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Subject: Surgical Treatments for Lymphedema and Lipedema

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DESCRIPTION:

Lymphedema

Lymphedema is an abnormal accumulation of interstitial fluid and fibroadipose tissue in subcutaneous tissues or body cavities. Lymphedema can be either primary or secondary. Primary lymphedema is related to developmental abnormalities of the lymphatic system whereas secondary lymphedema is attributed to the impairment of lymphatic vessels due to conditions such as trauma, tumor, surgery, er infection or secondary to cancer treatment. Regardless of the etiology, it is clinically characterized with chronic swelling, localized pain, atrophic skin changes and secondary infections.

When conservative treatment fails (e.g., compression therapy, manual lymphatic drainage, complete decongestive therapy) surgical treatment may be considered. Surgical treatments can be either physiologic or ablative. Physiologic procedures help restore lymphatic flow and include lymphovenous bypass and vascularized lymph node transplant. In advanced stages of lymphedema, where extensive interstitial tissue fibrosis has occurred, physiologic therapies may not provide sufficient volume reduction. Procedures such as ablative procedures (e.g., suction-assisted lipectomy, debulking) may be used to improve outcome.

Lipedema - Upper and Lower Extremities and Trunk

Lipedema is a symmetrical and typically progressive enlargement of subcutaneous fat deposits that in a vast majority of patients begins in the lower extremities or buttock/hip area but can involve eventually the arms. The feet and hands are frequently spared leading to the classic 'cuffing' pattern.

The incidence of lipedema is estimated to be 11% of women and, although a true understanding of its etiology is unknown, it clearly is associated with hormonal changes of puberty, pregnancy, and menopause; it can be diagnosed in men. It presents typically with pain, non-pitting edema, tenderness, or hyperesthesia and/or easy bruisability of the affected areas. The adipose tissue is frequently nodular and focally tender in these areas. The overlying skin is soft and symmetrical at first and, as the disease progresses through its stages, the overlying skin can become dimpled or develop asymmetric folds and masses with associated infections, maceration and increasingly disabling functional limitations. The most frequent intervention is liposuction and it is not unusual to require approximately 3 sessions. This results

in resolution of signs and symptoms in more than 50% of patients. Involvement and compliance with ongoing postoperative conservative care is an integral part of the overall treatment regimen.

Table 1 - International Society of Lymphology (ISL) guidance for staging lymphedema based on "softness" or "firmness" of the limb and the changes with an elevation of the limb.

Table 1. Recommendations for Staging Lymphedema

Stage	Description
Stage 0 (subclinical)	Swelling is not evident and most patients are asymptomatic despite impaired lymphatic transport
Stage I (mild)	Accumulation of fluid that subsides (usually within 24 hours) with limb elevation; soft edema that may pit, without evidence of dermal fibrosis
Stage II (moderate)	Does not resolve with limb elevation alone; limb may no longer pit on examination
Stage III (severe)	Lymphostatic elephantiasis; pitting can be absent; skin has trophic changes

POSITION STATEMENT:

NOTE: Coverage for surgical treatments for lymphedema is subject to the member's benefit terms, limitations and maximums. Refer to specific contract language regarding surgical treatments for lymphedema.

Lymphedema			
Lymph node transplant (LNT)	Lymph node transplant (LNT) (also known as lymph node transfer, vascularized lymph node transfer) meets the definition of medical necessity when criteria (I-III) are met:		
	I. Diagnostic criteria - must satisfy "A" and "B":		
	A. Signs and symptoms - must satisfy at least one:		
	Has a significant physical functional impairment (such as: difficulty ambulating or performing activities of daily living)		
	Has a history of chronic or recurrent skin condition such as: cellulitis, intertriginous infections or ulcerations		
	 Has significant pain or weakness in the affected extremity. 		
	AND		
	B. Quantitative measurements:		
	Unilateral disease - must satisfy at least one:		
	 a. Volumetry differential (circumferential measurements and/or perometry differential) >10% (if affected extremity dominant extremity) or >7% (affected extremity is non-dominant extremity) 		
	b. Bioimpedance (L-Dex) differential of at least 10 units		
	c. Lymphoscintigraphy findings must show a minimum of a one-hour delayed transit time to first-level		

lymph nodes, axillary lymph nodes (upper extremity lymphedema) or a dermal back flow pattern.

- 2. Bilateral disease must satisfy "a.":
 - a. Lymphoscintigraphy findings must show a minimum of a one-hour delayed transit time to first-level lymph nodes, axillary lymph nodes (upper extremity lymphedema) or dermal back flow.
- II. **General lymph node transplant eligibility criteria** must satisfy "A", "B", and "C":
 - A. BMI \leq 35kg/m2
 - B. Completed a course of conservative treatment defined as lymphedema therapy for a minimum of 20 hours/week for 6 months. Lymphedema therapy includes compression therapy (bandaging/garment/gauntlet) AND any of the following treatment modalities: manual lymphatic drainage, complete decongestive therapy, use of pneumatic compression pump, targeted exercises for lymphedema treatment
 - C. Member demonstrates the ability to tolerate post-surgical compression therapy and physical therapy sessions per treating lymphedema provider.

III. NONE of the following contraindications exist:

- A. Transient lymphedema: any swelling that may meet the threshold for lymphedema criteria but is not persistent for at least six months post last oncologic treatment
- B. Lipidema without lymphatic dysfunction
- C. ANY of the following uncontrolled comorbidities:
 - 1. Venous disease (DVT, superior vena cava syndrome)
 - 2. Congestive heart failure (CHF)
 - 3. Medication-induced swelling
 - 4. Liver disease, including but not limited to cirrhosis, hypoproteinemia
 - 5. Nephropathy including end-stage renal disease
 - 6. Peripheral arterial disease clinically significant such as rest pain, claudication or ischemic ulcers
 - 7. Pregnancy
 - 8. Dye anaphylaxis
 - 9. Active infection of the affected extremity (cellulitis/erysipelas).

Lymph node transplant (LNT) is considered **experimental or investigational** for all other indications and locations, including, but not limited to inguinal lymph nodes (lower extremity lymphedema) **AND** prophylactic LNT at time of axillary lymph node dissection, aka

	LYMPHA. The evidence is insufficient to determine the effects of the technology on health outcomes.			
Lymphovenous Bypass	Lymphovenous bypass (microsurgical anastomoses between lymphatic vessels and veins) meets the definition of medical necessity when the following criteria (I-III) are met:			
	I. Diagnostic criteria: must satisfy "A" and "B"			
	A. Signs and symptoms – must satisfy at least one:			
	There is significant physical functional impairment (such as: difficulty ambulating or performing activities of daily living)			
	A chronic or recurrent skin condition such as: cellulitis, intertriginous infections or ulcerations			
	3. Significant pain or weakness in the affected extremity			
	AND			
	B. Quantitative measurements:			
	For unilateral disease - must satisfy at least one:			
	a. Volumetry differential (circumferential measurements and/or perometry differential) >10% (if affected extremity dominant extremity) or >7% (affected extremity is non-dominant extremity)			
	b. Bioimpedance (L-Dex) differential of at least 10 units			
	c. Lymphoscintigraphy findings must show a minimum of a one-hour delayed transit time to first-level lymph nodes, axillary lymph nodes (upper extremity lymphedema) or dermal back flow			
	2. For bilateral disease – must satisfy "a"			
	a. Lymphoscintigraphy findings must show a minimum of a one-hour delayed transit time to first-level lymph nodes, axillary lymph nodes (upper extremity lymphedema) or dermal back flow.			
	General lymphovenous bypass eligibility criteria – must satisfy "A", "B", and "C":			
	A. Member has BMI ≤ 35kg/m²			
	B. ICG lymphangiography findings demonstrate the presence of lymphatic channels			
	C. Member has completed a course of conservative treatment defined as lymphedema therapy for a minimum of 20 hours/week for 6 months. Lymphedema therapy includes compression therapy (bandaging/garment/gauntlet) AND any of the following treatment modalities: manual lymphatic			

- drainage, complete decongestive therapy, use of pneumatic compression pump, targeted exercises for lymphedema treatment
- D. Member demonstrates the ability to tolerate post-surgical compression therapy and physical therapy sessions per treating lymphedema provider.

III. NONE of the following contraindication exist:

- A. Transient lymphedema: any swelling that may meet the threshold for lymphedema criteria but is not persistent for at least six months post last oncologic treatment
- B. Lipidema without lymphatic dysfunction
- C. Any of the following uncontrolled comorbidities:
- D. Venous disease (deep vein thrombosis (DVT), superior vena cava syndrome)
- E. Congestive heart failure (CHF)
- F. Medication-induced swelling
- G. Liver disease, including but not limited to cirrhosis, hypoproteinemia
- H. Nephropathy including end-stage renal disease
- I. Peripheral arterial disease clinically significant such as rest pain, claudication or ischemic ulcers
- J. Pregnancy
- K. Dye anaphylaxis
- L. Active infection of the affected extremity (cellulitis/erysipelas).

Lymphovenous bypass is considered **experimental or investigational** for all other indications, including, but not limited to inguinal lymph nodes (lower extremity lymphedema), prophylactic bypass at the time of axillary lymph node surgery, aka, LYMPHA. The evidence is insufficient to determine the effects of the technology on health outcomes.

Reductive Procedures: Excision/Debulking and/or Suction-Assisted Liposuction

Excision/debulking and/or Suction-Assisted Liposuction of the limb **meets the definition of medical necessity** when the following criteria (I-III) are met:

- I. Diagnostic criteria must satisfy "A" and "B":
 - A. **Signs and symptoms** must satisy one:
 - 1. There is significant physical functional impairment (such as performing activities of daily living)
 - 2. A chronic or recurrent skin condition such as: cellulitis, intertriginous infections or ulcerations.
 - 3. Significant pain or weakness in the affected extremity
 - B. Quantitative measurements:

- 1. **For unilateral disease** must satisfy one:
 - a. Volumetry differential (circumferential measurements and/or perometry differential)
 >10% (if affected extremity dominant extremity) or >7% (affected extremity is non-dominant extremity);
 - Bioimpedance (L-Dex) differential of at least 10 units.
- 2. For bilateral disease must satisfy "a":
 - a. Lymphoscintigraphy findings must show a minimum of a one-hour delayed transit time to first-level lymph nodes, axillary lymph nodes (upper extremity lymphedema) or inguinal lymph nodes (lower extremity lymphedema) or dermal back flow.
- II. General eligibility criteria must satisfy all:
 - A. Member has BMI $\leq 35 \text{kg/m}^2$
 - B. Member has MRI imaging findings consistent with moderate to severe fat hypertrophy
 - C. For upper extremity: member has been evaluated by a surgeon who performs lymphatic surgery who determined they are a not a candidate for VLNT or lymphovenous bypass before this reductive surgery
 - D. Member has completed a course of conservative treatment defined as lymphedema therapy for a minimum of 20 hours/week for 6 months
 - E. Lymphedema therapy includes compression therapy (bandaging/garment/gauntlet) AND any of the following treatment modalities: manual lymphatic drainage, complete decongestive therapy, use of pneumatic compression pump, targeted exercises for lymphedema treatment
 - F. Member demonstrates the ability to tolerate post-surgical compression therapy and physical therapy sessions per treating lymphedema provider.

III. NONE of the following contraindications exist:

- A. Transient lymphedema: any swelling that may meet the threshold for lymphedema criteria but is not persistent for at least six months post last oncologic treatment
- B. Any of the following uncontrolled comorbidities:
 - 1. Venous disease (deep vein thrombosis (DVT), superior vena cava syndrome)
 - 2. Congestive heart failure (CHF)
 - 3. Medication-induced swelling
 - 4. Liver disease, including but not limited to cirrhosis, hypoproteinemia

- 5. Nephropathy including end-stage renal disease
- 6. Pregnancy
- Active infection of the affected extremity (cellulitis/erysipelas)
- 8. Peripheral arterial disease clinically significant such as rest pain, claudication or ischemic ulcers.

Lipidema

Liposuction (Tumescent or Water-assisted) and/or Lipectomy

Liposuction (tumescent or water-assisted) and/or lipectomy with or without skin excision **meets the definition of medical necessity** when the following criteria are met:

- I. Signs and symptoms must satisfy at least one:
 - A. There is significant physical functional impairment (difficulty ambulating or performing activities of daily living)
 - B. Recurrent cellulitis, intertriginous infections or ulcerations
 - C. Pain and significant tenderness or hypersensitivity of affected areas
 - D. History of easy bruising or bruising without apparent cause in lipedema-affected area.
- II. Photographs are submitted documenting the affected extremities requested for treatment
- III. Thickened subcutaneous fat in the affected extremities bilaterally and symmetrically (legs, thighs, hips or buttocks, or occasionally arms are affected)
- IV. "Cuffing" (tissue enlargement ends abruptly at ankles or wrists, with sparing of hands and feet) (also called "braceleting" or "inverse shouldering"). Note: This may be absent in early or late stages.
- V. Absence of pitting edema (unless the member has co-morbid lymphedema)
- VI. Overlying skin/tissue in affected areas is soft to palpation (may be absent in late-stage disease or with associated lymphedema)
- VII. Minimally responsive to at least 3 consecutive months of optimal medical management (a comprehensive decongestive therapy regimen- education, manual lymph drainage, introduction of compression garments and, if indicated, physical mobilization)
- VIII. Morbidly obese members must first complete a formal weight loss program
- For extremity surgery: Absence of peripheral arterial disease (clinically significant such as rest pain, claudication or ischemic ulcers)

		Submission of a plan of care agreement signed by the member which states the member understands the requirement for ongoing conservative therapy postoperatively (the wearing of
		compression garments and possibly decongestive therapy in order to maintain the benefits of the surgery) AND that they understand there is a strong likelihood that 2 or 3 procedures might be required to achieve meaningful goals of surgical intervention.

BILLING/CODING INFORMATION:.

The following codes may be use for diagnostic imaging, physiologic interventions (i.e., lymphovenous bypass (LVB), vascularized lymph node transfer (VLNT)) and reductive interventions (i.e., suction-assisted lipectomy) in the treatment of lymphedema.

CPT Coding:

15757	Free skin flap with microvascular anastomosis	
15758	Free fascial flap with microvascular anastomosis	
15832	Excision, excessive skin and subcutaneous tissue (includes lipectomy); thigh	
15833	Excision, excessive skin and subcutaneous tissue (includes lipectomy); leg	
15836	Excision, excessive skin and subcutaneous tissue (includes lipectomy); arm	
15839	Excision, excessive skin and subcutaneous tissue (includes lipectomy); other area	
15860	Intravenous injection of agent (eg, fluorescein) to test vascular flow in flap or graft	
15877	Suction assisted lipectomy; trunk	
15878	Suction assisted lipectomy; upper extremity	
15879	Suction assisted lipectomy; lower extremity	
35206	Repair blood vessel, direct; upper extremity	
38308	Lymphangiotomy or other operations on lymphatic channels	
78195	Lymphatics and lymph nodes imaging	
93702	Bioimpedance spectroscopy (BIS), extracellular fluid analysis for lymphedema	
	assessment(s)	

Magnetic Resonance Imaging (MRI) (Upper Extremity (73218, 73219) and Magnetic Resonance (MR) Lymphangiography

Magnetic resonance imaging (MRI) may be helpful for differentiating fluid vs solid-phase predominant disease in a member who presents with mixed-phase lymphedema (i.e., both fluid and solid-phase components), as indicated by a limb volume differential > 10%/7% (dominant/non-dominant extremity), lymphoscintigraphy findings consistent with lymphedema (i.e., delayed transit time and/or dermal backflow), and an elevated L-DEX score (> 10 units), who do not respond to a formal 3-6 month trial of CDT/controlled compression therapy, despite strict adherence to protocol.

MRI findings of fibrofatty tissue predominance in the subcutaneous plane, helps confirm the patient's candidacy for up front liposuction, as physiologic intervention is unlikely to result in a significant improvement in limb volume reduction in this setting. Rather, staged physiologic intervention may be considered to stabilize fluid reductions in the limb, after it has been physically debulked, to allow the patient to eventually wean out of full-time compression garments.

MRI in a member who presents with the above and the MRI findings revealed that the member had fluid predominant disease, the member would be considered a poor candidate for surgical intervention either due to lack of adherence or response to therapy, compression and/or potential secondary factors contributing to limb swelling (i.e., venous insufficiency, endocrine/metabolic disorders, congestive heart failure (CHF), chronic kidney disease (CKD), liver disease, etc.) that may require further work-up.

Magnetic resonance (MR) lymphangiography may be helpful in both diagnosis and management of a members with lymphedema. MR lymphangiography images can provide information regarding structural and functional abnormalities of the lymphatic system.

The following information is required documentation for medical review: physician history and physical, physician operative report, pathology report, and attending physician visit notes that include documentation of medical indication.

LOINC Codes

DOCUMENTATION TABLE	LOINC CODES	LOINC TIME FRAME MODIFIER CODE	LOINC TIME FRAME MODIFIER CODES NARRATIVE
Physician history and physical	28626-0	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Physician operative report	28573-4	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Pathology report	27898-6	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Attending physician visit note	18733-6	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.

NOTE: Photos are not required with the initial review. Photos should be maintained as part of the medical record. Florida Blue may request photos as part of the review process.

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) was found at the time of the last guideline reviewed date.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request

DEFINITIONS:

Erysipelas: an infection of the upper layers of the skin (superficial). The most common cause is group A streptococcal bacteria, especially Streptococcus pyogenes. Erysipelas results in a fiery red rash with raised edges that can easily be distinguished from the skin around it.

RELATED GUIDELINES:

Pneumatic Compression Devices, 09-E0000-31

OTHER:

None applicable.

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 12/01/22.

GUIDELINE UPDATE INFORMATION:

01/01/22	New Medical Coverage Guideline.
12/15/22	Review; no change to position statement.
05/23/23	Update to Program Exceptions section.