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Liposuction for Lipedema (for Louisiana Only)

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➔ Instructions for Use

<u>Table of Contents</u>	<u>Page</u>
<u>Application.....</u>	<u>1</u>
<u>Coverage Rationale.....</u>	<u>1</u>
<u>Definitions.....</u>	<u>2</u>
<u>Applicable Codes.....</u>	<u>3</u>
<u>Description of Services.....</u>	<u>3</u>
<u>Clinical Evidence.....</u>	<u>3</u>
<u>U.S. Food and Drug Administration (FDA).....</u>	<u>5</u>
<u>References.....</u>	<u>6</u>
<u>Policy History/Revision Information.....</u>	<u>6</u>
<u>Instructions for Use.....</u>	<u>6</u>

Application

This Medical Policy only applies to the state of Louisiana.

Coverage Rationale

Lipedema

Liposuction for lipedema is considered reconstructive and medically necessary to treat Functional Impairment when all of the following criteria are met:

- **A diagnosis of lipedema 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 lower extremities in relationship to the trunk; and**
 - **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**
 - **Negative Stemmer Sign; and**
 - **Pressure induced pain and tenderness on palpation**
- **Failure to respond to 6 or more months of Conservative Treatment (compression or manual therapy); and**
- **Treatment plan includes all of 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**

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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

- Treatment for each body area (e.g., extremity) will take place within a 12-month period following the initial surgical treatment of that body area, unless it is medically contraindicated to proceed with complete surgical intervention during the allotted time; and
- Documentation that the request is not a re-treatment of a previously treated area; and
- The postoperative plan of care is to continue to wear compression garments as instructed and continue Conservative Treatment

Liposuction for lipedema is not medically necessary when performed for cosmetic purposes (i.e., procedures or services that change or improve appearance without significantly improving Functional Impairment).

Definitions

Class II or III Obesity: The National Heart, Lung and Blood Institute (NHLBI) (Jensen et al., 2013) 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 - Extreme 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 height, or an absolute BMI of 35-39.9 kg/m², whichever is lower*
- Class III obesity - 140% of the 95th percentile height, or an absolute BMI of >40 kg/m², whichever is lower

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

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 1 in 9 adult women. It is characterized as a disproportionate deposit of subcutaneous fat on the buttocks, hips and lower extremities and may affect the arms (Buck, 2017). Symptoms may include physical functional impairment (e.g., difficulty ambulating or performing activities of daily

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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 member specific benefit plan document 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.

<u>CPT Code</u>	<u>Description</u>
<u>15877</u>	<u>Suction assisted lipectomy; trunk</u>
<u>15878</u>	<u>Suction assisted lipectomy; upper extremity</u>
<u>15879</u>	<u>Suction assisted lipectomy; lower extremity</u>

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<u>Diagnosis Code</u>	<u>Description</u>
<u>E65</u>	<u>Localized adiposity</u>
<u>E88.2</u>	<u>Lipomatosis, not elsewhere classified</u>

Description of Services

Lipedema treatment options 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. Although liposuction is noncurative and may require multiple sessions, it may improve functionality, pain, swelling, physical appearance, and quality of life. In addition, postoperatively, patients often need to continue conservative treatment and avoid weight gain to maintain the results (Peled, 2016).

Clinical Evidence

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 1 minute with respect to the total injected dose and corrected for decay of the radiopharmaceutical in the

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subcutaneous lymphatics were used as functional quantitative parameters as well as the clearance percentages and inguinal uptake 2 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 2 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 2 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 inguinal 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 7.8 ± 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 wore 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.

An ECRI review, 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

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are clinical guidelines that recommend liposuction for patients with advanced lipedema (2020).

Wollina et al. (2019) conducted a single-center case series study to determine if micro-cannular liposuction with tumescent anesthesia (TA) is an effective treatment modality for patients with lipedema who are not responding to complex decongestive therapy (CDT). Outcomes included changes in the circumference of the treated area, pain (measured by a 10-point VAS), and mobility and bruising (both measure by a 3-point scale: 0=no improvement, 1=minor to medium improvement, 3=marked improvement or no impairment at all). A total of 111 patients with lipedema received 334 liposuction treatments. Seven patients were classified as having stage I lipedema, 50 had stage II and 48 had stage III. All were females between 20-81 years of age, with a median age of 44±16.8 years. All patients were treated with CDT for at least 6 months without improvement or deterioration of pain sensations and/or leg volume. The median follow-up period was 2.0±2.1 years. After treatment, the median reduction of limb circumference on thighs was 6 ±1.6 cm. The median pain level before treatment was 7.8±2.1 and 2.2±1.3 at the end of the treatment (p<0.3). An improvement of mobility was achieved in all patients i.e., marked improvement or complete loss of impairment reported by 86% of patients, minor to medium improvement reported by 14% of patients. Bruising after minor trauma improved somewhat in 20.9% and completely or almost completely in 29.1% (p<0.5). In 16.4% of patients, further CDT was no longer necessary. 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 and that the procedure should be performed in specialized centers. Limitations of this study include its case series design and short follow-up period. Additional prospective randomized trials are still needed to determine the safety and efficacy of liposuction for individuals diagnosed with lipedema.

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).

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 a number of devices for use in liposuction. See the following website for more information (use product codes MUU):

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<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>. (Accessed March 23, 2021).

References

- Buck DW 2nd, Herbst KL. Lipedema: A relatively common disease with extremely common misconceptions. *Plast Reconstr Surg Glob Open*. 2016;4(9):e1043. Published 2016 Sep 28.
- ECRI Institute. Liposuction for Treating Lipedema. Plymouth Meeting (PA): ECRI Institute; 2020 Mar 12. (Clinical Evidence Assessment).
- Goss JA, Greene AK. Sensitivity and Specificity of the Stemmer Sign for Lymphedema: A Clinical Lymphoscintigraphic Study. *Plast Reconstr Surg Glob Open*. 2019 Jun 25;7(6):e2295.
- Herbst KL. Rare adipose disorders (RADs) masquerading as obesity. *Acta Pharmacol Sin*. 2012 Feb;33(2):155-72.
- Jensen MD, Ryan DH, Apovian CM et al. National Heart, Lung and Blood Institute (NHLBI). Managing overweight and obesity in adults. Systematic evidence review from the Obesity Expert Panel, 2013.
- Kelly AS, Barlow SE, Rao G, et al. Severe obesity in children and adolescents: identification, associated health risks, and treatment approaches: a scientific statement from the American Heart Association. *Circulation*. 2013 Oct 8;128(15):1689-712.
- Peled WA, Kappos EA. Lipedema: diagnostic and management challenges. *Int J Womens Health*. 2016 Aug 11;8:389-95.
- Peprah K, MacDougall D. Liposuction for the treatment of lipedema: A review of clinical effectiveness and guidelines [Internet]. Ottawa (ON): Canadian Agency for Drugs and Technologies in Health; 2019 Jun 7. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK545818/> (Accessed March 23, 2021).
- Pratt JSA, Browne A, Browne NT, et al. ASMBS pediatric metabolic and bariatric surgery guidelines, 2018. *Surg Obes Relat Dis*. 2018 Jul;14(7):882-901.
- van de Pas CB, Boonen RS, Stevens S, et al. Does tumescent liposuction damage the lymph vessels in lipoedema patients? *Phlebology*. 2020;35(4):231-236.
- Witte T, Dadras M, Heck FC, et al. Water-jet-assisted liposuction for the treatment of lipedema: Standardized treatment protocol and results of 63 patients. *J Plast Reconstr Aesthet Surg*. 2020 Sep;73(9):1637-1644.
- Wold LE, Hines EA Jr, Allen EV. Lipedema of the legs; a syndrome characterized by fat legs and edema. *Ann Intern Med*. 1951 May;34(5):1243-50.
- Wollina U, Heinig B. Treatment of lipedema by low-volume micro-cannular liposuction in tumescent anesthesia: Results in 111 patients. *Dermatol Ther*. 2019 Mar;32(2):e12820.

Policy History/Revision Information

Date	Summary of Changes
TBD	<ul style="list-style-type: none">New Policy

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

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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.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. The UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Archived Policy Versions

Effective Date	Policy Number	Policy Title
<u>mm/dd/yyyy -</u> <u>mm/dd/yyyy</u>	<u>#####</u>	<u>Title of Policy Hyperlinked</u>