four stages: Stage 1 is characterized by an even skin surface with an enlargement of the hypodermis; Stage 2 is characterized by an uneven skin pattern with the development of palpable, nodular changes in the subcutaneous fat; in Stage 3 there are larger growths of nodular fat causing severe contour deformity of the thighs and around the knee; Stage 4 is described as lipolymphedema.¹

TREATMENT

The standard non-surgical therapy for lipedema is complete or complex decongestive therapy (CDT). CDT consists of several possible approaches, including manual lymph drainage (a

massage technique), compression therapy, and physical mobilization. Manual lymphatic drainage, compression stockings, intermittent pneumatic compression, skin care, and exercise are often used to control pain and symptoms. Diet is also used to prevent or treat obesity associated with lipedema. Patients with lipedema are advised to avoid weight gain. Obesity and "yo-yo" dieting have been shown to exacerbate lipedema. Even with conservative and supportive treatments, the disease may progress, and further treatment may be necessary.

Indications for surgical treatment are primarily pain and functional disability, which can be subjective and do not always correlate with external appearance. The goal of treatment is to reduce pain and improve mobility by surgical removal of the nodular fatty abnormalities in symptomatic patients who have failed conservative treatment. Surgical options include liposuction (several techniques have been used) and a combination of liposuction and surgical excision (surgical removal of large deposits of affected tissue and overlying skin). When the abnormalities are extensive, multiple sessions of liposuction are necessary because of limitations in the amount of tissue that can be removed safely at one session. Patients may require ongoing conservative treatment postoperatively.

Regulatory Status

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

Medical Policy Statement

The safety and effectiveness of suction assisted lipectomy and surgical removal of excessive abnormal adipose tissue by excision involving the arms, legs, trunk and buttocks has been established for selected patients. It may be considered a useful therapeutic option when indicated.

All surgical interventions should be performed by hospital credentialed, board certified plastic surgeons. Photographs should accompany all requests.

Inclusionary and Exclusionary Guidelines

Inclusions:

Liposuction/excision/debulking for lipedema of the **extremities** may be a therapeutic option when **ALL** of the following criteria are met.:

- The diagnosis of lipedema can be documented by clinical exam and photography on the basis of all of the following:
 - Typical appearance of extremity involvement with thickened subcutaneous fat in the affected extremities bilaterally and symmetrically:
 - Pain and/or hypersensitivity to touch in lipedema affected areas
 - History of easy bruising or bruising without apparent cause in lipedema affected areas

- Tenderness and nodularity of fat deposits in lipedema affected areas (dimpled or orange peel texture)
- Documentation of significant physical functional impairment (e.g., difficulty ambulating or difficulty performing activities of daily living) or medical complications such as recurrent cellulitis or skin ulcerations.
- A failed response to three or more consecutive months of conservative management (compression or manual therapy); and
- Lack of improvement on lipedema affected areas with weight loss
- Lack of improvement of swelling with limb elevation
- Absence of pitting edema (no "pitting" when finger or thumb pressure is applied to the area of fat) (unless there is comorbid lymphedema)

Liposuction for lipedema of the **trunk** may be a therapeutic option when **ALL** of the following criteria are met:

- The diagnosis of lipedema can be documented by clinical exam and photography on the basis of all of the following:
 - Pain and/or hypersensitivity to touch in lipedema affected areas
 - History of easy bruising or bruising without apparent cause in lipedema affected areas
 - Tenderness and nodularity of fat deposits in lipedema affected areas (dimpled or orange peel texture)
- A failed response to three or more consecutive months of conservative management (compression or manual therapy); and
- Lack of improvement of weight loss on lipedema affected areas

Exclusions:

- Liposuction/excision/debulking for indications other than lipedema and/or lymphedema (reference lymphedema-surgical treatment policy) that do not meet criteria is considered cosmetic and therefore not covered.
- Liposuction/excision/debulking of excess adipose tissue or excessive subcutaneous skin for the diagnosis of lipedema involving the head and neck area.

CPT/HCPCS Level II Codes (Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)

Established codes:						
15832	15833	15836	15877	15878	15879	
15834	15835	38999*	99199*			

*May be used when criteria is met

Other codes (investigational, not medically necessary, etc.):

15839 15876

Note: Individual policy criteria determine the coverage status of the CPT/HCPCS code(s) on this policy. Codes listed in this policy may have different coverage positions (such as established or experimental/investigational) in other medical policies.

Rationale

Rapprich et al (2011) studied the effectiveness of the removal of the hypertrophic fatty tissue of lipedema using advanced liposuction techniques, which utilize vibrating microcannulas under tumescent local anesthesia.² Twenty-five patients were examined before and six months after liposuction. The data included measurements of the volume of the legs and several parameters of typical pain and discomfort. These parameters were measured using visual analogue scale (VAS, scale 0-10). The volume of the leg was reduced by 6.99%. Pain, as the predominant symptom in lipedema, was significantly reduced from 7.2 ± 2.2 to 2.1 ± 2.1 (p < 0.001). Quality of life as a measure of the psychological strain caused by lipedema improved from 8.7 ± 1.7 to 3.6 ± 2.5 (p < 0.001). Other parameters also showed a significant improvement and the over-all severity score improved in all patients.

Schmeller et al (2012) studied the longer-term effect of liposuction on the appearance (body shape) and associated complaints.³ A total of 164 patients who had undergone conservative therapy over a period of years, were treated by liposuction under tumescent local anesthesia with vibrating microcannulas. In a monocentric study, 112 could be reevaluated with a standardized questionnaire after a mean of 3 years and 8 months (range 1 year and 1 month to 7 years and 4 months) following the initial surgery and a mean of 2 years and 11 months (8 months to 6 years and 10 months) following the last surgery. All patients showed a distinct reduction of subcutaneous fatty tissue (average 9846 mL per person) with improvement of shape and normalization of body proportions. Additionally, they reported either a marked improvement or a complete disappearance of spontaneous pain, sensitivity to pressure, edema, bruising, restriction of movement and cosmetic impairment, resulting in an increase in quality of life; all these complaints were reduced significantly (P<0.001). Patients with lipedema stage II and III showed better improvement compared with patients with stage I. Physical decongestive therapy could be either omitted (22.4% of cases) or continued to a much lower degree. No serious complications (wound infection rate 1.4%, bleeding rate 0.3%) were observed following surgery.

Dadras and colleagues 2017 studied the outcomes of liposuction used as a treatment for lipedema on 25 patients who underwent 72 liposuction procedures and completed a standardized questionnaire.⁴ Lipedema-associated complaints and the need for combined decongestive therapy (CDT) were assessed for the preoperative period and during 2 separate postoperative follow-ups using a visual analog scale and a composite CDT score. The mean follow-up times for the first postoperative follow-up and the second postoperative follow-up were 16 months and 37 months, respectively. Patients showed significant reductions in spontaneous pain, sensitivity to pressure, feeling of tension, bruising, cosmetic impairment, and general impairment to quality of life from the preoperative period to the first postoperative follow-up. A comparison of the preoperative period to the last postoperative follow-up, after 4 patients without full preoperative CDT were excluded from the analysis, indicated that the need for CDT was reduced significantly. An analysis of the different stages of the disease also indicated that better and more sustainable results could be achieved if patients were treated in earlier stages.

In 2017, Reich-Schupke et al developed guidelines on the diagnosis and management of lipedema, supported by the German Society of Phlebology (DGP).⁵ Their recommendations

are based on a systematic literature search and the consensus of eight medical societies and working groups. The guidelines state that the diagnosis is established on the basis of medical history and clinical findings. Characteristically, there is a localized, symmetrical increase in subcutaneous adipose tissue in arms and legs that is in marked disproportion to the trunk. Other findings include edema, easy bruising, and increased tenderness. Further diagnostic tests are usually reserved for special cases that require additional workup. Lipedema is described as a chronic, progressive disorder marked by the individual variability and unpredictability of its clinical course. Treatment consists of four therapeutic mainstays that should be combined as necessary and address current clinical symptoms: complex physical therapy (manual lymphatic drainage, compression therapy, exercise therapy, and skin care); liposuction and plastic surgery; diet; and physical activity, as well as psychotherapy if necessary. Surgical procedures are indicated if symptoms persist despite thorough conservative treatment, or if there is progression of clinical findings and/or symptoms. If present, morbid obesity should be therapeutically addressed prior to liposuction.

Wollina et al (2019) reported on 111 patients mostly with advanced lipedema treated by a lowvolume microsuction cannula technique between 2007 and 2018.⁶ The median age of the patients was 44 years. Eighty percent of patients had at least one comorbidity. There was an association of longstanding and advanced disease to obesity and diseases of the metabolic syndrome-spectrum. The median total amount of lipoaspirate was 4,700 ml, with a range of 950-14,250 ml. The median reduction of limb circumference was 6 cm. The median pain level before treatment was 7.8 and 2.2 at the end of the treatment. An improvement of mobility was achieved in all patients. Bruising was also reduced. Serious adverse events were observed in 1.2% of procedures, the infection rate was 0% and the bleeding rate was 0.3%. The authors concluded that liposuction is an effective treatment for painful lipedema; however, they recommended the procedure be performed only in specialized centers.

Peprah and MacDougall (2019) in an assessment of surgery for lipedema by the Canadian Agency for Drugs and Technologies in Health (CADTH) reached the following conclusions: "Evidence of limited quality from five uncontrolled before-and-after studies suggests that liposuction may be effective in reducing the size of the extremities and complaints associated with lipedema such as spontaneous pain, easy bruising, sensitivity to pressure, impairment in quality of life, restrictions to mobility, edema, feeling of tension and general impairment. The findings have to be interpreted with caution, given that they are from single arm, non-randomized studies based on patients' self-assessment data collected using tools that have not been validated for the assessment lipedema-related complaints. One clinical practice guideline recommends tumescent liposuction, performed by a skilled healthcare professional at a specialized facility, as the treatment of choice for patients with a suitable health profile and/or inadequate response to conservative and supportive measures. The strength of the recommendations in the clinical guidelines and links to supporting evidence were not provided."⁷

Podda et al (2021) evaluated the efficacy and safety of liposuction compared to standard decongestive therapy (CDT).¹⁰ LIPLEG is a randomized controlled multicenter investigatorblinded trial. Women with lipedema (n=405) without previous liposuction will be allocated 2:1 to liposuction or CDT. The primary outcome of the trial is leg pain reduction by \geq 2 points on a visual analogue scale ranging 0-10 at 12 months on CDT or post-completion of liposuction. Secondary outcomes include changes in leg pain severity, health-related quality of life, depression tendency, hematoma tendency, prevalence of oedema, modification physical therapy scope, body fat percentage, leg circumference and movement restriction. The primary analysis bases on intention-to-treat. Success proportions are compared using the Mantel-Haenszel test stratified by lipedema stage at a 5% two-sided significance level. If this test is statistically significant, the equality of the response proportions in the separate strata is evaluated by Fisher's exact test in a hierarchical test strategy. The authors concluded that surgical treatment of lipedema is safe and effective to reduce pain and other lipedema-related health issues.

SUMMARY OF EVIDENCE

A small number of retrospective cohort studies from Europe suggest that lipedema is a rare but distinct clinical entity, which can be accompanied by disabling symptoms that can be relieved by removal of abnormal fatty tissue by liposuction or a combination of liposuction and surgical excision. A variety of liposuction techniques have been used. The assessment of clinical improvement is more subjective than objective, but improvement in symptoms appears to be durable for up to 5 years. There are many unanswered questions regarding who should be a candidate for treatment, the extent of treatment, the potential complications, and the duration of the therapeutic effect. Discussion with experts in the United States confirm these observations but also confirm that careful patient selection is important, that parameters for surgical treatment are evolving, and that treaters should be board-certified Plastic Surgeons credentialed for performing liposuction by the hospital or health care system in which they work.

SUPPLEMENTAL INFORMATION

PRACTICE GUIDELINES AND POSITION STATEMENTS

National Institutes of Health Rare Disease Information⁸

Under the Genetic and Rare Disease Information section, NIH states "There is no one effective treatment for lipedema. Management to alleviate symptoms and prevent progression involves exercise, diet and nutrition, emotional support, and management of co-existing health problems that may cause leg-swelling. The main conservative treatment is complete decongestive therapy (also called complex decongestive therapy, or CDT). CDT combines several approaches including manual lymph drainage (a message technique), compression therapy, and physical mobilization. Surgery may be considered if conservative and supportive therapies are not effective. Surgical options may include liposuction using specialized techniques for lipedema (such as water jet-assisted liposuction) and excision (surgical removal of large deposits of affected tissue).

Dutch Society of Dermatology and Venereology⁹

In 2016, the DSDV created guidelines on lipedema using the International Classification of Functioning, Disability and Health of the World Health Organized. Recommendations included ensuring early detection and an individually outlined follow-up, the committee advises the use of a minimum data set of (repeated) measurements of waist circumference, circumference of involved limbs, body mass index and scoring of the level of daily practice and psychosocial distress. Promotion of a healthy lifestyle with individually adjusted weight control measures, graded activity training programs, edema reduction, and other supportive measures are pillars of conservative therapy. Tumescent liposuction is the treatment of choice for patients with a suitable health profile and/or inadequate response to conservative and supportive measures.

Ongoing and Unpublished Clinical Trials

Currently unpublished trial that might influence this review is listed in Table 1.

Table 1. Summary of Key Trials

NCT No	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT04272827	Evaluation between surgical therapy of Lipedema compared to complex physical decongestive therapy alone	450	Jul 2025
NCT05284266	The national lipedema study—standard treatment versus liposuction	220	Dec 2027

NCT: national clinical trial

Government Regulations National:

No NCD found for surgical treatments for lipedema.

Local:

No LCD found for surgical treatments for lipedema.

Medicare lists facility and non-facility fees for listed codes along with RVUs.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

• Lymphedema—Surgical Treatments

References

- 1. Buck DW, Herbst KL. Lipedema: a relatively common disease with extremely common misconceptions. Plast Reconstr Surg Glob Open. 2016;4(9):e1043.
- 2. Rapprich S. Dingler A, and Podda M. Liposcution is an effective treatment for lipedema results of a study with 25 patients. Jan 2011.J Dtsch Dermatol Ges.9(1):33-40.
- 3. Schmeller W, Hueppe M, and Vollrath-Meier I. Tumescent liposuction in lipedema yields good long-term results. Jan 2012. Br J Dermatol. 166(1):161-168.
- 4. Dadras M, Mallinger P, Corterior C, et al. Liposuction in the treatment of lipedema: a longitudinal study. Jul 2017. 44(4):324-331.

- 5. Reich-Schupke S, Schmeller W, Brauer W, et al. Guidelines for lipedema. Jul 2017. J Dtsch Dermatol Ges. 15(7):758-767.
- 6. Wollina U and Heining B. Treatment of lipedema by low-volume micro-cannular liposuction in tumescent anesthesia: results in 111 patients. Mar 2019. Clin cosmet Investig Dermatol. 32(2):e12820.
- 7. Peprah K, and MacDougall D. Liposuction for the treatment of lipedema: a review of clinical effectiveness and guidelines. Jun 2019. CADTH Rapid Response Report: Summary with Critical Ap[praisal. Ottawa. ON: Canadian Agency for Drugs and Technologies in Health.
- 8. National Institutes of Health. Genetic and Rare Disease Information. Lipedema. Available at: <u>https://rarediseases.info.nih.gov/diseases/10542/lipedema</u>. Accessed November 2024.
- 9. Halk A, and Damstra R. First Dutch Guidelines on lipedema using the international classification of functioning, disability ad health. Apr 2016. Phlebology.0(0): 1-8.
- 10. Podda M, Kovacs M, Hellmich M, et al. A randomized controlled multicenter investigator blinded clinical trial comparing efficacy and safety of surgery versus complex physical decongestive therapy for lipedema (LIPLEG). Rand Controlled Trial. Oct 2021; 22(1): 758.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through November 2024, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
3/1/21	2/25/21		Joint policy established. 3/10/21: added codes 15834 and 15835 per discussion with committee members due to these codes represent extremities not trunk area.
3/1/22	12/14/21		Routine policy maintenance, no change in policy status.
3/1/23	12/20/22		Added coverage of trunk lipedema with criteria. Code 15877 now established. No new literature found, routine policy maintenance.
3/1/24	12/19/23		Routine policy maintenance, no change in policy status. Vendor managed: N/A (ds)
3/1/25	12/17/24		Updated rationale, added reference 10, no change in policy status. Vendor managed: N/A (ds)

Next Review Date: 4th Qtr. 2025

Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN:	Revised:
BCBSM:	Revised:

BLUE CARE NETWORK BENEFIT COVERAGE POLICY: LIPEDEMA-SURGICAL TREATMENTS

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Per policy criteria
BCNA (Medicare Advantage)	See government section
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.
- Duplicate (back-up) equipment is not a covered benefit.