

United Healthcare[®] Community Plan

> UnitedHealthcare[®] Community Plan Medical Policy

Liposuction for Lipedema (for Louisiana Only)

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Instructions for Use

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Application

This Medical Policy only applies to the state of Louisiana.

Coverage Rationale

Lipedema

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

- A diagnosis of **Lipedema** lipedema that meets the following criteria:
 - o Absence of pitting edema from Lipedema lipedema; and
 - o Bilateral and symmetrical manifestation with minimal involvement of the feet; and
 - Disproportionate adipocyte hypertrophy of the <u>affected extremity</u> lower extremities in relationship to the trunk; 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 <u>Class II or III Obesity</u>; and
 - o Negative Stemmer Sign; and
 - $\ensuremath{\mathsf{o}}$ $\ensuremath{\mathsf{Pressure}}$ induced pain and tenderness on palpation
- Failure to respond to 6 or more months of <u>Conservative Treatment</u> (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 lipedema is

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an independent cause of the <u>Functional Impairment</u> (interference with activities of daily living) and the surgery is expected to restore or improve the <u>Functional</u> Impairment; and

- o 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
- o 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 Lipedemalipedema 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 <u>--</u> 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 \geq 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 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 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.

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

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Codes labeled with an asterisk (*) are not on the Louisiana Medicaid Fee Schedule and therefore may not be covered by the state of Louisiana Medicaid Program.

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

Description of Services

Lipedema 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 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. Commonly used liposuction

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methods for lipedema are tumescent anesthesia (TA) liposuction, and water assisted liposuction (WAL). 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; Peprah and MacDougall, 2019).

Clinical Evidence

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 largevolume lipo suction 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 diseaserelated 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 \leq 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 2022 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 followup. Nonserious complications such as bruising and post operative bleeding were common.

Baumgartner et al. (2021) reported the results of a single center working group of 60 patients to monitor the 12-year success of liposuction for treating lipedema from the patients' perspective. (The authors previously reported 4- and 8-year outcomes, and those results are summarized below (Baumgartner et al. 2016). Patients were mailed a questionnaire with questions regarding any relevant changes, and if conservative measures had continued. Prior to liposuction, 18 patients had Stage I lipedema, and 42 had Stage II. On a scale of 0-4, with 4 being "none", patients were asked to indicate to what extent they are currently experiencing the following: spontaneous pain, sensitivity to pressure, edema, bruising, restriction of movement, cosmetic impairment, reduction in quality of life. In addition to these individual impairments, an overall impairment score was calculated which was the mean value of all seven. The results showed significant improvement in scores across all indicators, as well as overall impairment score. of the 60 patients in this study, 37 underwent combined decongestive therapy (CDT) with manual lymph drainage (MLD) plus compression garments before surgery. These patients were separately evaluated as a sub-group in order to assess treatment success, and the results

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showed seven patients required fewer conservative treatments, either MLD or compression, and 10 no longer needed any conservative treatment. The authors concluded that these results demonstrate a permanent improvement in lipedema symptoms for patients with Stage I and II lipedema. This study is limited by a lack of Stage III lipedema patients, and that it relies on patient reported outcomes only.

Van 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 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 \pm 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 \pm 2.1 to 1.0 \pm 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

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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 An ECRI clinical evidence assessment 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 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 microcannular 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 $(p \leftarrow 0.3)$. 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 \leftarrow 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

<u>supporting evidence and the strength of the recommendations were not provided (Peprah & MacDougall, 2019).</u>

In 2016, Baumgartner et al. presented the outcomes of liposuction for treating lipedema from the patients' perspective at 4- and 8-years post procedure. In this single-center study, 112 patients with lipoedema lipedema were treated with liposuction and followed up after 4 years. Patients were asked to complete a questionnaire scoring on a 0-4 scale, 0 being "none" and 4 being "very strong". The questions were regarding spontaneous pain, sensitivity to pressure, edema, bruising, restriction of movement, cosmetic impairment and reduction in QoL. Scoring also included an overall score which was the mean value of the combined scores. At 8 years, 85 of the same patients were available for providing subjective assessment of surgery using the same questionnaire and scoring method. The results showed in general, the 4 years results were still in place at 8 years, with some worsening of bruising, restricted movement, cosmetic impairment, reduced QoL and overall impairment that was not clinically relevant. In addition, an unchanged significant reduction in the extent of the conservative treatment (CDT) still required or used was also observed. The authors believe this may be an expression of disease progression or increasing age of the patients who were all between age 50-69 at the time of surgery. The authors concluded that liposuction appears to be the most effective and long-lasting treatment for lipedema, even though only one-third of patients were completely symptom free. Conservative treatment continues to play a significant role. This study is limited by a lack of Stage III lipedema patients, and that it relies on patient reported outcomes only.

(CADTH) published Canadian Agency for Drugs and Technologies Health Report that appraised clinical effectiveness studies and guidelines posuction for the treatment The informat: controlled before-and that data from atudica nationta with liposuction experienced a significant improvement in pain <u>eoneitiwitw</u> dema, bruising, feeling of tension, and quality of life, and experienced eductions in extremity size. movement, and that 5% of patients. stated quideline <u>also</u> liposuction, performed by a skilled healthcare professional considered the treatment of choice for patients with a suitable health profile supporting evidence and the MacDougall, 2019).

A clinical trial evaluating liposuction versus complex decongestive therapy (LIPLEG) is ongoing. Further information can be found at: https://clinicaltrials.gov/ NCT04272827

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

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- 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

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

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First International Consensus Conference on Lipedema

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:

• 2-6 treatment sessions may be required

- The liposuction technique should cause the least possible trauma to blood vessels, nerves, and lymphatics
- Bilateral areas should be treated during the same treatment session to minimize asymmetry
- Compression stockings should be worn for 2-4 weeks postoperatively
- Patients will require long-term follow-up

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 lipocdemalipedema is inadequate but raises concerns of major adverse events such as fluid imbalance, fat embolism, deep vein thrombosis, and toxicity from local anaesthetic 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 <u>several</u> a number of devices for use in liposuction. <u>See</u> Refer to the following website for more information (use product codes MUU): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed <u>March 10</u> October 18, 2022).23, 2021)

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Policy History/Revision Information

Date	Summary of Changes
TBD	Coverage Rationale
	 Revised coverage criteria pertaining to the diagnosis of lipedema; replaced criterion requiring "disproportionate adipocyte hypertrophy of the lower extremities in relationship to the trunk" with "disproportionate adipocyte hypertrophy of the affected extremity" Added notation to indicate 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
	Definitions
	 Updated definition of: Class II or III Obesity Lipedema
	Supporting Information
	 Updated Description of Services, Clinical Evidence, FDA, and References sections to reflect the most current information

Liposuction for Lipedema (for Louisiana Only)

UnitedHealthcare Community Plan Medical Policy

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