Clinical Policy: Liposuction for Lipedema

Description
Lipedema is a chronic, progressive disease characterized by abnormal adipose tissue distribution, resulting in pain and functional impairment. Surgical intervention through liposuction has shown to have positive outcomes in individuals with lipedema by improving functionality, pain, swelling, and quality of life.

Policy/Criteria
I. It is the policy of health plans affiliated with Centene Corporation that liposuction for the treatment of lipedema requires mandatory secondary medical director review and may be considered medically necessary when meeting all of the following criteria:
   A. Physical functional impairment (i.e. difficulty ambulating or performing activities of daily living);
   B. Pain and tenderness on palpation in affected areas;
   C. Subcutaneous nodules of adipose tissue;
   D. Negative Stemmer sign unless the individual has coexisting lymphedema (Stemmer sign is negative if the skin can be lifted up at the base of the second toe or second finger);
   E. Absence of pitting edema unless the individual has coexisting lymphedema;
   F. Failure to respond to six consecutive months of conservative treatment including compression therapy, manual lymphatic drainage, and documented history of participation in a physician-supervised weight loss program;
   G. Medical records and photographs documenting at least one of the following chronic and persistent complications that remains refractory to conservative therapy for at least six consecutive months:
      1. Bilateral and symmetrical manifestation of fat accumulation in affected areas;
      2. Disproportionate proliferation of fatty tissue on the limbs but not on the hands or feet (“cuff” phenomenon);
      3. Disproportionate adipose hypertrophy of the lower extremities in relationship to the trunk;
   H. Lipedema tissue is resistant to six months of conservative therapy including physician supervised diet and exercise;
   I. Lack of improvement in swelling from elevation of limbs in lipedema-affected areas;
   J. Tendency to bruise easily in affected areas.

II. It is the policy of health plans affiliated with Centene Corporation that liposuction for lipedema is not medically necessary for any indications other than those specified above.

Background
Lipedema is a chronic disorder in which adipose tissue accumulates bilaterally on the extremities, causing pain in the affected areas. Fat deposition in lipedema is often symmetrical, accumulating in the legs, hips, buttocks, and in some cases, the arms, but does not involve the
Liposuction for Lipedema

hands or feet. Lipedema primarily affects women, impacting an estimated 10% of the overall female population, and develops during times of hormonal changes, such as puberty, pregnancy, and menopause. The pathophysiology of lipedema is unknown, and diagnosis is based on clinical findings and ruling out other possible diagnoses.

Lipedema is frequently unrecognized or misdiagnosed as lymphedema or obesity. Lymphedema is the abnormal accumulation of interstitial fluid and fibroadipose tissues due to disruption in the lymphatic system. Distinguishing lipedema from lymphedema proves challenging because the two conditions may coexist in advanced stages of lipedema. Individuals with lipedema typically have adequate lymphatic function as opposed to those with lymphedema. Common characteristics of lymphedema that differ from lipedema include positive Stemmer sign, unilateral swelling of the extremities that does not spare the hands or feet, asymmetric limb measurement, and nonpitting edema, although pitting edema can be seen in earlier stages of lymphedema.

Although lipedema can also occur with obesity, there are distinguishing characteristics in lipedema not present with obesity, such as painful adipose tissue, especially when palpated. The adipose tissue in lipedema is also unresponsive to weight loss interventions through diet and exercise or bariatric surgery. Additional characteristics of lipedema that differ from obesity include excessive fat deposits that primarily target the bilateral lower extremities and do not affect the hands or feet, easy bruising in affected areas, a feeling of heaviness in the affected extremities, and tissue inflammation causing pain and, in some cases, numbness. Pain in the affected areas can cause functional mobility to deteriorate, which impacts activities of daily living and overall quality of life.

Currently there is no known cure for lipedema, and the primary focus of treatment is to reduce symptoms and functional limitations to improve quality of life and prevent disease progression and secondary complications. Treatment options for lipedema include conservative therapy and surgical intervention. Conservative treatment consists of promoting a healthy lifestyle through diet and exercise tailored to the individual, complex decongestive therapy (CDT), psychosocial support, and education on self-management. CDT encompasses manual lymph drainage therapy, compression therapy, skin care, and therapeutic exercise to help control symptoms and pain. While studies have shown a 5-10% reduction in tissue volume through conservative therapy and temporary improvement in symptoms, repeat treatment is typically required within days. There is also a lack of evidence for the efficacy of conservative therapy, especially in preventing the progression of lipedema.

Surgical intervention through liposuction should be evaluated in individuals unresponsive to conservative therapy whose lipedema symptoms persist and impair functional mobility and quality of life. Liposuction is the most common surgical intervention for lipedema and typically includes tumescent anesthesia liposuction and water assisted liposuction. Liposuction is not considered a cure for lipedema and multiple sessions may be required. Several studies have evaluated the effectiveness of liposuction in the treatment of lipedema in patients unresponsive to conservative treatment.
CLINICAL POLICY

Liposuction for Lipedema

Multiple studies evaluating the effectiveness of liposuction in the treatment of lipedema have demonstrated improvement in reduction of subcutaneous adipose tissue, pain, functional impairment, bruising, and quality of life.\textsuperscript{5,11-15} A notable single center study was performed on 85 patients with lipedema that were previously evaluated four years after liposuction.\textsuperscript{4-5} A questionnaire was provided eight years after liposuction to compare current state to the previous results. Results concluded that improvement in pain, sensitivity to palpation, swelling, bruising, mobility, and quality of life remained consistent four years after surgery. Additionally, the reduced need for conservative treatment eight years after liposuction was comparable to that observed four years after surgery.\textsuperscript{4} Results from this study are notable since they demonstrate the first long-lasting positive effects that liposuction can offer to patients with lipedema.\textsuperscript{4} Study limitations include study designs and high attrition, and currently there is not a published randomized controlled trial evaluating the effectiveness and long term impacts of liposuction in the treatment of lipedema.\textsuperscript{5,9}

International Congress on Lipedema

In June 2017 the First International Consensus Conference on Lipedema was held and current European literature and guidelines regarding liposuction for lipedema with tumescent local anesthesia were reviewed. International experts convened and reviewed multiple studies from Germany that demonstrate long-term benefits up to 8 years after liposuction for lipedema using tumescent local anesthesia. A consensus statement from this conference concluded that lymph-sparing liposuction using tumescent local anesthesia is the only effective treatment for patients with lipedema.\textsuperscript{6,10,18}

German Society of Phlebology

According to the German Society of Phlebology liposuction is considered a therapeutic option for lipedema and is indicated if symptoms persist or if disease progression occurs despite conservative treatment.\textsuperscript{6,16} The recommendations are based on a systematic literature search and the consensus of eight medical societies and working groups.\textsuperscript{16} The guidelines conclude that treatment of lipedema consists of 4 therapeutic mainstays which include CDT, liposuction, diet, and physical activity.\textsuperscript{16} Guidelines also state that treatment should also include psychotherapy if necessary, and therapeutic intervention for morbid obesity should be initiated prior to liposuction.\textsuperscript{16,18}

Dutch Society of Dermatology and Venereology

In 2011, the Dutch Society of Dermatology and Venereology created guidelines on lipedema, recommending tumescent anesthesia liposuction as a treatment of choice for patients with a suitable health profile who have inadequately responded to conservative treatment.\textsuperscript{17-18}

National Institute of Health and Care Excellence (NICE)

According to NICE, concerns for the safety of liposuction for chronic lipedema include major adverse events such as fluid imbalance, fat embolism, deep vein thrombosis, and toxicity from local anesthetic agents. Per NICE, “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.” There is currently a randomized controlled trial in progress in Germany, and NICE will review this guidance once the trial is published.\textsuperscript{9,18}
CLINICAL POLICY
Liposuction for Lipedema

Coding Implications
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ICD-10-CM Diagnosis Codes that Support Coverage Criteria

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Reviews, Revisions, and Approvals

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References


Page 4 of 6
Liposuction for Lipedema


Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or
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The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

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Note: For Medicaid members/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.

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