

UnitedHealthcare® Community Plan Medical Policy

Liposuction for Lipedema (for Kentucky Only)

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Ü Instructions for Use

| Table of Contents | Page |
|-------------------------------------|---------------------------------------|
| Application | |
| Coverage Rationale | · · · · · · · · · · · · · · · · · · · |
| Definitions. | |
| Applicable Codes | |
| Description of Services | 3 |
| Clinical Evidence | |
| U.S. Food and Drug Administration | - |
| References | - |
| Policy History/Revision Information | |
| Instructions for Use | |
| <u> </u> | |

Related Policies

- Bariatric Surgery (for Kentucky Only)
- Cosmetic and Reconstructive Procedures (for Kentucky Only)
- Panniculectomy and Body Contouring Procedures (for Kentucky Only)

Application

This Medical Policy only applies to the state of Kentucky.

Coverage Rationale

Liposuction for Lipedema is considered reconstructive and medically necessary to treat <u>Functional Impairment</u> when all the following criteria are met:

- A diagnosis of <u>Lipedema</u> that meets the following criteria:
 - Absence of pitting edema from Lipedema; and
 - Bilateral and symmetrical manifestation with minimal involvement of the feet; and
 - Disproportionate adipocyte hypertrophy of the affected extremity; and
 - o Photographs of the area to be treated that document disproportional fat distribution consistent with diagnosis; and
 - Failure of the limb adipose hypertrophy to respond to recommended bariatric surgery or other medically supervised weight loss modalities, if Class II or III Obesity; and
 - o Negative Stemmer Sign; and
 - Pressure induced pain and tenderness on palpation and
- Failure to respond to 3 or more months of Conservative Treatment (compression or manual therapy); and
- Treatment plan includes all the following:
 - Assessment by the referring primary care provider or a specialist in vascular conditions (different from the treating surgeon) confirms that Lipedema is an independent cause of the Functional Impairment (interference with activities of daily living) and the surgery is expected to restore or improve the Functional Impairment; and
 - Documentation that the liposuction for the extremity or trunk in its entirety will take place within a 12-month period following the initial surgical treatment (unless medically contraindicated); and
 - When more than one procedure is necessary on the same region of the extremity and/or trunk (e.g., anterior or posterior of the trunk, upper and lower area of the extremity), documentation that the liposuction volume exceeds a clinically acceptable amount for one surgery (more than 5000 cc total aspirate); and
 - The postoperative plan of care is to continue to wear compression garments as instructed and continue Conservative Treatment

Note: Quality evidence does not support the superiority of one liposuction technique/approach (such as water-assisted or high-volume liposuction) over another technique/approach for Lipedema.

Liposuction for Lipedema is not reconstructive and/or medically necessary for the following:

- When performed for cosmetic purposes (i.e., procedures or services that change or improve appearance without significantly improving Functional Impairment); or
- When performed on the trunk and/or extremity that was previously treated in its entirety

Definitions

Class II or III Obesity: The National Heart, Lung, and Blood Institute (NHLBI) Practical Guide Identification, Evaluation, and Treatment of Overweight and Obesity in Adults classifies the ranges of BMI in adults as follows:

- < 18.5 Underweight
- 18.5 to 24.9 kg/m² Normal Weight
- 25-29.9 kg/m² Overweight
- 30-34.9 kg/m² Obesity Class I
- 35-39.9 kg/m² Obesity Class II
- > 40 kg/m² Obesity Class III

The American Society of Metabolic and Bariatric Surgeons (ASMBS; Pratt et al., 2018), classifies severe obesity in adolescents as follows:

- Class II obesity 120% of the 95th percentile in weight or a BMI of 35-39.9 kg/m², whichever is lower*
- Class III obesity 140% of the 95th percentile in weight or a BMI of ≥ 40 kg/m², whichever is lower

Conservative Treatment: Conservative Treatment includes non-surgical interventions, which encompass adhering to a healthy lifestyle through diet and exercise, complete decongestive therapy (i.e., bandaging, compression garments, manual lymphatic drainage,) and emotional, psychological, and social support (Peled, 2016).

Functional or Physical or Physiological Impairment: A Functional or Physical or Physiological Impairment causes deviation from the normal function of a tissue or organ. This results in a significantly limited, impaired, or delayed capacity to move, coordinate actions, or perform physical activities and is exhibited by difficulties in one or more of the following areas: physical and motor tasks; independent movement; performing basic life functions.

Lipedema: An adipose tissue disorder affecting nearly one in nine adult women. It is characterized as a disproportionate deposit of subcutaneous fat on the buttocks, hips and lower extremities and may affect the upper extremities (Buck, 2017). Symptoms may include physical Functional Impairment (e.g., difficulty ambulating or performing activities of daily living), pain and tenderness upon pressure, bilateral and symmetrical manifestation with minimal involvement of the feet, bruising, minimal pitting edema, negative Stemmer Sign, and failure to respond to extreme weight loss modalities (Wold, 1951). Additional symptoms may include hypothermia of the skin, telangiectasias, or swelling that worsens with orthostasis during summer months (Herbst, 2012).

Stemmer Sign: Stemmer's test is a physical examination finding used to diagnosis lymphedema. Upon physical examination if the examiner cannot pinch the skin of the dorsum of the foot or hand, then the test is considered a positive finding, which is associated with lymphedema (Goss, 2019).

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

| CPT Code | Description |
|----------|---|
| 15877 | Suction assisted lipectomy; trunk |
| 15878 | Suction assisted lipectomy; upper extremity |
| 15879 | Suction assisted lipectomy; lower extremity |

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^{*}Also as defined by the American Heart Association (Kelly et al., 2013).

| Diagnosis Code | Description |
|----------------|---------------------------------------|
| E65 | Localized adiposity |
| E88.2 | Lipomatosis, not elsewhere classified |

Description of Services

Lipedema (also known as Lipohyperplasia dolorosa) is a chronic, progressive disorder and is characterized by fat tissue build up in the arms, legs, thighs, and buttocks. The exact cause of Lipedema is largely unknown however it most commonly appears in women during puberty, pregnancy and menopause. It is often misdiagnosed as lymphedema or obesity, and there are currently no definitive diagnostic tests. Lipedema management aims to minimize symptoms, prevent progression, and improve function and include conservative and surgical (e.g., liposuction) treatments. Conservative Treatment includes promoting a healthy lifestyle through diet and exercise, complete decongestive therapy (i.e., manual lymphatic massage, bandaging, and skin care) as well as emotional, psychological, and social support. When Conservative Treatment fails, liposuction may be considered. Commonly used liposuction methods for Lipedema are tumescent anesthesia (TA) liposuction, and water assisted liposuction (WAL). Treatment may improve functionality, pain, swelling, physical appearance, and quality of life. Depending on the volume to be removed, serial procedures may be required for each extremity or for the trunk. In addition, postoperatively, patients often need to continue Conservative Treatment and avoid weight gain to maintain the results (Peled, 2016; Peprah and MacDougall, 2019). Liposuction is considered permanent, as the fat cells are removed (ASPS).

Clinical Evidence

In a 2024 meta-analysis, Amato et al. evaluated the effectiveness of liposuction for treatment of lipedema, specifically if it should be recommended as the first-line treatment. Seven articles comprised of 451 patients were included and the primary outcomes assessed were post-operative pain, bruising, QoL, edema/swelling, and mobility impairment. Also evaluated were the necessity for post-operative conservative therapy and safety (including complications or adverse events). All selected studies were conducted in Europe. Follow up times ranged from 3 months to 12 years. The results showed a substantial decrease in spontaneous pain across all studies. Only three of the included articles examined the impact on edema and swelling and these also showed a significant decrease in edema scores. Four studies evaluated bruising and also showed significant reduction. In the four studies that evaluated improved mobility, there were also significant improvement. There were five evaluating QoL which also showed significant improvement. Improvements in these parameters were consistent across all measurement tools. Four studies showed the need for continued conservative therapy in approximately 51%. Safety reporting was variable and four studies reported this. The most common were temporary hemoglobinemia, temporary burning sensation. Other infrequent events included mild arm-vein phlebitis, microscopic pulmonary fat embolism, acute pulmonary edema and wound infection and bleeding. The authors concluded that liposuction significantly lowers post-operative complaint scores for spontaneous pain, edema, bruising, mobility impairment, and QoL impairment. These findings do not encompass the entire spectrum of lipedema, particularly the inflammatory impact, highlighting the need for a comprehensive approach to understanding and treating lipedema. (Studies by Baumgartner 2021, and Wollina 2019 previously cited in this policy are included in this systematic review).

Fijany et al. (2024) conducted a systematic review and meta-analysis of 10 articles on the different liposuction techniques and reported on the safety and efficacy. Techniques include traditional tumescent liposuction (TTL), power-assisted liposuction (PAL), and waterjet- assisted liposuction (WAL). A total of 2542 procedures in 906 patients were included. Combined outcomes for all techniques significantly improved pain, bruising, edema, tension, pressure sensitivity, cosmetic impairment, and general impairment, and the one study that used WAL showed it to be more effective for reducing tension and general impairment. Collectively, complication rates were low and included hematoma, infection, seroma, deep vein thrombosis. Limitations of this review include relatively small sample sizes of included studies and heterogeneity of reported outcomes. Furthermore, the majority were retrospective, introducing potential bias and additional studies with larger sample sizes and long-term results are needed to validate these findings.

In a 2022 retrospective, single-center, noncomparative study, Kruppa et al. evaluated patients with lipedema who underwent liposuction. Surgical treatment was performed under general anesthesia with at least 24 hours of post-operative observation. A tumescent solution consisting of saline and epinephrine, and power-assisted or water-jet assisted liposuction was performed. The surgical goal was fat removal equivalent to approximately 6% of the patient's body weight, and often required megaliposuction (defined as large-volume liposuction with a minimum of 4 liters of pure fat or 5 liters of total aspirate). After a minimum of 6 months since last treatment, patients completed a disease related questionnaire. The primary endpoint was the need for complex decongestive therapy based on a composite score, and secondary endpoints included the severity of disease-related complaints as measured on a visual analogue scale. 106 patients underwent 298 large volume liposuction procedures with a mean lipoaspirate of 6355 ml. The results showed

after a median follow up of 20 months, the median complex decongestive therapy score reduction by 37.5 percent. This reduction was greater in patients with a BMI ≤ 35, and in Stage I and II patients. There was also an overall improvement in lipedema associated symptoms. There was no correlation between aspiration volume and primary or secondary endpoints. The authors concluded that liposuction decreases the need for conservative treatment and reduces the intensity of lipedema-associated complaints in long-term follow-up of up to 20 months. This study is limited by a retrospective, single center design and lack of a control group. Furthermore, primary and secondary endpoint results relied on subjective patient reporting. Additionally, the sample size may have been too small to detect important but unusual adverse events.

A Hayes evolving evidence review entitled Liposuction for the Treatment of Lipedema concluded that the evidence from 3 very poor-quality studies suggests that liposuction leads to clinically significant improvements in quality of life, disability, and pain and reduced need for conservative treatment in women with lipedema at 2 to 3 years of follow-up. Nonserious complications such as bruising and post operative bleeding were common. Two new studies were included in the 2024 update that do not change these conclusions. (Hayes, 2024).

In 2020, Sandhofer et al. reported on the findings of the First International Consensus Conference on Lipedema. A group of international experts convened to review the current European guidelines and the literature and concluded that lymph-sparing liposuction for lipedema using tumescent local anesthesia is the only effective treatment option for patients who do not respond to conservative, non-surgical treatment. Several publications reported long term benefits of up to 8 years. Additionally, the following were reported in the literature; 2-6 sessions may be required, technique selection should cause the least amount of trauma to vessels, nerves and lymphatics, bilateral areas should be treated at the same time to avoid asymmetry and patients will require long term follow up.

Van de Pas et al. (2020) conducted a case series study to investigate whether lymphatic system function changed in patients diagnosed with lipedema and treated with tumescent liposuction. Lymphoscintigraphy was performed to quantify the lymph outflow. Mean clearance percentages of radioactive protein loaded after one minute with respect to the total injected dose and corrected for decay of the radiopharmaceutical in the subcutaneous lymphatics were used as functional quantitative parameters as well as the clearance percentages and inguinal uptake two hours post injection. The results of lymphatic function in patients with lipedema were compared with values obtained from normal healthy volunteers. In 117 patients with lipedema, clearance two hours post injection in the right and left foot was disturbed in 79.5 and 87.2% respectively, and normal in 20.5 and 12.8% respectively compared to normal volunteers. The inguinal uptake after two hours in the right and left groin was disturbed in 60.3 and 64.7% respectively and normal in 39.7 and 35.3% respectively compared to normal volunteers. A subset analysis was conducted with 50 of the 117 patients, which compared lymphoscintigraphies before and six months after tumescent liposuction. In this subset analysis, the mean clearance of both right and left foot (or of both feet) was slightly improved, 0.01 (p = 0.37) after tumescent liposuction. Mean inquinal uptake of the groin was also slightly improved, 0.02 (p = 0.02). The authors concluded that tumescent liposuction does not diminish the lymphatic function and can be regarded as a safe treatment. They also stated that a larger study is needed to confirm these results. Limitations of this study include its design as a case series without a contemporaneous comparison to another treatment modality, all of the procedures were performed by a single professional who had performed liposuction on patients with lipedema for 15 years, and that the subset analysis included only a small proportion (i.e., 43%) of the study population and a follow-up period of only 6 months.

Witte et al. (2020) conducted a case series study to assess the long-term results of water-jet-assisted liposuction (WAL) using a standard treatment protocol for the treatment of lipedema. Patients who participated in the study received questionnaires preoperatively and postoperatively assessing lipedema characteristics and symptom severity with visual analog scales (VASs). The primary outcome was pain. A total of 155 participants received treatment and of those, 63 had pre- and postoperative questionnaires available for analysis. The median age was 35 years, mean BMI was 28.4 ±0.6, and all patients had stages I or II lipedema diagnosed by two separate specialists. After a median follow-up of 21.5 months, the VAS score of all 10 tested items had significant decreases. Pain was reduced from 6.5 ±2.1 to 1.4 ±1.7 (p < 0.001). General impairment dropped from 7.8 ±2.1 to 1.0 ±1.4 (p < 0.001) and esthetic impairment from 8.7 ±2.3 to 3.1 ±2.5 (p < 0.001). All patients were compression garments and/or received manual lymphatic drainage preoperatively; this was reduced to 44% of patients needing any conservative treatment postoperatively. No significant complications occurred in any of the patients. Postoperative swelling was present for a mean of 4.3 weeks; patients were absent from work for a mean of 2.7 weeks postoperatively. No recurrence of excess subcutaneous fat was observed in the patients in the follow-up period. The authors concluded that liposuction using their WAL technique is an efficient method of surgical treatment of early-stage lipedema and leads to a marked decrease in symptom severity and need for conservative treatment. Limitations of this study include its case series design, that only patients with early stages of lipedema (i.e., stages I and II) were included, and that 41% (63/155) of the study population had pre- and post-treatment assessments completed. The study was not designed to compare the benefits or risks of WAL compared to other approaches.

A 2020 ECRI clinical evidence assessment, updated in 2024, entitled Liposuction for Treating Lipedema, evaluated evidence from 5 pre- and post-treatment studies and states that the evidence suggests that liposuction may reduce pain and improve quality of life for up to 8 years in patients with lipedema. However, due to a high risk of bias, the evidence cannot be considered conclusive, and larger, multi-center, controlled studies with standardized inclusion criteria are needed to assess the safety and effectiveness of liposuction for treating lipedema. The review also assessed clinical guidelines and states that despite the lack of strong evidence, there are clinical guidelines that recommend liposuction for patients with advanced lipedema. The conclusions did not change with the 2024 update.

The Canadian Agency for Drugs and Technologies in Health (CADTH) published a Rapid Response Report that appraised clinical effectiveness studies and guidelines on liposuction for the treatment of lipedema. The information was sourced from five uncontrolled before-and-after studies and one clinical guideline. The reviewers concluded that data from the studies showed that patients with lipedema who were treated with liposuction experienced a significant improvement in pain, sensitivity to pressure, edema, bruising, feeling of tension, and quality of life, and experienced significant reductions in extremity size, restriction of movement, and the need for conservative therapy. The reviewers also reported that the benefits of liposuction remained up to 88 months, and that liposuction was generally well tolerated; most adverse events occurred in < 5% of patients. They also stated that a clinical guideline recommends that tumescent liposuction, performed by a skilled healthcare professional at a specialized facility, be considered the treatment of choice for patients with a suitable health profile and/or inadequate response to conservative and supportive measures however, the quality of the supporting evidence and the strength of the recommendations were not provided (Peprah & MacDougall, 2019).

A clinical trial evaluating liposuction versus complex decongestive therapy (LIPLEG) is active but no longer recruiting and results have not been published. Further information can be found at: https://clinicaltrials.gov/study/NCT04272827?term=NCT04272827&rank=1.

Clinical Practice Guidelines

American Society of Plastic Surgeons (ASPS)

In a 2003 practice advisory, the ASPS does not make recommendations for lipedema specifically, but makes the following recommendations for liposuction:

- No single liposuction technique or cannula is best suited for all patients in all circumstances
 - Factors such as the patient's overall health, the patient's body mass index, the estimated volume of aspirate to be removed, the number of sites to be addressed, and any other concomitant procedures to be performed should be considered
- There is no scientific data available that support a specific volume maximum at which point liposuction is no longer safe, however the risk of complications is higher as the volume of aspirate and the number of anatomic sites treated increases
- 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
- In certain circumstances, it may be in the best interest of the patient to perform large volume procedures as separate serial procedures and avoid combining with additional procedures
- Compression garments and elastic stockings are generally used for several weeks postoperatively

British Association of Aesthetic Plastic Surgeons (BAAPS)/British Association of Plastic, Reconstructive and Aesthetic Surgeons (BAPRAS)

In a 2023 joint summary document on the safety of and guidelines for liposuction for lipedema, BAAPS and BAPRAS states that despite a lack of randomized controlled studies, there is compelling evidence to support liposuction for improving the QOL on patients with lipedema, and make the following recommendations:

- Liposuction is rehabilitative and should be performed by experienced surgeons with a special interest in lipedema
- Treatment involves a multidisciplinary team, and in addition to surgery team, should include:
 - o A lymphedema nurse specialist
 - o A dietician
 - o A psychological assessment and screening for body dysmorphic disorder
 - o Referral to a bariatric surgeon for patients with concomitant obesity to reduce perioperative risk
- It may be in the best interests of the patient to perform large-volume liposuction as separate serial procedures
- Avoid combining liposuction with other procedures
- Measured compression garments must be used immediately post-operatively

Dutch Society of Dermatology and Venereology

With little consistent information regarding the diagnostic or therapeutic parameters for lipedema, in 2017, the Dutch Society of Dermatology and Venerology published the results of a task force that convened to create evidence -based and expert opinion guidelines for treating lipedema using the International Classification of Functioning, Disability and Health of the World Health Organization (Halk et al., 2017). The following recommendations were made:

- Tumescent liposuction (TLA) is the treatment of choice for patients with a suitable health profile and/or inadequate response to conservative and supportive measures
- Prior to TLA, associated deteriorating components, such as edema, obesity, unhealthy lifestyle, lack of physical
 activity, lack of knowledge about the disease, and psychosocial distress, should be addressed
- Following TLA, women generally require ongoing conservative therapy, and weight normalization should remain a goal
- TLA requires the specialized skills of a healthcare provider and should only be performed at a specialized center
- Multiple sessions are often necessary to remove the extensive amount of adipose tissue

Fat Disorders Resource Society

In 2021, a variety of lipedema experts convened to review the literature and, using the Delphi Method, developed Standards of Care for Lipedema in the United States (Herbst et al.). Regarding liposuction, the following standards of care were developed:

- Lipedema reduction surgery is currently the only available technique for removing abnormal lipedema tissue
- Indications for lipedema reduction surgery include a diagnosis of lipedema with demonstrated compliance and adherence to or failure of conservative therapies
- Lipedema reduction surgery should be performed by surgeons experienced in the care of people with lipedema, with expert knowledge of the anatomy and function of lymphatic collection systems
- The arterial and venous vascular status should be evaluated, as lipedema is associated with comorbid conditions that increase the risk of venous thromboembolism
- The types of suction lipectomy recommended for people with lipedema are based around tumescent liposuction
- Liposuction of lipedema tissue may require larger than traditional suction aspirate volumes and multiple surgeries with proper intervals in-between
- Lipedema reduction surgery may be less effective in advanced stages of lipedema and in patients with severe obesity
- Consider overnight observation after surgery for significant comorbidities or high-volume aspirate
- Compression garments should be worn regularly to prevent rebound edema
 - For early stage lipedema they should be worn for 2-3 months
 - o For advanced lipedema and/or lipolymphedema may need to continue compression garments for life

Wounds UK

Wounds UK 2017 Best Practice Guidelines on the management of lipedema make the following recommendations regarding liposuction:

- Patients should be advised and encouraged to undertake non-surgical treatment for at least 6-12 months as a first step
- Non-lipedema fat should have been reduced as much as possible before surgery
- Patients should not have medical conditions that increase the risk of complications from anesthesia or bleeding
- Pre-operative counselling is very important to ensure that the patient has realistic expectations of what can be
 achieved, understands the procedure and the importance of post-operative care (including compression therapy), and
 comprehends that there is no evidence that liposuction is curative
- Should be carried out by a surgeon who is appropriately qualified to treatment someone with lipedema and who works as part of a multidisciplinary team

National Institute for Health and Care Excellence (NICE)

A March 2022 NICE interventional procedures guidance document states that the evidence on the safety of liposuction for chronic lipedema is inadequate but raises concerns of major adverse events such as fluid imbalance, fat embolism, deep vein thrombosis, and toxicity from local anesthetic agents. Evidence on the efficacy is also inadequate, based mainly on retrospective studies with methodological limitations. Therefore, this procedure should only be used in the context of research.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

The FDA has approved several devices for use in liposuction. Refer to the following website for more information (use product codes MUU): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed September 9, 2024)

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Policy History/Revision Information

| Date | Summary of Changes |
|------------|---|
| 02/01/2025 | Definitions |
| | Updated definition of "Class II or III Obesity" |
| | Supporting Information |
| | Updated Clinical Evidence and References sections to reflect the most current information |
| | Archived previous policy version CS203KY.04 |

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state, or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state, or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state, or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state, or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

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