

SURGICAL TREATMENTS FOR LIPEDEMA AND LYMPHEDEMA

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Summary of Changes

Deletions:

• Section I. A. 1. Deleted the following inclusion criterion for liposuction for lipedema: *Body Mass Index (BMI)* \leq 32 at time of surgery

• Section I A. 2. Deleted the following exclusion for liposuction for lipedema: Body Mass Index (BMI) > 32

Additions:

• Added Section II. GOVERNMENTAL REGULATIONS

Changes:

• Lymphedema: R1 indicated that all microsurgical procedures for lymphedema are considered experimental, investigational or unproven. R2 now considers these procedures medically necessary only following a confirmed diagnosis of lymphedema. These procedures are still considered experimental, investigational or unproven when performed prophylactically.

Clarifications:

Restructured section I. A. Lipedema.

I. POLICY/CRITERIA

A. Lipedema

- 1. Liposuction/excision/debulking of extremities may be medically necessary when all of the following apply:
 - a. **Documented diagnosis of lipedema**. The diagnosis of lipedema can be documented only if all the following are met:
 - i. Appearance of bilateral and symmetric extremity involvement (thickened subcutaneous fat in the affected extremities bilaterally and symmetrically); and,
 - ii. Disproportionate adipocyte hypertrophy of the lower extremities in relationship to the trunk; and,
 - iii. Absence of pitting edema; and,
 - iv. Pain and/or hypersensitivity to touch in affected areas; and
 - v. Easy bruising with clinical documentation; and
 - vi. Tenderness and nodularity of fat deposits in lipedema affected areas (dimpled or orange peel texture); and,
 - vii. A negative Stemmer sign; and,
 - viii. Evidence of *cuffing* tissue enlargement ends abruptly at ankles or wrists, with sparing of hands and feet (also called *braceleting* or *inverse shouldering*); and,



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- b. Lack of improvement in swelling from elevation of limbs in lipedemaaffected areas; and,
- c. Lack of effect of weight loss on lipedema affected areas; and,
- d. A failed response to six or more consecutive months of conservative management (compression garments and manual lymph drainage); and
- e. There is significant physical function impairment (i.e. difficulty ambulating or performing activities of daily living) and/or there are medical complications such as recurrent cellulitis or skin ulcerations; and,
- f. Assessment by independent provider (e.g., specialist in vascular conditions) confirming that lipedema is an independent cause of the functional impairment and proposed surgery is expected to restore or improve the functional impairment; and,
- g. Attestation that the request is not for a re-treatment of a previously treated area; and,
- h. Attestation that retreatment for each body area (e.g., extremity) will take place within a 12-month period following the initial surgical treatment of that body area; and,
- i. The postoperative plan of care is to continue to wear compression garments as instructed and continue conservative treatment

2. Exclusions:

- a. Liposuction/excision/debulking for indications other than lipedema is considered cosmetic (i.e., procedures or services that change or improve appearance without significantly improving functional impairment) and not medically necessary and therefore not covered.
- b. Lipedema involving the trunk and back.
- c. Request is for a re-treatment of a previously treated area.

B. Lymphedema

- 1. The following surgical treatments for lymphedema are considered experimental, investigational or unproven:
 - a. Excisional procedures (e.g., debulking and liposuction)
 - b. Microsurgical treatment (e.g., microsurgical lymphatico-venous anastomosis, lymphatic- capsular-venous anastomosis, lymphovenous bypass) performed prophylactically (without a confirmed diagnosis of lymphedema)
 - c. Prophylactic lymphovenous bypass (also known as lymphatic microsurgical preventive healing approach or LYMPHA)
 - d. Vascularized lymph node transfer
 - e. Tissue transfer (e.g., omental or mesenteric flap).
- 2. The use of bioimpedance spectroscopy also known as bioelectrical impedance spectroscopy (e.g., SOZO) in the detection, diagnosis, or surveillance of

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primary lymphedema or non-cancer related lymphedema is not medically necessary as conventional measurement methods remain the standard of care.

(See Breast Related Procedures Medical policy #91545 for medical necessity criteria for the use of bioimpedance in the detection, diagnosis, or surveillance of breast cancer related lymphedema)

II. GOVERNMENTAL REGULATIONS

Centers for Medicare & Medicaid Services (CMS)

National Coverage Determinations (NCDs)	
Pneumatic Compression Devices <u>280.6</u>	
Local Coverage Determinations (LCDs)	
CGS Administrators, LLC	None identified
First Coast Service Options, Inc.	None identified
National Government Services, Inc.	None identified
Noridian Healthcare Solutions, LLC	None identified
Novitas Solutions, Inc.	None identified
Palmetto GBA	None identified
WPS Insurance Corporation	None identified
Articles	
Noridian Healthcare Solutions, LLC	Lymphedema Decongestive Treatment
	<u>A55710</u> <u>A52959</u>

III. MEDICAL NECESSITY REVIEW

Prior authorization for certain drug, services, and procedures may or may not be required. In cases where prior authorization is required, providers will submit a request demonstrating that a drug, service, or procedure is medically necessary. For more information, please refer to the Priority Health Provider Manual.

IV. APPLICATION TO PRODUCTS

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

- **❖** HMO/EPO: This policy applies to insured HMO/EPO plans.
- ❖ POS: This policy applies to insured POS plans.
- * PPO: This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.



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- * ASO: For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.
- * INDIVIDUAL: For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.
- * MEDICARE: Coverage is determined by the Centers for Medicare and Medicaid Services (CMS) and/or the Evidence of Coverage (EOC); if a coverage determination has not been adopted by CMS, this policy applies.
- * MEDICAID/HEALTHY MICHIGAN PLAN: For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule located at: http://www.michigan.gov/mdch/0,1607,7-132-2945 42542 42543 42546 42551-159815--,00.html. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: http://www.michigan.gov/mdch/0,1607,7-132-2945 5100-87572--,00.html, the Michigan Medicaid Provider Manual will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.

V. BACKGROUND

Lymphedema

The International Society of Lymphology (ISL) staging guidelines for **lymphedema** states:

- Stage 0: Latent or Subclinical -impaired lymphatic transport no evident swelling/edema, subtle changes in tissue fluid/composition changes in subjective symptoms may last months or years before progression
- Stage I: Spontaneously Reversible early accumulation of protein-rich fluid pitting edema, no evidence of dermal fibrosis subsides with elevation
- Stage II: Spontaneously Irreversible accumulation of protein-rich fluid pitting edema may progress to nonpitting as excess fat and fibrosis develop does not resolve with elevation alone
- Stage III: Lymphostatic Elephantiasis nonpitting significant fibrosis trophic skin changes such as fat deposits, acanthosis, and warty overgrowths

National Lymphedema Network (NLN): The NLN published a position paper on the diagnosis and treatment of lymphedema in 2011. Per the NLN website, this position paper has been retracted and is currently in the process of being updated.

American Society of Plastic Surgeons (ASPS): The ASPS does not have a guideline or position statement with evidence-based recommendations for the treatment of lymphedema. They do address surgical options for lymphedema on the ASPS website.

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Decongestive therapy program includes gradient compression bandaging or compression gradient sleeve or stockings, exercise program (with or without compression), extremity elevation of extremity for peripheral lymphedema, and objective measurement of lymphedema.

Pressure gradient sleeves or stockings are used for early treatment of lymphedema, as well as a maintenance measure after a reduction in swelling is achieved. These sleeves and stockings are available with different compression levels ranging from 20 to 60 mmHg. They should provide the highest compression tolerated by the patient. A compression garment must provide graduated compression (avoiding a tourniquet effect), typically starting with a minimum distal compression of 30 mmHg.

Edema can be objectively measured utilizing a tape measure, perometry (infra-red optical electronic scanner along with a computer), and water displacement. The important factor is consistency with the type of measurement and person performing the comparisons. Measurements are usually taken more frequently (e.g., every week) at the beginning of treatment and less frequently (e.g., monthly) after the effectiveness of treatment has been established. Documentation of pneumatic pump effectiveness for lymphedema should include edema measurements, visualized changes to the limb, and functional improvements (e.g., ROM, strength, writing, ambulation) facilitated by the decrease in edema obtained through use of the pneumatic compression device.

Exercise activates the pumping mechanisms of the musculoskeletal system, stimulating venous and lymphatic return. Exercises are performed with the compression bandage in place. Range of motion exercises, in combination with compression and elevation, are helpful in the management of lymphedema. A systematic review evaluated 4 randomized controlled trials that compared exercise with the use of compression garments to exercise alone. Although there was no statistically significant benefit to wearing a compression garment during exercise, there was insufficient evidence to support or refute the current recommendation for wearing a compression garment during exercise due to a moderate to high risk of study bias in a small number of studies.

There is a paucity of literature surrounding the use of IPC in the home setting. The use of intermittent pneumatic compression (IPC) devices for the prevention of a deep vein thrombosis (DVT) may be an option in certain clinical situations, especially when the use of pharmaceuticals for anticoagulation is not an option (e.g., hemorrhage, high bleeding risk) for hospitalized patients. A large, multi-center, well designed randomized controlled trial identified that the use of an IPC device reduced the risk of DVT in individuals who have had a stroke, with an absolute risk reduction of 3.6% in individuals receiving IPC compared to no IPC. Recent systematic reviews support the perioperative use of IPC for plastic surgery and neurosurgery but these results are based on studies of hospitalized patients.

Manual lymphatic drainage (MLD) is a specific manual technique designed to lessen lymphatic swelling by enhancing lymph drainage. This can be done alone but it often

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accompanies complex decongestive therapy. Although previous systematic reviews found contradictory results utilizing MLD, a Cochrane review found that MLD offered benefit when combined with compression bandages for lymphedema caused by breast cancer. Functional improvement and quality of life, however, could not be determined as data was insufficient. MLD may also be an option when compression cannot be tolerated. It is hypothesized that MLD stimulates lymph transport by encouraging interstitial fluid back into the lymphatics.

Bioimpedance analysis (BIA) is a noninvasive method that detects increases in tissue fluid based on increased flow of electricity. This technique is rapid and relies on small electrical currents that do not cause any pain or discomfort. BIA relies on the differing abilities of body tissues to conduct low level (200 to 800 microamperes) alternating electrical currents. Although lymph, blood, and muscle tissue exhibit low impedance (or resistance) to the flow of electricity, fat and bone exhibit high impedance. Changes in bioimpedance can be used to measure changes in body fluid composition due to conditions such as diabetes, cirrhosis of the liver, and lymphedema (LE). BIA can be performed at a single frequency or multiple frequencies ranging from 5000 to 1 million cycles per second. Multiple frequency BIA (MFBIA) is often referred to as bioimpedance spectroscopy (BIS) to distinguish it from the single frequency BIA (SFBIA). NCCN's Survivorship: Lymphedema (2023) recommends survivors at risk for lymphedema be regularly screened for lymphedema by symptom assessment, clinical exam, and, if available, bioimpedance spectroscopy. Early detection/diagnosis and early referral are key for optimal lymphedema management because stages 0 and 1 are reversible, whereas stages 2 and 3 are less responsive to treatment.

Lipedema

Lipedema is a **rare disorder** of adipose tissue that primarily affects females and is often misdiagnosed as obesity or lymphedema. There are numerous synonyms to refer to this condition (e.g. adipositas dolorosa, lipomatosis dolorosa, painful lipohypertrophy).

The disorder is well-known in Europe but is largely unrecognized and underdiagnosed in the United States. Lipedema is a distinct entity that must be differentiated from obesity and lymphedema, although it may progress to involve the venous and lymphatic systems, which increases the difficulty of its diagnosis (3). In contrast to primary lymphedema, the lymphatic system remains unimpaired in the initial stages of lipedema and can keep up with the increased amount of interstitial fluid. In the majority of the cases, lipedema is located in lower limbs with the feet unaffected. There is usually minimal pitting edema.

The typical presentation is of a woman with bilateral "stovepipe" enlargement of the legs and without involvement of the feet with a sharp demarcation between normal and abnormal tissue at the ankle, referred to as the "cuff sign." This is often combined with a symmetrical involvement of arms, particularly the upper arms, with sparing of hands. Lipedema may be isolated to the arms without involvement of the legs, but this is

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extremely rare. Patients may complain of tenderness and pain and sustain easy bruising. Elevating the limbs has no effect on the involved limbs.

The pathogenesis is unknown and no curative treatment is available. Advanced lipedema may progress into lymphedema. When lipedema remains untreated, increased lymphatic load continually exceeds lymphatic transport capacity resulting in the decompensation of the lymphatic system therefore, uni-, or much more typically, bilateral lymphedema can develop. The pressure of the fat tissue itself causes obstruction of the lymphatic vessels resulting in secondary lymphedema. Additionally, the deposition of protein-rich edema causes fibrosis of the tissue, further impairing lymphatic drainage. The combination of lymphatic insufficiency and lipedema is called lipolymphedema or lympho-lipedema.

Concomitant severe venous insufficiency is rare; however, varicosity is often seen among lipedematous patients.

There are currently four reported stages of lipedema:

- Stage 1 involves an even skin surface with an enlarged hypodermis;
- Stage 2 involves an uneven skin pattern with the development of a nodular or mass-like appearance of subcutaneous fat, lipomas, and/or angiolipomas;
- Stage 3 involves large growths of nodular fat causing severe contour deformity of the thighs and around the knee; and
- Stage 4 involves the presence of lipolymphedema

Management of lipedema is complex and distinct from lymphedema. The proposed main conservative treatment is complete or complex decongestive therapy (CDT). CDT combines several approaches including manual lymph drainage (a massage technique), compression therapy, and physical mobilization. Manual lymphatic drainage, compression stockings, intermittent pneumatic compression, skin care and exercise are often used to control pain and symptoms. Diet is also used to prevent or treat obesity associated with lipedema. It is suggested that lipedema patients avoid weight gain. Obesity and "yo-yo" dieting have been shown to exacerbate lipedema. Even with conservative and supportive treatments, the disease may progress and further treatment may be necessary. For a defined subset of lipedema patients who are unresponsive to conservative treatment, a surgical option may be liposuction using specialized techniques (e.g., water jet-assisted liposuction).

VI. CODING INFORMATION

ICD-10 codes that apply:

R60.9 Edema, unspecified

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CPT/HCPCS Codes:

- 15832 Excision, excessive skin and subcutaneous tissue (includes lipectomy); thigh (Not covered for Medicare)
- 15833 Excision, excessive skin and subcutaneous tissue (includes lipectomy); leg (Not covered for Medicare)
- 15834 Excision, excessive skin and subcutaneous tissue (includes lipectomy); hip (Not covered for Medicare)
- 15835 Excision, excessive skin and subcutaneous tissue (includes lipectomy); buttock (Not covered for Medicare)
- 15836 Excision, excessive skin and subcutaneous tissue (includes lipectomy); arm (Not covered for Medicare)
- 15837 Excision, excessive skin and subcutaneous tissue (includes lipectomy); forearm or hand (*Not covered for Medicare*)
- 15878 Suction assisted lipectomy; upper extremity (Not covered for Medicare and Medicaid)
- 15879 Suction assisted lipectomy; lower extremity (Not covered for Medicare and Medicaid)
- 99199 Unlisted special service, procedure or report

ICD-10 codes that apply:

- C20 Malignant neoplasm of rectum
- C21-C21.8 Malignant neoplasm of anus and anal canal
- C22-C22.9 Malignant neoplasm of liver and intrahepatic bile ducts
- C23 Malignant neoplasm of gallbladder
- C24-C24.9 Malignant neoplasm of other and unspecified parts of biliary tract
- C25-C25.9 Malignant neoplasm of pancreas
- C26-C26.9 Malignant neoplasm of other and ill-defined digestive organs
- C43-C43.9 Malignant melanoma of skin
- C44-C44.99 Other and unspecified malignant neoplasm of skin
- C50-C50.929 Malignant neoplasm of breast
- C51-C51.9 Malignant neoplasm of vulva
- C52 Malignant neoplasm of vagina
- C53-C53.9 Malignant neoplasm of cervix uteri
- C54-C54.9 Malignant neoplasm of corpus uteri
- C55 Malignant neoplasm of uterus, part unspecified
- C56-C56.9 Malignant neoplasm of ovary
- C57-C57.9 Malignant neoplasm of other and unspecified female genital organs
- C58 Malignant neoplasm of placenta
- C60-C60.9 Malignant neoplasm of penis
- C61 Malignant neoplasm of prostate
- C62-C62.92 Malignant neoplasm of testis
- C63-C63.9 Malignant neoplasm of other and unspecified male genital organs



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C64-C64.9 Malignant neoplasm of kidney, except renal pelvis

C65-C65.9 Malignant neoplasm of renal pelvis

C66-C66.9 Malignant neoplasm of ureter

C67-C67.9 Malignant neoplasm of bladder

C68-C68.9 Malignant neoplasm of other and unspecified urinary

organs D05-D05.92 Carcinoma in situ of breast

CPT/HCPCS Codes:

Covered for above diagnosis codes only

93702 Bioimpedance spectroscopy (BIS), extracellular fluid analysis for lymphedema assessment(s)

NOT COVERED FOR INDICATIONS IN THIS POLICY

15877 Suction assisted lipectomy; trunk

IV. REFERENCE

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