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Corporate Medical Policy

Surgical Treatment for Lipedema

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Description of Procedure or Service

Lipedema is a chronic progressive disease of deposition of abnormal subcutaneous fat disproportionately affecting the lower extremities. Patients with lipedema may develop secondary lymphedema if the fat deposits compromise the lymphatic system.

Disease prevalence data is conflicting, ranging from rare to up to 11% of women and post-pubertal girls, with a probable familial predisposition.

The diagnosis is based on physical findings and exclusion of other diagnoses, especially obesity and lymphedema, with which lipedema may share overlapping clinical features. In lipedema, there is typically a sharp separation between normal and abnormal tissue at the ankle ("cuff" sign), and it typically spares the hands, feet and trunk. Moderate to severe pain with digital pressure on the abnormal fat deposits and easy bruising seem to be common complaints. Four stages of lipedema have been described based on severity, with stage one characterized by smooth and soft skin but enlarged underlying hypodermis, stage 2 by skin indentation over palpable nodules, stage 3 by folds and divots over deforming, larger fat masses and development of concomitant lymphedema in stage 4. Functional limitations are usually not present until later stages, and literature has reported a greater impact of liposuction surgery on improving ambulation when performed in later stages.

The abnormal fat reportedly does not respond to normal weight loss interventions, and the mainstay of treatment consists of conservative measures to reduce lower extremity symptoms, disability and functional limitations, to improve quality of life and prevent disease progression. The primary focus of treatment is weight normalization (if coexisting obesity is present), exercise, and decongestive lymphatic therapy.

Liposuction has been proposed as a surgical treatment option for lipedema.

***Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.

Policy

Surgical Treatment for Lipedema may be considered medically necessary when the criteria below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore, member benefit language should be reviewed before applying the terms of this medical policy.

When Surgical Treatment for Lipedema is covered

Liposuction/excision/debulking for the treatment of lipedema may be considered **medically necessary** when ALL the following criteria are met:

- The individual has been diagnosed with lipedema and has the following clinical findings:
 - Bilateral symmetric fat deposition, disproportionately affecting the limbs and sparing the hands and feet; AND
 - History of easy bruising or bruising without apparent cause in lipedema affected areas; AND
 - Pain and/or hypersensitivity to touch in lipedema affected areas; AND
 - There is significant physical functional impairment, e.g., difficulty ambulating or performing activities of daily living, or medical complications such as recurrent cellulitis or skin ulcerations; AND
- There has been a lack of effect of weight loss measures as documented in the medical records through nutrition and medical interventions and clinic visits over six consecutive months; AND
- The individual has not responded to at least three consecutive months of conservative management to include each of the following: medical grade compression garments, complex decongestive lymphatic therapy (also referred to as manual lymph drainage), intermittent sequential pneumatic compression, (documentation of conservative management must be submitted); AND
- Absence of pitting edema (no "pitting" when finger or thumb pressure is applied to the area of fat) (unless there is comorbid lymphedema); AND
- Surgical interventions must be performed by hospital credentialed, board certified plastic surgeon.

When Surgical Treatment for Lipedema is not covered

Liposuction for lipedema is considered investigational when the above criteria are not met.

Liposuction for lipedema of is considered investigational for use in the trunk and back.

Policy Guidelines

Evidence assessment

The body of evidence for treatment of lipedema using liposuction is limited to a small number of singlearm studies based on patient subjective self-assessment using clinical scales not validated for lipedema.

In 2019, the Canadian Agency for Drugs and Technologies in Health (CADTH) reviewed the clinical effectiveness of liposuction for treatment of lipedema across five uncontrolled before-and-after studies conducted in Germany. The studies ranged in size from 25 to 111 patients. The severity of patients' conditions varied across studies and included stages 1-3; one study did not report stage at time of treatment. Mean follow-up across studies ranged from 24 to 90 months. Use of conservative therapy prior to liposuction varied across studies, some reporting 6 months of conservative therapy or duration not

specified. Efficacy outcomes included changes in patients' complaints after liposuction using questionnaires and visual analog scales, none of which had been validated for assessment of lipedemarelated complaints. All studies reported on pain and bruising, four studies reported on quality of life and three on movement.

All of the studies suggested that liposuction was effective in reducing extremity size, symptoms of pain and bruising, quality of life, mobility and general impairment.

One of the five studies subsequently reported 12-year follow-up data, however, only 36% of patients returned their questionnaires and none were patients with original stage 3 disease.

Except for one study that treated consecutive patients, it was not clear how patients were enrolled in the studies. In one study, 80% of patients had comorbidities including obesity, lymphedema and diabetes, and the extent to which these concurrent diseases affected patients' complaints and reported outcomes was unclear.

In summary, the evidence for use of liposuction for lipedema in patients who have failed conservative therapy is limited to non-randomized, small and heterogeneous studies at high risk of bias, all of which measured outcomes using clinical instruments that have not been validated in lipedema. Therefore, the reliability of the reported outcomes is uncertain. In addition, the durability of the procedure is unknown. The evidence is based mainly on expert opinion to determine that the technology results in an improvement in the net health outcome.

Clinical Practice and Professional Society Guidelines

The American Society of Plastic Surgeons (ASPS) has not published clinical practice guidelines for treatment of lipedema. However, they state that certain measures should be taken to ensure proper patient care and quality and safety with use of liposuction. To ensure only providers with appropriate training and expertise are credentialed, the ASPS recommends the following:

- Plastic surgery training or other formal training in liposuction methods that is recognized as sufficient by a governing medical body (e.g., American Board of Medical Specialties)
- Liposuction training as part of board-specific requirements and maintenance of certification activities
- Hospital admitting privileges

In 2021, a consensus standard of care guideline was published by a U.S. committee of lipedema experts (Herbst, 2021). The guideline includes therapeutic recommendation for use of liposuction in patients who have failed conservative measures.

In 2017, the Dutch Society of Dermatology and Venerology organized a task force to create guidelines on lipedema, stating they are based on the International Classification of Functioning, Disability and Health (ICF) of the World Health Organization. The guidelines define clinimetrics that should be measured to identify disease-related disability and problems in daily functioning but offer no guidance as to how to quantify or classify these clinical measurements or use them for decision making of appropriate timing of surgical intervention.

Ongoing Clinical Trials

An ongoing trial (NCT04272827), estimated to enroll 450 patients, will study the efficacy and safety of surgical therapy of lipedema compared to complex physical decongestive therapy alone. All patients will undergo a run-in phase of up to seven months for edema elimination and maintenance of results using complex decongestive therapy (CDT). Afterwards, patients will be randomly assigned to one of the two treatment groups 2:1 (intervention: control). In the intervention arm, patients will receive liposuction treatment (number of surgeries at the discretion of the treating study physician: a maximum of four surgical procedures, with a minimum of 5 and a maximum of 7 weeks between each surgery) with, if

necessary, concomitant CDT to maintain the surgical results as required by the patient. After randomization, the control group will be treated for 12 months with complex decongestive therapy (CDT) alone. After these 12 months, patients in the control arm can opt for liposuction treatment if they continue to meet the inclusion and exclusion criteria. The primary endpoint (regarding pain in the legs in stages I, II or III) will be assessed after an observation period of 12 months after final liposuction surgery, followed by a follow-up period for 24 months to observe and document the further course. Estimated study completion date is September 2025.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 15832, 15833, 15834, 15835, 15836, 15837, 15839, 15877, 15878, 15879

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

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Choosing a Plastic Surgeon for Liposuction | ASPS (plasticsurgery.org)

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.169, 11/2021

Medical Director Review 5/2022

Medical Director Review 8/2022

Specialty Matched Consultant Advisory Panel Review 8/2022

Medical Director Review 8/2023

Specialty Matched Consultant Advisory Panel Review 8/2023

Policy Implementation/Update Information

5/31/22 New policy developed. Surgical Treatment for Lipedema is considered medically necessary when medical criteria and guidelines outlined in the policy are met. Medical Director review 5/2022. (tt)

- 9/13/22 When covered section updated. When not covered section updated. Policy Guidelines updated. Billing/Coding section updated. References updated. Medical Director review 8/2022. Specialty Matched Consultant Advisory Panel Review 8/2022. (tt)
- 8/29/23 References updated. Medical Director review 8/2023. Specialty Matched Consultant Advisory Panel Review 8/2023. No change to policy statement. (tt)

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