**SCOPE:**

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

**APPLIES TO:**

All lines of business

**BENEFIT APPLICATION**

Medicaid 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.

**POLICY CRITERIA**

Surgical treatment for lymphedema is considered *investigational and not covered*, 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).
      (**NOTE:** Liposuction is considered *cosmetic* for Medicare members only.)
   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)
BILLING GUIDELINES

Per this medical policy, when liposuction (also known as suction-assisted lipectomy, codes 15832 – 15879) is requested for the treatment of lymphedema, it is considered cosmetic for Medicare members and investigational for all other lines of business.

CPT CODES

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DESCRIPTION

Lymphedema

Lymphedema is the abnormal accumulation of subcutaneous fat and fluid in body tissue.\(^1\) 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.\(^1,2\)

Primary lymphedema results from a congenital inadequacy and gradual occlusion of lymphatics due to congenital lymphatic system dysplasia.\(^2\) 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.\(^1,2\)

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.\(^1,2\)

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): 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.
  - **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.

**REVIEW OF EVIDENCE**

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 March 2020.

Of note, systematic reviews and randomized controlled trials that focused solely on treatment of breast cancer related lymphedema were not reviewed below.

*Systematic Reviews*

In 2017 (updated 2019), Hayes published a review of systematic reviews that evaluated surgical treatments for lymphedema.² The review was based on what Hayes deemed a representative review of good quality, published by Carl et al. in 2017, as well as primary studies published after the Carl et al. review.³ Of note, this review did not include any randomized controlled trials for any surgical treatment for lymphedema. Two additional systematic reviews were also evaluated but not selected for inclusion in the Hayes review because they predated and were superseded by the Carl et al. review, and were limited in scope.⁴⁵

The Hayes review (updated in 2019) focused on the following procedures:
- lymphovenous anastomosis (LVA)
- vascularized lymph node transfer (VLNT)
- liposuction
- excision
- combination surgeries and other surgeries not addressed above

The Hayes review, provided the following ratings and conclusions regarding quality of evidence for the following surgical procedures:
LVA: Hayes rating of C, based on low-quality evidence from studies showing modest to moderate reductions in limb size. Per the Hayes review:

“Although the meta-analyses of various measures were statistically significant when studies were combined, not all studies included in the systematic review reported statistically significant limb size reduction, which may have been due to inadequate power. The subsequently published cohort study showed limb size reduction after LVA. QOL was generally not assessed using a standard instrument, which decreases the overall quality of this outcome; however, available results suggest most patients were satisfied with their improvement.”

VLNT: Hayes rating of C, based on low-quality and inconsistent evidence that VLNT results in reductions in limb size, and the observation that VNLT may be associated with a higher rate of complications than reported for other surgeries. Per the Hayes review:

“Although the average circumference reduction derived from meta-analysis was statistically significant, the average absolute and excess volume reductions were not. Benefits over conservative care are suggested by the results of a single RCT; additional comparative trials are needed to attempt to establish consistency. As reviewed in the selected SR, patients were generally pleased with their surgery, but standard instruments were not used to assess QOL.”

Liposuction: Hayes rating of C, based on low-quality evidence. Per the Hayes review:

“Limb reduction in the reviewed cohort studies and 2 subsequently published studies consistently suggest substantive reduction in the size of the affected limb for most patients. Studies reported that patients indicated improvements in well-being; however, it is unclear whether standard instruments were used to assess QOL in the SR.”

Excision: Hayes rating of C, based on limited, low-quality evidence from several studies reporting moderate improvement in limb size, with a moderate incidence of complications.

Of the single systematic review and two primary studies included, measures of limb reduction differed between studies and confidence intervals (CIs) were not reported, thereby making the range of limb reduction difficult to determine and the statistical significance of the reductions questionable. Relatively few studies addressed excision, and QOL was not assessed using a standard measurement.

Combination surgeries and all other surgical interventions: Hayes rating of D2, based on the paucity of evidence.

Two studies evaluating liposuction combined with flap transfer, “reported a decrease in the average size of the affected limb. QOL was only assessed in two individuals, providing an insufficient amount of evidence to substantiate conclusions.”

Overall, the Hayes review indicated that although there were a large number of primary studies published for each surgical intervention, these studies recruited small numbers of patients, often with heterogeneity in terms of affected site, stage and cause of lymphedema. The majority of studies, for any given surgical treatment, were retrospective in nature, mainly noncomparative, and were inconsistent in terms of outcomes reported. In addition, “duration of follow-up after surgery for lymphedema was
generally only 1 to 2 years, so it is unclear whether benefits can be maintained in the long term." In addition, “the role of surgery and adjunctive supporting treatment (e.g., continued wearing of compression garments, continued decongestive therapy) has not been well differentiated by comparative studies.” Similar results and limitations were also cited by previously published systematic reviews.4-7

Several additional systematic reviews were identified after the publication of the Hayes review.8-13 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**

**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.1

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.
CENTERS FOR MEDICARE & MEDICAID

As of 4/9/2020, Centers for Medicare & Medicaid (CMS) has non-coverage guidance for suction-assisted lipectomy, which may be applied to lymphedema. The LCD: Plastic Surgery (L37020) indicates that: 14

“...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.”

POLICY 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 additional, current clinical practice guidelines do not strongly support the use of surgical treatments for lymphedema.

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 Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days notice of policy changes that are restrictive in nature.

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.

REGULATORY STATUS

Mental Health Parity Statement

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.

MEDICAL POLICY CROSS REFERENCES

- Breast Reconstruction, SUR162
- Compression Bandages, Stockings, and Wraps, DME188
- Compression: Outpatient Pneumatic Devices, DME191
- Durable Medical Equipment, DME214
- Massage Therapy: PEBB and Providence Health and Services (PH&S), MED278

REFERENCES


