

Surgical Treatments for Lymphedema

MEDICAL POLICY NUMBER: 222

Effective Date: 3/1/2024
Last Review Date: 2/2024
Next Annual Review: 2/2025
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INSTRUCTIONS FOR USE: Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement. 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.

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

## PLAN PRODUCT AND BENEFIT APPLICATION

Commercial

Medicaid/OHP\*

Medicare\*\*

### \*Medicaid/OHP Members

*Oregon*: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

Notice to Medicaid Policy Readers: For comprehensive rules and guidelines pertaining to this policy, readers are advised to consult the Oregon Health Authority. It is essential to ensure full understanding and compliance with the state's regulations and directives. Please refer to OHA's prioritized list for the following coverage guidelines:

### Surgical Treatments for Lymphedema: Guideline Note 43

PHP follows Oregon Administrative Rules (OARs) 410-120-1200 and 410-141-3820 through 3830 for coverage of Lipedema Treatment.

### \*\*Medicare Members

This *Company* policy may be applied to Medicare Plan members only when directed by a separate *Medicare* policy. Note that investigational services are considered “**not medically necessary**” for Medicare members.

## COVERAGE CRITERIA

- I. Surgical treatment for lymphedema is considered **not medically necessary**, including but not limited to the following (A.-B.):
  - A. Excisional procedures, including but not limited to the following (1.-2.):
    1. Liposuction (also known as suction-assisted lipectomy or suction-assisted protein lipectomy).
    2. Debulking
  - B. Physiologic procedures, including but not limited to the following (1.-2.):
    1. Vascularized lymph node transfer
    2. Lymphatic bypass techniques, including but not limited to:
      - a. Lymphovenous anastomosis
      - b. Lymphatic-lymphatic bypass
      - c. Lymphovenous bypass
    3. Tissue transfer (e.g., omental)

- II. Lymphatic physiological microsurgery performed during nodal dissection or breast reconstruction to prevent lymphedema, including, but not limited to LYMPHA (Lymphatic Microsurgical Preventing Healing Approach), is considered **not medically necessary**.

Link to [Evidence Summary](#)

## POLICY CROSS REFERENCES

- [Breast Surgery: Reduction Mammoplasty, Reconstructive Surgery, and Implant Management](#), MP58
- [Compression Bandages, Stockings, and Wraps](#), MP146
- [Compression: Outpatient Pneumatic Devices](#), MP145
- [Durable Medical Equipment, Prosthetics, Orthotics, and Supplies \(DMEPOS\)](#), MP142
- Massage Therapy: PEBB and Providence Health and Services (PH&S)

The full Company portfolio of current Medical Policies is available online and can be [accessed here](#).

## POLICY GUIDELINES

### BACKGROUND

#### Lymphedema

Lymphedema is the abnormal accumulation of subcutaneous fat and fluid in body tissue.<sup>1</sup> It leads to chronic swelling that can cause disability, pain and cosmetic issues. The condition is most common in the arms and legs. In addition to increasing the likelihood of cellulitis, lymphedema impairs quality of life (QOL) due to symptoms such as limb tightness, heaviness, weakness, and loss of sensation, in addition to aesthetic concerns.<sup>2</sup>

Primary lymphedema results from a congenital inadequacy and gradual occlusion of lymphatics due to congenital lymphatic system dysplasia. Secondary lymphedema results from damage to the lymphatic system or removal of lymph nodes by surgery, radiation, infection or injury. Most commonly, lymphedema occurs secondary to cancer or cancer treatment.

#### Current Treatments

Treatment is intended to reduce the size of the limb, improve function, and prevent complications such as infection and lymphangiosarcoma. Current conservative treatments for lymphedema include manual lymph drainage (MLD), which stimulates the movement of fluids in the tissues away from the affected limb, and comprehensive decongestive therapy (CDT). CDT combines MLD massage techniques with compressive bandaging, skin care and exercises. These techniques aim to reduce the pain and discomfort associated with lymphedema.<sup>1</sup>

Surgical treatments currently being investigated for severe lymphedema are intended either to reduce the size of the limb or to restore lymphatic flow. Surgical strategies fall into two categories: excisional and physiologic, described here:

#### Excisional procedures:

- removal or ablation of skin and/or adipose or fibrotic tissue
- includes the following procedures:
  - *Liposuction (also known as suction-assisted lipectomy or suction-assisted protein lipectomy):* adipose tissue and fibrosis are removed by suction from the affected limb through multiple small incisions.
  - *Excision:* removes skin and subcutaneous tissue to decrease bulk.

#### Physiologic procedures:

- involving reconstruction of damaged anatomy to improve physiologic function, such as lymphatic flow/drainage or lymphangiogenesis
- includes the following procedures:
  - *Lymphatic bypass procedures:* intended to reconstruct lymph vessels to redirect excess lymphatic fluid into venous circulation.
    - Includes but is not limited to lymphovenous anastomosis (LVA), lymphatic-lymphatic bypass and lymphovenous bypass.
    - Includes LYMPHA (lymphatic microsurgical preventive healing approach), preventive use of LVA
  - *Vascularized lymph node transfer (VLNT):* free tissue transfer of the patient's own soft tissue, including vascularized lymph nodes, commonly from the supraclavicular lymph nodes and superficial inguinal lymph nodes, to the affected limb.
  - *Flap/Tissue Transfer:* the transfer of omental and/or mesenteric tissue has recently been studied as a treatment for lymphedema.

In addition, combination surgical procedures are also being investigated (e.g. excision plus liposuction) as a potential treatment option.

## **REGULATORY STATUS**

### **U.S. FOOD AND DRUG ADMINISTRATION (FDA)**

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

## **CLINICAL EVIDENCE AND LITERATURE REVIEW**

### **EVIDENCE REVIEW**

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of surgical procedures as a treatment for lymphedema. Below is a summary of the available evidence identified through January 2024.

## **Systematic Reviews**

### Liposuction

- In 2020 (reviewed 2023), Hayes published a health technology assessment of liposuction for the reductive surgical treatment of lymphedema.<sup>2</sup> The review was comprised of 10 studies investigating the efficacy and safety of liposuction alone, liposuction plus controlled compression therapy (CCT), or liposuction plus complex decongestive therapy (CDT). Study sample sizes ranged from 20 to 130 patients and follow-up times ranged from 6 month to 5 years. Studies included one randomized trial, 2 prospective matched pairs studies, 1 prospective comparative cohort study, 1 prospective noncomparative cohort study (pretest/posttest analysis), and 5 noncomparative cohort studies. One prospective matched study found no significant changes at 3 and 12 months in lymphatic function after liposuction plus CCT compared to CCT alone. Nine studies examined limb size reduction, finding significantly greater improvement with liposuction plus CCT compared to CCT alone in women with breast cancer treatment-related lymphedema. Four studies analyzed patient-reported outcomes such as HRQOL and symptoms. The RCT found that submental liposuction compared to no liposuction was associated with significantly greater improvement in patient assessments among patients with head and neck cancers. The 3 other studies also found improvement in symptoms and physical and psychosocial functioning after liposuction for patients with breast cancer treatment-related upper extremity lymphedema (UEL), and other UELs. All studies assessing safety found no major complications.

Hayes found that the body of evidence available was overall of low quality. The RCT was considered of fair quality, while the rest of the studies were graded as poor or very poor due to small samples, short term follow, lack of randomization, lack of comparator groups, and high risk of bias due to retrospective design.

Hayes concluded that there was low-quality evidence to suggest that liposuction followed by compression therapy has a low risk of complications and is associated with improvements in limb volume and patient-reported baseline symptoms, giving liposuction plus compression therapy a C rating. Hayes also concluded that there is very low quality of evidence that is insufficient to draw conclusions for liposuction for the reductive surgical treatment of adult patients with head and neck cancer treat-related lymphedema, giving it a D2 rating.

### Microsurgical Treatment

- In 2020 (reviewed 2023), Hayes published a health technology assessment of lymphovenous anastomosis (LVA) for the physiological microsurgical treatment of lymphedema.<sup>3</sup> The review included 11 studies, comprising of 4 retrospective comparative cohort studies and 7 noncomparative studies with pretest-posttest analysis. Three studies examined lymphatic functioning or anastomosis patency. One comparative study found that patients in the vascularized supraclavicular lymph node transfer (VSLNT) group had higher rates of improvement compared to LVA (54% versus 23%, P=0.046) and none of the patients regained normal lymphatic function or

were able to stop use of compression therapy. In the noncomparative studies, LVA patency rates were high (75% at 12 months and 92% at 36 months), but reduced over time. Eleven studies examined limb size reduction. Among the 4 comparator studies, results were mixed. The combination of bypass microvascular breast reconstruction (MBR) with vascularized lymph node transfer (VLNT) and LVA was more efficacious than no-bypass MBR with VLNT, LVA was more effective than complete decongestive therapy in 1 study but VLNT was more effective than LVA in the same study, LVA had similar efficacy as free lymph node transplant surgery in 1, and VSLNT was more efficacious than LVA in 1 study. All noncomparative studies showed reduction in limb size after treatment.

Hayes found that the body of evidence supporting the efficacy and safety of LVA for the treatment of upper or lower extremity lymphedema was moderate in size and low in overall quality. The majority of the studies were noncomparative and each study had a number of limitations, including retrospective design, lack of power analyses, no randomization, small sample sizes, lost to follow up, and inconsistent reporting of efficacy and safety outcomes. Hayes gave LVA for the treatment of lymphedema a C rating, stating,

“This Rating reflects an overall low-quality body of evidence suggesting that LVA may be efficacious in improving outcomes in selected patients with lymphedema as evidenced by improvements in baseline symptoms and limb volume. This Rating also reflects the substantial uncertainty that remains about the efficacy, safety, and patient selection criteria for LVA due to the absence of prospective comparative studies with adequate controls and follow-up duration. LVA appears to carry a low risk of complications.”<sup>3</sup>

- In 2020 (reviewed 2022), Hayes published a health technology assessment on lymph tissue transfer for physiological microsurgical treatment of lymphedema.<sup>4</sup> Twelve studies investigating lymph node transplant (LNT) were included in the analysis, including 1 randomized trial, 2 retrospective comparative cohort studies, 1 prospective comparative cohort study, 7 noncomparative studies with pretest-posttest analysis, and 1 prospective noncomparative study. Three studies examined lymphatic function. One comparative study found that patients treated with VSLNT had a higher percentage of improved lymphatic function compared to those treated with LVA. Two noncomparative studies found improvement in lymphatic transport index and in lymphatic drainage after VLNT. Eleven studies examined limb size reduction. All 4 comparative studies found a significantly greater reduction with LNT compared with other interventions. The randomized trial found a significantly greater mean reduction in excess volume from baseline to follow-up of 20.9% for VLNT plus physical therapy compared to a 6.8% reduction from physical therapy alone. The RCT also found improved infection rates, pain scores, and overall function in the VLNT group. LNT was shown to be associated with a low risk of developing manageable donor-site and recipient site complications. No deaths were reported and major complications were rare.

Hayes determined that the body of evidence available on the safety and efficacy of LNT for lymphedema is overall low quality. Limitations included heterogeneity across studies, retrospective designs, lack of power analysis and predefined primary endpoints, lack of randomization, and small sample sizes. Hayes gave LNT for the microsurgical treatment of moderate to severe primary or secondary lymphedema a C ratings, stating,

“This Rating reflects consistent low-quality evidence suggesting that LNT is relatively safe and is associated with improvements in limb volume and patient-reported baseline symptoms. This Rating also reflects individual study limitations, heterogeneity among the studies in lymphedema site and etiology, and remaining questions regarding patient selection criteria for LNT and optimal procedural parameters, including selection of donor and recipient sites.”<sup>4</sup>

- In 2019 (updated in 2022), Hayes published a health technology assessment of microsurgery for primary prevention of breast cancer related lymphedema.<sup>5</sup> The review included 8 studies total, 1 randomized trial, 2 retrospective cohort studies, 2 pretest-posttest studies, 1 case-control study, and 2 case series investigating LYMPHA (lymphatic microsurgical preventive healing approach), with follow-up durations ranging from 3 to 48 months post-surgery. The main outcome included in the studies was rate of lymphedema. The studies generally had low rates of lymphedema, ranging from 0% to 12.5%. In studies comparing LYMPHA to no LYMPHA, patients receiving LYMPHA were less likely to develop lymphedema. The RCT (n=46) compared LYMPHA to LYMPHA at the time of axillary lymph node dissection (ALND). One patient in the LYMPHA group developed lymphedema at 6-month follow up compared to 7 patients in the control group. Incidence of lymphedema was significantly greater in the control group at 3 months follow up. Among the other non-randomized comparator studies, one study found no significant difference between LYMPHA during ALND, cases where LYMPHA could not be completed, and historical controls; and two other studies found that LYMPHA significantly reduced rates of lymphedema compared to no LYMPHA. Noncomparative studies found that secondary lymphedema occurred in 0% to 5% of women with breast cancer who received LYMPHA. Only 2 studies systematically reported adverse events. One event was reported in each study.

Hayes found that the overall body of evidence evaluating LYMPHA for prevention of breast cancer-related lymphedema was low quality. Five studies were deemed of low quality and 3 of very low quality. Limitations of studies included small sample sizes, lack of power analyses, retrospective design, lack of randomization, poor reporting of data, and heterogeneity in patient populations and treatment protocols. Few studies reported procedure-related complications. Hayes gave a C rating for the use of LYMPHA for the prevention of lymphedema in women undergoing treatment for breast cancer, stating,

“This Rating is based on an overall low-quality body of evidence that suggests that the LYMPHA procedure resulted in a relatively low incidence of transient or persistent lymphedema. This Rating reflects substantial uncertainty in the comparative effectiveness of preventive microsurgery with no preventive surgical procedure, the impact of the procedure on additional conventional preventive therapies, patient quality of life, and related adverse events.”<sup>5</sup>

- In 2020, ECRI published a clinical evidence assessment on lymphatic microsurgical preventive healing approach (LYMPHA) for preventing lymphedema.<sup>6</sup> ECRI reviewed one systematic review and meta-analysis (19 studies, n=3035) investigating LYMPHA for patients with breast cancer who underwent ALND. ECRI also reviewed one prospective single-center study, one retrospective single-center study, and one case series. The systematic review included mostly case series, all with high risk of bias. The SR found that lymphedema risk was lower for ALND plus LYMPHA than for ALND alone (2.1% vs 14.1%; p= 0.029). The other studies reviewed found improvements in incidence of lymphedema for patients undergoing LYMPHA as well. Only one of the case series investigated cancers other than breast. While there were no RCTs identified and the studies were deemed to

have high risk of bias due to single-center focus, retrospective designs, small sample size, lack of randomization or comparator groups, ECRI rated LYMPHA for preventing lymphedema as “Evidence is somewhat favorable”.

Similar results and limitations were also cited by other systematic reviews on surgery for lymphedema.<sup>7-17</sup> Despite consistent reported improvements in patients’ quality of life, findings were limiting by the low-quality of studies included for review (e.g. lack of randomization, lack of blinding), small sample sizes, inadequate follow-up, and heterogenous patient characteristics. Each review called for additional studies to further validate results reported to date.

## **CLINICAL PRACTICE GUIDELINES**

### **Nation Comprehensive Cancer Network**

The NCCN Guidelines for Survivorship, Version 1.2023, list the following as appropriate treatments for lymphedema due to cancer procedures:<sup>18</sup>

- “Survivor lymphedema education, including self-care management
- Refer to certified lymphedema therapist (if available) for consideration of the following:
  - Compression garments
    - Review fit of garments
    - Review use of garments
  - Progressive resistance training under supervision
  - Manual lymphatic drainage
- Refer to physical therapy for range-of-motion exercises.”<sup>18</sup>

NCCN does not have any recommendations for surgery as a treatment or for the prevention of lymphedema.

### **National Institute for Health and Care Excellence (NICE)**

In August 2017, NICE published interventional procedure guidance on the use of liposuction for chronic lymphedema, stating that the current evidence on the safety and efficacy of liposuction for chronic lymphedema is adequate.<sup>1</sup>

However, this statement was based on six case series that ranged in size from 15 to 146 patients, and a small systematic review of 105 patients (four studies). All included studies were cited as having “study design issues”, including but not limited to one or more of the following:

- patient heterogeneity:
  - primary versus secondary lymphedema
  - affected site (e.g., upper limb, lower limb, breast, hip, etc.)
- limited short-term follow-up (one year or less),
- small sample size (only two primary studies included over 100 patients)
- retrospective study design

Furthermore, this guidance was based on a “rapid review”, and not a systematic review of the evidence.



## American Venous Forum (AVF)

In 2017, The AVF issued clinical practice guidelines regarding the surgical treatment of chronic lymphedema *suggesting* the following weak recommendations based on low- to very low-quality evidence:

- Excision or liposuction may be considered for patients with late-stage nonpitting edema who fail conservative measures.
- Microsurgical lymphatic reconstruction may be considered when performed in centers of excellence for patients with early-stage secondary lymphedema.<sup>19</sup>

In 2022, the AVF published an expert opinion consensus

### **EVIDENCE SUMMARY**

There is insufficient published evidence that surgical treatments are safe and effective methods of treatment for lymphedema due to any disease process. The available evidence consists of several systematic reviews, all of which were based entirely on nonrandomized studies. In general, the primary studies for any given surgical procedure were limited by small sample size, heterogeneity of patients in terms of site, stage and cause of lymphedema. Most studies report relatively short-term follow-up, and most were of retrospective noncomparative design. In addition, current clinical practice guidelines do not strongly support the use of surgical treatments for lymphedema. Therefore, surgery for the treatment of lymphedema is considered not medically necessary.

There is insufficient evidence to support LYMPHA surgery during nodal dissection or breast reconstruction to prevent lymphedema. The available evidence consists of nonrandomized studies, most with retrospective designs and high risk of bias. Additional randomized studies are needed with large sample sizes and long term follow up to determine safety and efficacy of LYMPHA. Furthermore, there are currently no identified clinical practice guidelines recommending preventive surgery for patients with cancer undergoing lymph node removal. Therefore, lymphatic physiological microsurgery performed during nodal dissection or breast reconstruction to prevent lymphedema, including, but not limited to LYMPHA (Lymphatic Microsurgical Preventing Healing Approach), is considered not medically necessary.

## **BILLING GUIDELINES AND CODING**

<b>CODES*</b>		
<b>CPT</b>	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 or 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	Lymphangiectomy or other operations on lymphatic channels
	38589	Unlisted laparoscopy procedure, lymphatic system
	38999	Unlisted procedure, hemic or lymphatic system

**\*Coding Notes:**

- The above code list 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.
- 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 [Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website](#) 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.

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## **POLICY REVISION HISTORY**

<b>DATE</b>	<b>REVISION SUMMARY</b>
2/2023	Converted to new policy template.
4/2023	Annual update, changed investigational to not medically necessary
3/2024	Annual review. No changes.