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July 29 2020

Director of Medical Policy

Noridian Medicare

P.O. Box 39

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To: Director of Medical Policy

Subject: Reimbursement Policy for Liposuction for Lipedema

## Introduction

This is a request for a Medical Policy evaluation in regard to reimbursement for liposuction for *lipedema*, a reconstructive and *medically necessary* procedure that is the only remaining treatment once all conservative treatment measures have been exhausted. This document is to help you establish a formal policy.

Using the Anthem Blue Cross/Blue Shield policy as a template and supported with fifty medical research papers, the following is a formal, revised policy that will help patients suffering from this progressive and debilitating disease.

The procedure has many names, including:

Tumescent Liposuction

Tumescent Local Anesthesia (TLA)

Microcannular Tumescent Liposuction[[1]](#endnote-1)

Lymph-Sparing Liposuction

Lymph-Sparing, Tumescent Liposuction[[2]](#endnote-2)

Water-Assisted Liposuction (WAL™)

Power-Assisted Liposuction (PAL™)

Laser-assisted Lipolysis (LAL)

Ultrasonic Liposuction (Vaser™)

In this document, to distinguish liposuction for lipedema from *cosmetic* liposuction, I will refer to the procedure as “lymph-sparing liposuction.” Providers may use any combination of the terms above including simply “liposuction.” This request will explain what lipedema is, recommended documentation requirements for liposuction reimbursement, and why lymph-sparing liposuction should be reimbursed.

I will make the case that lymph-sparing liposuction for lipedema is reconstructive, medically necessary and reimbursing this procedure would be advantageous to the patient and the insurance company. The procedure will slow the progression of lipedema, a progressive and debilitating condition, saving the insurance company thousands of dollars of care for a condition that has no cure and will only get worse without treatment.

The purpose of lymph-sparing liposuction is to:

1. Restore to a normal appearance.
2. Improve/restore function (mobility and gait).
3. Address pain and bruising issues.
4. Improve Quality Of Life (QOL).

These all meet the AMA™, American Society of Plastic Surgeons (ASPS), Medicare and Title XVIII Social Security Act requirements for a reconstructive surgical procedure. Per the Noridian Medicare Reconstructive LCD:

Reconstructive surgery is performed to restore bodily function or to correct a deformity resulting from disease, injury, trauma, birth defects, congenital anomalies, infections, burns or previous medical treatment, such as surgery or radiation therapy. Reconstructive surgery is reasonable and necessary when the purpose is to improve necessary functioning of a malformed body part whereas surgery addressing appearance alone is considered cosmetic and not covered.[[3]](#endnote-3)

Federal law, Section 1862(a)(1)(A) of Title XVIII of the Social Security Act reads:

Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items or services—

(10) where such expenses are for cosmetic surgery or are incurred in connection therewith, ***except*** as required for the prompt repair of accidental injury or **for improvement of the functioning of a malformed body member** [emphasis mine];[[4]](#endnote-4)

This document will prove, based on a wealth of research, that lymph-sparing liposuction is not experimental, investigational, or unproven (E/I/U). There are dozens of positive, peer-reviewed research studies on liposuction for lipedema documenting that the procedure is safe and effective both short and long-term. [[5]](#endnote-5)

Many Primary Care Physicians are unfamiliar with lipedema and misdiagnosis it. [[6]](#endnote-6) Many confuse it with edema, obesity, and lymphedema–all separate conditions. Due to the fact that there are few qualified surgeons for liposuction for lipedema, we also ask that you add an *out-of-network* waiver or exception.

Not *all* lipedema patients will be eligible for the surgery. As part of the pre-authorization package, it must be documented that conservative measures have been followed for at least six months, with limited results and that no other options are available to address the patient’s reduced functionality, lower quality of life, and pain. The patient must also be well enough for the procedure and all comorbidities–for instance heart problems–have been addressed. Research supports this:

“Implications of this new definition of liposuction [as reconstructive and medically necessary] should induce third-party public payers and insurance companies to reconsider their remuneration and reimbursement policies.”[[7]](#endnote-7)

Lymph-sparing liposuction meets and often exceeds the medical necessity requirements for other comparable procedures that *are* reimbursed such as breast reconstruction, cleft palate repair, and panniculectomy [tummy tuck] after bariatric surgery. Lipedema is a painful, disfiguring, and debilitating disease that impairs the patients’ ability to walk, exercise, and diminishes their quality of life. Without treatment it progresses into a malformed and disfiguring appearance that will impede the patient’s ability to even stand and walk. It meets not just one of the reconstructive criteria–it meets *all of them*. The procedures referenced above have all been historically denied as cosmetic at one time. Most are now reimbursed as reconstructive and medically necessary (some, like panniculectomy are reimbursed in the most egregious cases).

We are asking that you:

1. **Implement** a positive reimbursement policy for liposuction for lipedema, a misunderstood and under-diagnosed condition.
2. **Differentiate** between *reconstructive* liposuction for *lipedema* (lymph-sparing liposuction) and *cosmetic* liposuction in your policy manual.
3. **Designate** lymph-sparing liposuction as reconstructive and medically necessary given that the patient’s documentation meets medically necessary requirements as outlined in this policy review request.
4. Do not list liposuction singularly as cosmetic or liposuction for lipedema as an investigational or experimental or unproven procedure.

If you have any questions or need additional information you may reach me at (901) 517-1705 or by e-mail: [lipoforlipedemareimbursement@gmail.com](mailto:lipoforlipedemareimbursement@gmail.com). My mailing address is:

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Sincerely,

Jeffrey Restuccio, CPC, COC

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## **Overview: Lipedema**

Lipedema, initially described at the Mayo clinic in 1940,[[8]](#endnote-8) [[9]](#endnote-9) is a loose, connective-tissue (fat) disease (lipomatosis) with a pathological deposition of fibrotic fatty tissue on the limbs of women sparing the trunk, hands and feet,[[10]](#endnote-10) [[11]](#endnote-11) resulting in a disproportionate body habitus. Deposition of lipedema fat increases with stage and body mass index (BMI) and likely involves sex hormones during times when weight is gained (puberty, pregnancy and menopause). Lipedema is inherited in 60% of women likely through genes affecting microvessels resulting in excess fluid bound to glycosaminoglycans in the interstitial space.[[12]](#endnote-12)

Unique to lipedema is fat that is highly resistant to loss by diet, exercise, or bariatric surgery.[[13]](#endnote-13) [[14]](#endnote-14) [[15]](#endnote-15) Lipedema is often confused with secondary obesity or lymphedema. Women with lipedema and/or obesity can develop lymphedema called lipolymphedema.

There is no cure for lipedema, but treatments aimed at reducing the lymphedema component of lipedema such as manual decongestive therapy, wrapping, exercise, compression garments and pumps, and some medical foods and medications are helpful. Expertly performed suction assisted lipectomy is the treatment of choice for suitable lipedema patients with an inadequate response to conservative and supportive measures.[[16]](#endnote-16)

Lipedema is thought to affect 11% of the female population,[[17]](#endnote-17) with rates of 6-39% reported.[[18]](#endnote-18) With a total US population of 330 million, and 50.8% female (census.gov), as many as 18 million women in the United States could have lipedema–and the majority have not been diagnosed.

Lipedema is a progressive disease that gradually worsens and expands to afflict not only the legs but also the upper extremities and other portions of the body in some cases. The NIH recognizes surgery as the only technique to remove abnormal fat tissue and cautions that such surgery should only be undertaken by surgeons with expertise in treating lipedema.[[19]](#endnote-19)

Treatment protocols comprise conservative (decongestive lymphatic therapy) and surgical (liposuction) approaches. Early diagnosis and treatment are mandatory for this disorder otherwise gradual enlargement of fatty deposition causes impaired mobility and further comorbidities like arthrosis and lymphatic insufficiency.[[20]](#endnote-20)

Lipedema progresses in stages; while historically as many as four stages have been used; three stages of lipedema with a progression into lipolymphedema is now considered more accurate. [[21]](#endnote-21)

Women with lipedema Stage 3 are very different than women with Stage 1 or 2, therefore separate codes for stages is important for prevalence studies, determination of progression or regression of stages and for clinical assessment and care. Descriptions of the three stages of lipedema are as follows:

Stage 1: Normal skin surface with enlarged hypodermis (lipedema fat).

Stage 2: Uneven skin with indentations in fat and larger hypodermal masses.

Stage 3: Bulky extrusions of skin and fat causing large deformations especially on the thighs and around the knees that drastically inhibit mobility[[22]](#endnote-22)

Research indicates that it’s best to provide surgical intervention before the malformed appearance of stage 3 and lipolymphedema is reached. In addition, the stages above do not address the issue of pain many patient’s experience in the lower stages.

Lymphedema can occur secondary to obesity [[23]](#endnote-23) [[24]](#endnote-24) *or* lipedema, both forms of lipolymphedema secondary to a fat excess. Lymphedema is a common comorbid condition in severe obesity individuals with BMIs greater than 50 Kg/ m2.In the US the prevalence of obesity was 42% in 2017-18 and is increasing. [[25]](#endnote-25) Lipolymphedema is likely the second most common of lymphedema and may soon become the most common cause of lymphedema.

## ICD-10-CM Codes for Lipedema (2020)

Currently (July 2020) there is no ICD-10-CM diagnosis code in the United States specific to lipedema.\* The three codes below are used, in order of usage, for lipedema:

R60.9: Edema

Q82.0: Familial Hereditary Edema

E88.2: Adiposis dolorosa; Lipomatosis dolorosa (Dercum’s disease)

In the ICD-10-CM index, a search for lipedema returns:

Lipedema–See R60.9: edema.

The code I89.0: Secondary lymphedema may also be included for *lipolymphedema*, a serious progression of lipedema found in the most debilitating cases.

\* Specific codes for lipedema have been submitted to the NCHS/CDC (June 12, 2020) for the 2022 ICD-10-CM code set and are awaiting approval.

## CPT™ Codes for Liposuction (2020)

There are currently four liposuction CPT™ codes.

|  |  |
| --- | --- |
| 15876 | Suction assisted lipectomy; head and neck |
| 15877 | Suction assisted lipectomy; trunk |
| 15878 | Suction assisted lipectomy; upper extremity |
| 15879 | Suction assisted lipectomy; lower extremity |

The four codes describe suction assisted lipectomy/liposuction, sometimes abbreviated as SAL; this is another name for liposuction. Some practitioners prefer to use the unlisted code below to differentiate the procedure from cosmetic liposuction:

|  |  |
| --- | --- |
| 38999 | Unlisted procedure, hemic or lymphatic system |

The code above should be allowed for the procedure with any of the names for the procedure unique to lipedema below listed in the BOX 19: Reserved for Local Use (the comments section of the Claim Form).

1. Tumescent Liposuction
2. Tumescent Local Anesthesia
3. Lymph-Sparing Liposuction
4. Lymph-Sparing, Tumescent Liposuction
5. Water-Assisted Liposuction (WAL).
6. Power-Assisted Liposuction (PAL)[[26]](#endnote-26)
7. Laser-assisted Lipolysis (LAL)[[27]](#endnote-27)

We request you accept either the specific CPT™ codes above or the unlisted procedure code for liposuction for lipedema.

## Medical Carrier Reimbursement Policy Information

While strictly cosmetic liposuction (to improve appearance) is not reimbursed, reconstructive lymph-sparing liposuction (for lipedema, removal of a lipoma, and in conjunction with a panniculectomy) is currently paid by several medical insurance carriers in multiple states.

Anthem-Blue Cross policy NC00009, Cosmetic and Reconstructive Services Published 11/12/2019 considers lymph-sparing liposuction as for lipedema as medically necessary and reconstructive and a reimbursable procedure.[[28]](#endnote-28)

This policy covers the following 14 states: CA, CO, CT, GA, IN, KY, ME, MO, NH, NV, NY, OH, VA, and WI. It also covers Amerigroup, an Anthem subsidiary providing Medicare Part-C and Medicaid services in the following six states: Arizona, New Jersey, New Mexico, Tennessee, Texas, and Washington.

## Anthem NC.0009 Cosmetic and Reconstructive Services Policy

**Lipectomy/Liposuction:**

Lipectomy or liposuction for the treatment of lymphedema (for example, related to surgical mastectomy) or lipedema is considered medically necessary when all of the following criteria are met (A through D):

A. There is a significant physical functional impairment (for example, difficulty ambulating or performing activities of daily living) or medical complication, such as recurrent cellulitis; and

B. When lipectomy or liposuction is reasonably expected to improve the physical functional impairment; And C. Individual has not responded to at least 3 consecutive months of optimal medical management (for example, conservative treatment with compression garments and manual lymph drainage); and

D. The plan of care is to wear compression garments as instructed and continue conservative treatment postoperatively to maintain benefits.

Lipectomy or liposuction is considered cosmetic and not medically necessary when the reconstructive criteria in this section are not met or when the medically necessary criteria in this section are not met.

## Concepts of Medical Necessity, Reconstructive and Cosmetic

The coverage eligibility of medical and surgical therapies to treat musculoskeletal abnormalities is often based on a determination of whether repair of the abnormality is considered medically necessary, reconstructive or cosmetic in nature. In many instances the concept of reconstructive overlaps with the concept of medical necessity.

For example, services intended to correct a significant physical functional impairment as a result of trauma will be considered medically necessary and thus eligible for coverage, regardless of the contract language pertaining to reconstructive services, unless some other exclusion applies. Reconstructive means that the service “Returns the person to whole.”

Categories of conditions without associated functional impairment that may be included as reconstructive definitions, include or may be due to the following:

1. Surgery
2. Accidental trauma or injury
3. Diseases
4. Congenital anomalies
5. Severe anatomic variants
6. Chemotherapy.

In 2019, Wollina and colleagues published a case series on liposuction for the treatment of lipedema (n=111; stage 1=7, stage II=50, stage III=48). Participants were treated consecutively at a single center between 2007 and 2018. Most individuals were treated by micro-cannula liposuction in tumescent anesthesia, but some were treated with laser-assisted liposuction. Reduction of circumference was assessed using a tape measure. Pain was measured by a 10-point VAS, and mobility and reduction of bruising was evaluated using a 3-point scale. All participants had been treated with CDT for at least 6 months prior to surgery and had lipedema of the legs (27 individuals also had involvement in the arms). The mean follow-up was 2.0 ± 2.1 years. An improvement in the perception of mobility was achieved in all subjects; marked improvement or a complete reversal of impairment was reported in 86% of trial subjects.[[29]](#endnote-29)

At follow-up, the median reduction of limb circumference was 6 cm. The median pain level before treatment was reduced from 7.8 to 2.2. Bruising after minor trauma improved somewhat in 20.9% of individuals and completely or almost completely in 29.1% of individuals. A total of 16.4% of individuals no longer needed CDT. For 18 individuals, a follow-up of 5-7 years was available and showed no relapse in lipedema. Common adverse events included temporary methemoglobinemia (100%), bruising (98%), and burning sensations (82%). Less common adverse events included mild arm-vein phlebitis (2 cases), noninfectious panniculitis (1 case), arm edema from toluidine blue extravasation (1 case), epileptic attack during methemoglobinemia (1 case), postsurgical anemia requiring a blood transfusion (1 case), pulmonary fat embolism 2 days after surgery (1 case), and acute pulmonary edema 24 hours after surgery (1 case).

There were no fatalities, wound infections, or surgical interventions. In 4.5% of cases, liposuction was completed with other surgical procedures, such as thigh lifts, laser lipolysis, or debulking surgery. The authors concluded that an improvement of mobility could be achieved in all subjects and that liposuction is an effective treatment for painful lipedema. The authors also noted that centers performing liposuction should carefully monitor individuals for 24 hours and must be able to deal with possible complications.

In a 2015 survey of lipedema treatments of 85 patients, the author concluded:

In all 85 patients liposuction significantly reduced pain, bruising and the tendency of swelling in the extremities. It therefore led to a significant improvement in the quality of life of the patients.[[30]](#endnote-30)

**The Anthem Policy indicates the following:**

ICD-10 Diagnosis

All diagnoses, including but not limited to the following:

E65 Localized adiposity

E88.2 Lipomatosis, not elsewhere classified

I89.0 Lymphedema, not elsewhere classified (this code would indicate secondary lymphedema or lipo-lymphedema.

Q82.0 Hereditary lymphedema

**[Note:** The ICD-10-CM Index crosswalk code for lipedema: R60.9 Edema, is *not* one of the codes listed; until lipedema is awarded its own specific code, R60.9 *should* be included in all policies.]

CPT code: 15877 Suction assisted lipectomy; trunk

## Peer-Reviewed Research Supporting Lymph-Sparing Liposuction

Lipedema is referenced in over 300 research studies. There are over forty, peer-reviewed, medical journal articles reviewing the benefits, efficacy, and safety of lymph-sparing liposuction as the only surgical treatment for lipedema.[[31]](#endnote-31) [[32]](#endnote-32) In a 2010 study by Mollina he concludes:

Tumescence liposuction is a treatment option for lipedema and Dercum's disease. With careful monitoring the procedure is safe even for patients in advanced stages, higher age and with co-morbidities. [[33]](#endnote-33)

Van de Pas, in 2019 reported:

Lipoedema legs have a delayed lymph transport. Tumescent liposuction does not diminish the lymphatic function in lipoedema patients, thus tumescent liposuction can be regarded as a safe treatment.[[34]](#endnote-34)

The latest publication at the time of this writing is very favorable toward lymph-sparing liposuction: *Prevention of Progression of Lipedema With Liposuction Using Tumescent Local Anesthesia*: Results of an International Consensus Conference (2020). The results and conclusion from the report:

**Results:** Multiple studies from Germany have reported long-term benefits for as long as 8 years after liposuction for lipedema using tumescent local anesthesia.

**Conclusion:** Lymph-sparing liposuction using tumescent local anesthesia is currently the only effective treatment for lipedema. [[35]](#endnote-35)

**The peer-reviewed, medical research paper,** *Lipedema: A Call to Action!* [[36]](#endnote-36)addresses liposuction as a surgical option, the need for medical carrier reimbursement**,** long-term efficacy**,** tumescent local anesthesia (TLA)[aka lymph-sparing liposuction] is different than cosmetic liposuction, the highly effective outcomes as well as improvement in functionality and Quality of Life.[[37]](#endnote-37) Excerpts and specific, additional research references are below:

For patients with minimal or no improvement following conservative approaches, the following two surgical options may be considered: liposuction and lipectomy.[[38]](#endnote-38)

Notably, techniques employed in lipedema patients differ from those adopted for cosmetic purposes [[39]](#endnote-39) [[40]](#endnote-40). Following introduction of Tumescent Local Anesthesia (TLA), super‐TLA, and vibrating cannulas, this risk has considerably decreased. Several investigations have shown that TLA is highly effective in terms of restoring to a normal appearance as well as functional outcomes.

**Schmeller et al.** described an average reduction of 9,846 mL of subcutaneous fatty tissue after treatment, with an additional amelioration of sensitivity to pressure, edema, bruising, functional limitation, and cosmetic complaint (P < 0.001). Moreover, no serious complication occurred following the procedure, with wound infection rates of 1.4% and bleeding rates of 0.3% (Schmeller W. et. al., 2012).

Very recently**, Wollina et al**. reported on 111 patients mostly with advanced lipedema treated by microcannular liposuction in tumescent anesthesia between 2007 and 2018. They described a median total amount of lipoaspirate of 4,700 mL, a median reduction of limb circumference of 6 cm, and a median pain level lowering from 7.8 to 2.2 at the end of treatment as well as improved mobility and bruising. Serious adverse events were observed in 1.2% of procedures, with infection and bleeding rates being 0% and 0.3%, respectively (Wollina U, et. al., 2019).

Unfortunately, lipedema surgical treatments are still too often not reimbursed by health insurance companies, thus representing an expensive option for the overwhelming majority of patients (Halk, AB, et al., 2017). In addition, despite several promising short‐term results, only a few studies have evaluated the long‐term efficacy of TLA for lipedema treatment[[41]](#endnote-41) [[42]](#endnote-42).

## Reimbursement: The Lymph-Sparing, Tumescent Liposuction Procedure

Prior to surgery, surgeons assess lymphatic landmarks, including peri-saphenous lymphatic collection pathways to plan to execute the surgery without their disruption.[[43]](#endnote-43) A great deal of skill is required to not injure lymphatics. The surgery takes at least 4 hours and will often remove over 12 + Liters or 25 lbs of aspirate. This is not just fat removed, but also proteoglycans and other extracellular matrix components. A term that best describes the complexity of the procedure but is not in common use is Fibro-Lipo-Lymph-Aspiration. [[44]](#endnote-44)

Data supports the improvements in lymphatic function and symptoms that result from surgery.[[45]](#endnote-45) All the data from phlebologist / venous and lymphatic specialists in Germany (Rapprich, Schmeller) show improvements in Quality of Life and lymphatic-function surrogates like the need for compression and compression pump use.[[46]](#endnote-46)

**Fair Market Value**: currently surgeons charge between $7,000 and $16,000 per procedure. This is an enormous burden on those suffering the most from lipedema.

**Reduction in conservative treatment and progression:** Research shows lymph-sparing liposuction yields good long-term results in reduction of lipedema pain and in stopping the progression of lipedema to lipolymphedema.[[47]](#endnote-47) [[48]](#endnote-48) [[49]](#endnote-49) Currently the four CPT codes (15876-15879) for suction-assisted lipectomy (liposuction) have no Medicare RVU’s. Some may submit the unlisted code: 38999, referenced earlier.

A study by the commonwealth of Virginia, analyzing ten-years of insurance data shows:

“that costs of lymphedema treatment are an insignificant part of insured healthcare costs, and that treatment of lymphedema may reduce costs of office visits and hospitalizations due to lymphedema and lymphedema-related cellulitis.”[[50]](#endnote-50)

## Liposuction for Lipedema Documentation Requirements

We feel that it is reasonable to require minimal documentation to support liposuction for *lipedema* as reconstructive and medical necessity.

1. The patient will submit letters of medical necessity and a confirmed lipedema diagnosis from your primary care doctor and surgeon.
2. Document the progression of the disease and treatment.
3. Include all physical exam notes, labs, test, and relevant surgical operative reports.
4. Document and quantify all efforts concerning weight loss and managing obesity.
5. Document the patient has adhered to a low carbohydrate diet [either ketogenic diet or the more balanced anti-inflammatory diet] and exercise for at least six months.
6. Document at least six months of conservative treatment and that the patient has been compliant with all treatment and therapy recommendations which may include:
   1. Compression stocking care
   2. Combined decongestive therapy (CDT).
   3. Manual Lymphatic Drainage (MLD).
   4. Lymphedema therapy
7. The Provider should provide an expert opinion letter indicating that all conservative treatment has failed and the progression of the disease will worsen without surgical treatment.
8. All comorbidities and any safety issues concerning treatment (risks for surgery) have been addressed.
9. Patient has provided photographs.
10. The documentation illustrates that the procedure will improve functionality, mobility, Quality of Life and restores the patient to a more normal appearance.

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## Summary

1. Liposuction for lipedema is a reconstructive and medically necessary procedure that should be reimbursed. It meets the four reconstructive requirements as outlined by the AMA™, ASPS and Medicare.
2. Differentiate between reconstructive liposuction (Lymph-Sparing Liposuction) and cosmetic liposuction in your policy manual.
3. Numerous research studies indicate both its efficacy and safety.
4. Liposuction for lipedema is not investigational, experimental or unproven.
5. The patient must provide documentation concerning the nature of their condition and demonstrate that conservative measures have been followed for at least six months.
6. Implement a positive reimbursement policy for surgical treatment of lipedema, a misunderstood and under-diagnosed condition.

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