Medicare Medical Policy

Surgical Treatments for Lymphedema

MEDICARE MEDICAL POLICY NUMBER: 341

Effective Date: 3/1/2025	MEDICARE COVERAGE CRITERIA	. 2
Last Review Date: 2/2025	POLICY CROSS REFERENCES	
Next Annual Review: 2/2026	POLICY GUIDELINES	
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INSTRUCTIONS FOR USE: Company Medicare Medical Policies serve as guidance for the administration of plan benefits and do not constitute medical advice nor a guarantee of coverage. Company Medicare Medical Policies are reviewed annually to guide the coverage or non-coverage decision-making process for services or procedures in accordance with member benefit contracts (otherwise known as Evidence of Coverage or EOCs) and Centers of Medicare and Medicaid Services (CMS) policies, manuals, and other CMS rules and regulations. In the absence of a CMS coverage determination or specific regulation for a requested service, item or procedure, Company policy criteria or applicable utilization management vendor criteria may be applied. These are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

The Company reserves the right to determine the application of Medicare Medical Policies and make revisions to these policies at any time. Any conflict or variance between the EOC and Company Medical Policy will be resolved in favor of the EOC.

SCOPE: Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as "Company" and collectively as "Companies").

PRODUCT AND BENEFIT APPLICATION

MEDICARE COVERAGE CRITERIA

IMPORTANT NOTE: More than one Centers for Medicare and Medicaid Services (CMS) reference may apply to the same health care service, such as when more than one coverage policy is available (e.g., both an NCD and LCD exist). All references listed should be considered for coverage decision-making. The Company uses the most current version of a Medicare reference available at the time of publication; however, these websites are not maintained by the Company, so Medicare references and their corresponding hyperlinks may change at any time. If there is a conflict between the Company Medicare Medical Policy and CMS guidance, the CMS guidance will govern.

Service	Medicare Guidelines
Suction Assisted Lipectomy (aka,	Local Coverage Determination (LCD) for Plastic Surgery
Suction Assisted Protein Lipectomy	(<u>L37020</u>)
or SAPL)	
	NOTE: This LCD states, "when the procedure is utilized to
	remove a lipoma, it is considered reconstructive surgery. The
	clinical record must clearly demonstrate medical necessity
	for the lipoma removal as most such tumors are benign and
	do not require removal. All other uses are currently
	considered cosmetic in nature and non-covered." Therefore,
	suction assisted lipectomy is considered cosmetic for any
	condition other than lipomas.

Medicare Coverage Criteria: "MA organizations may create publicly accessible internal coverage criteria... when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs." (§ 422.101(b)(6) – see Policy Guidelines below)

- Medicare Coverage Manuals: Medicare does not have criteria for surgical treatments for lymphedema in a coverage manual.
- National Coverage Determination (NCD): Medicare does not have an NCD for surgical treatments for lymphedema.
- Noridian J-F Local Coverage Determination (LCD)/Local Coverage Article (LCA): As of the
 most recent policy review, with the exception of the above LCD for SAPL, no Medicare
 Administrative Contractors (MACs) have LCDs for surgical treatments for lymphedema.
- Therefore, in the absence of established Medicare coverage criteria in a manual, NCD, LCD, or other regulatory guidance, Company criteria below are applied for medical necessity decisionmaking. In this case, Medicare coverage criteria are considered "not fully established" as defined under CFR § 422.101(6)(i)(C) as there is no Medicare coverage criteria available for many of these procedures.

• **NOTE:** The summary of evidence, as well as the list of citations/references used in the development of the Company's internal coverage criteria, are publicly available and can be found using the Company medical policy link below [CFR § 422.101(6)(ii)(A) and (B)].

Vascularized Lymph Node Transfer (VLNT)

Company medical policy for <u>Surgical Treatments for Lymphedema</u>

Lymphatic Venous Anastomosis (aka, Lymphaticovenous anastomosis or LVA)

Lymphatic-lymphatic bypass

Lymphovenous bypass

Tissue transfer (e.g., omental)

Lymphatic physiological microsurgery performed during nodal dissection or breast reconstruction to prevent lymphedema (e.g., LYMPHA or lymphatic microsurgical preventing healing approach)

Autologous lymph node transplantation;

Lymphatico-lymphatic bypass;

Lymphatic-venous-lymphatic plasty

 These procedures are considered not medically necessary for Medicare Plan members based on the Company medical policy. <u>See Policy Guidelines below.</u>

IMPORTANT NOTICE: While some services or items may appear medically indicated for an individual, they may also be a direct exclusion of Medicare or the member's benefit plan. Such excluded services or items by Medicare and member EOCs include, but are not limited to, services or procedures considered to be cosmetic, not medical in nature, or those considered not medically reasonable or necessary under *Title XVIII of the Social Security Act, §1862(a)(1)(A)*. If there is uncertainty regarding coverage of a service or item, please review the member EOC or submit a pre-service organization determination request. Note that the Medicare Advance Beneficiary Notice of Noncoverage (ABN) form cannot be used for Medicare Advantage members. (Medicare Advance Written Notices of Non-coverage. MLN006266 May 2021)

POLICY CROSS REFERENCES

- Breast Reconstructive Surgery, Implant Management, and Reduction Mammoplasty, MP523
- Compression Bandages, Stockings, and Wraps, MP139
- Pneumatic Compression Devices, MP138
- Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS), MP302

The full Company portfolio of Medicare Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

BACKGROUND

Lymphedema surgery can be classified as either excisional or reconstructive.

Excisional surgical procedures for lymphedema involve resection of redundant tissue that may develop in long-standing severe lymphedema and elephantiasis and may include such procedures as debulking and liposuction (also known as lipoplasty, suction-assisted lipectomy, circumferential suction-assisted lipectomy [CSAL], liposuction in lymphedema and lympho-liposuction). Suction Assisted Protein Lipectomy (SAPL) has been used to reduce the *solid* component of swelling in chronic lymphedema.

Reconstructive (physiologic) surgical procedures attempt to improve lymphatic drainage with either anastomoses between lymphatic systems (i.e., linking subcutaneous tissues with the deep lymphatics), creating lymphovenous anastomoses or creation of artificial lymph channels. These include such procedures as microsurgical treatment (eg, microsurgical lymphatico-venous anastomosis, lymphatic-capsular-venous anastomosis, lymphovenous bypass), lymph node transfer (LVT; also known as vascularized lymph node transfer or VLNT) and tissue transfers. Microsurgical procedures target the *fluid* component that predominates at earlier stages of the disease.

MEDICARE AND MEDICAL NECESSITY

For Medicare, only medically reasonable and necessary services or items which treat illness or injury are eligible for Medicare coverage, as outlined in *Title XVIII of the Social Security Act, §1862(a)(1)(A)*. MA organizations (MAOs) make medical necessity determinations based on coverage and benefit criteria, the member's unique personal medical history (e.g., diagnoses, conditions, functional status, comorbidities, etc.), physician recommendations, and clinical notes, as well as involvement of a plan medical director, where appropriate. (§ 422.101(c)(1))

In addition:

"MA organizations may create publicly accessible internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs. Current, widely-used treatment guidelines are those developed by organizations representing clinical medical specialties, and refers to guidelines for the treatment of specific diseases or conditions. Acceptable clinical literature includes large, randomized controlled trials or prospective cohort studies with clear results, published in a peer-reviewed journal, and specifically designed to answer the relevant clinical question, or large systematic reviews or meta-analyses summarizing the literature of the specific clinical question." (§ 422.101(b)(6) and Medicare Managed Care Manual, Ch. 4, §90.5)

The Plan's Medicare policy for PHA Medicare Medical Policy Development and Application (MP50) provides details regarding Medicare's definition of medical necessity and the hierarchy of Medicare references and resources during the development of medical policies, as well as the Plan's use of evidence-based processes for policy development.

Since there are not fully established coverage criteria for most lymphedema surgical treatments available in applicable Medicare statutes, regulations, NCDs or LCDs, then Company medical policy criteria will be applied. See the Medicare Coverage Criteria table above for more information regarding the use of internal coverage criteria when Medicare coverage criteria are not fully established.

REGULATORY STATUS

U.S. FOOD & DRUG ADMINISTRATION (FDA)

While clearance by the Food and Drug Administration (FDA) is a prerequisite for Medicare coverage, the 510(k) premarket clearance process does not in itself establish medical necessity. Medicare payment policy is determined by the interaction of numerous requirements, including but not limited to, the availability of a Medicare benefit category and other statutory requirements, coding and pricing guidelines, as well as national and local coverage determinations and clinical evidence.

BILLING GUIDELINES AND CODING

GENERAL

See the associated local coverage article (LCA) for related billing and coding guidance for services addressed by Medicare coverage policy:

LCA: Billing and Coding: Plastic Surgery (A57222)

CODE	CODES*		
CPT	14000	Adjacent tissue transfer or rearrangement, trunk; defect 10 sq cm or less	
	14001	Adjacent tissue transfer or rearrangement, trunk; defect 10.1 sq cm to 30.0 sq cm	
	14020	Adjacent tissue transfer or rearrangement, scalp, arms and/or legs; defect 10 sq cm or less	
	14021	Adjacent tissue transfer or rearrangement, scalp, arms and/or legs; defect 10.1 sq cm to 30.0 sq cm	
	14040	Adjacent tissue transfer or rearrangement, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands and/or feet; defect 10 sq cm or less	
	14041	Adjacent tissue transfer or rearrangement, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands and/or feet; defect 10.1 sq cm to 30.0 sq cm	
	14060	Adjacent tissue transfer or rearrangement, eyelids, nose, ears and/or lips; defect 10 sq cm or less	
	14061	Adjacent tissue transfer or rearrangement, eyelids, nose, ears and/or lips; defect 10.1 sq cm to 30.0 sq cm	
	14301	Adjacent tissue transfer or rearrangement, any area; defect 30.1 sq cm to 60.0 sq cm	

	14302	Adjacent tissue transfer or rearrangement, any area; each additional 30.0 sq cm,
		or part thereof (List separately in addition to code for primary procedure)
	15832	Excision, excessive skin and subcutaneous tissue (includes lipectomy); thigh
	15833	Excision, excessive skin and subcutaneous tissue (includes lipectomy); leg
	15834	Excision, excessive skin and subcutaneous tissue (includes lipectomy); hip
	15835	Excision, excessive skin and subcutaneous tissue (includes lipectomy); buttock
	15836	Excision, excessive skin and subcutaneous tissue (includes lipectomy); arm
	15837	Excision, excessive skin and subcutaneous tissue (includes lipectomy);
		forearm/hand
	15838	Excision, excessive skin and subcutaneous tissue (includes lipectomy); submental
		fat pad
	15839	Excision, excessive skin and subcutaneous tissue (includes lipectomy); other area
	15876	Suction assisted lipectomy; head and neck
	15877	Suction assisted lipectomy; trunk
	15878	Suction assisted lipectomy; upper extremity
	15879	Suction assisted lipectomy; lower extremity
	38308	Lymphangiotomy or other operations on lymphatic channels
	38589	Unlisted laparoscopy procedure, lymphatic system
	38999	Unlisted procedure, hemic or lymphatic system
	49904	Omental flap, extra-abdominal (eg, for reconstruction of sternal and chest wall
		defects)
	49905	Omental flap, intra-abdominal (List separately in addition to code for primary
		procedure)
	49906	Free omental flap with microvascular anastomosis
HCPCS	None	

*Coding Notes:

- The code list above is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit. According to Medicare, "presence of a payment amount in the MPFS and the Medicare physician fee schedule database (MPFSDB) does not imply that CMS has determined that the service may be covered by Medicare." The issuance of a CPT or HCPCS code or the provision of a payment or fee amount by Medicare does not make a procedure medically reasonable or necessary or a covered benefit by Medicare. (Medicare Claims Processing Manual, Chapter 23 Fee Schedule Administration and Coding Requirements, §30 Services Paid Under the Medicare Physician's Fee Schedule, A. Physician's Services)
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be denied as not covered. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, prior authorization is recommended.
- See the non-covered and prior authorization lists on the Company <u>Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website</u> for additional information.
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling
 edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and
 Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website
 for coding guidelines and applicable code combinations.

REFERENCES

None

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
8/2022	New Medicare Advantage medical policy (converted to new format 2/2023)
7/2023	Annual review; no criteria changes but language revision due to Company policy change
	from "investigational" to "not medically necessary"
3/2024	Annual review; no criteria changes
3/2025	Annual review; no criteria changes