Surgery for the Prevention and Treatment of Lymphedema (for Idaho Only)

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Instructions for Use

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Related Policy

- Pneumatic Compression Devices (for Idaho Only)

Application

This Medical Policy only applies the state of Idaho, including Idaho Medicaid Plus plans.

Coverage Rationale

Surgical procedures for the prevention or treatment of Lymphedema are unproven and not medically necessary due to insufficient evidence of safety and/or efficacy. These procedures include but are not limited to:

- Axillary Reverse Mapping (ARM)
- Liposuction/Lipectomy
- Microsurgical treatment
  - Lymphaticovenous Anastomosis
  - Lymphovenous bypass
- Vascularized Lymph Node Transfer

Definitions

Axillary Reverse Mapping: A technique that injects blue dye in the upper extremity to allow visualization and preservation of lymphatic channels and lymph nodes during axillary lymph node dissection (Jena).

Liposuction/Lipectomy: A procedure that uses vacuum suction to remove subcutaneous adipose tissue in certain anatomical areas (Bartow).

Lymphaticovenular/Lymphaticovenous Anastomosis: A surgical procedure that connects small lymphatic vessels to adjacent venules to shunt excess lymphatic fluid (American Society of Plastic Surgeons).

Lymphedema: The build-up of fluid in soft body tissues when the lymph system is damaged or blocked (NCI).

Vascularized Lymph Node Transfer: A surgical procedure that transfers skin, fat, and lymph nodes for lymphatic reconstruction (American Society of Plastic Surgeons).

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
15830	Excision, excessive skin and subcutaneous tissue (includes lipectomy); abdomen, infraumbilical panniculectomy
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
15847	Excision, excessive skin and subcutaneous tissue (includes lipectomy), abdomen (e.g., abdominoplasty) (includes umbilical transposition and fascial plication) (List separately in addition to code for primary procedure)
15876	Suction assisted lipectomy; head and neck
15877	Suction assisted lipectomy; trunk
15878	Suction assisted lipectomy; upper extremity
15879	Suction assisted lipectomy; lower extremity
38999	Unlisted procedure, hemic or lymphatic system
49906	Free omental flap with microvascular anastomosis

Description of Services

Lymphedema is a chronic, progressive, and often incurable disease in which there is impaired drainage of interstitial fluid through the lymphatic system resulting in the accumulation of fluid and hypertrophic fat. There are two types of Lymphedema. Primary Lymphedema, in which there is abnormal development of the lymphatic system, and secondary Lymphedema which is caused by damage to the lymphatic system from trauma, infections, and cancer surgeries and radiation. It is characterized by nonpitting swelling of an extremity (that typically excludes the fingers and toes) or trunk. It is associated with wound healing impairment, recurrent skin infections, and decreased quality of life.

The first line treatment of Lymphedema is conservative management with complete decongestive therapy (CDT) which is a combination of compressive garments, skin hygiene, limb compression, manual lymphatic drainage, and exercise. Pneumatic compression may also provide additional improvement when used adjunctively. For patients whose Lymphedema is not controlled by CDT, surgical procedures such as Liposuction/Lipectomy, subcutaneous excision, and microsurgical procedures such as lymphovenous bypass (LVA) and Vascularized Lymph Node Transfer (VLNT) have been proposed (Kareh 2020; NCI 2019). LVA is a super microsurgical technique in which an anastomosis is created between the congested lymphatic vessel and a vein to improve lymphatic fluid transport.

Clinical Evidence

Axillary Reverse Mapping (ARM)

Axillary reverse mapping (ARM) is a technique used during lymph node dissection in which a dye is injected into the upper arm to identify the lymphatics and lymph nodes that are primarily draining that extremity. It helps the surgeon identify and potentially preserve those lymph nodes, or in some cases remove the lymph nodes but preserve the lymphatics of the upper arm. While promising, many studies involve relatively small patient cohorts, short follow-up periods, inconsistent

techniques and lack standardized outcome measures. These limit the generalizability of the results, make it difficult to assess the long-term efficacy and risks, particularly regarding lymphedema development over time as well as making it complex to draw definitive conclusions regarding the safety, efficacy and long term outcomes of ARM for preventing lymphedema.

Abbaci (2022) reported the results of the ARMONIC clinical trial that assessed the ARM technique in a large cohort of patients, and to analyze the predictive clinical factors for ARM lymph node metastasis, and to determine whether fluorescence signal intensity in ARM nodes could be a predictive factor of subsequent lymphedema. One hundred and nine patients received mastectomy and ALND for primary cancer. Prior to mastectomy incision, indocyanine green (ICG) was injected intradermally in the ipsilateral upper extremity in the second interdigital space and then on the inner face of the elbow. The presence of ICG was then detected with a near-infrared fluorescence (NIR) fluorescence camera. After mastectomy and during ALND, fluorescent lymph nodes were identified by the surgeon and removed separately and isolated from the rest of the axillary lymph nodes for pathological examination. The results showed that fluorescent lymphatic ducts were visible in the forearm in more than 83% of the patients and in the upper arm in more than 66% patients prior to mastectomy incision. ARM lymph nodes were not detected in 6 patients. Of the103 patients with a successful ARM procedure, 55 had metastatic axillary lymph nodes in the final histology, and 20 had metastatic ARM lymph nodes. Eighteen patients had both metastasis-positive ARM nodes and ALND. Two patients had only metastatic ARM lymph nodes but not in the rest of the axillary lymph nodes. Of all 223 ARM lymph nodes, 195 had no tumor cells, 3 had isolated tumor cells, 3 had micro-metastases, 15 had macro-metastases and 7 had macro-metastases with extracapsular invasion. The authors concluded that although the ARM procedure identifies lymph nodes, signal intensity may not be a reliable diagnosis tool to consider the conservation of the arm lymph node. Participants were not followed long term to assess the correlation with signal intensity and subsequent lymphedema.

In a 2021 systematic review and meta-analysis of randomized controlled trials, Guo et al. assessed the effectiveness of ARM during ALND in preventing breast cancer related lymphedema as the primary outcome. Secondary outcomes were oncological safety and shoulder movement. Five RCTs were included that were comprised of 1,659 participants. A total of 786 patients received ARM of the nodes and lymphatics during ALND and 873 patients received conventional ALND (control). Follow up time ranged from 6-37 months. Three studies used blue dye alone, 1 study combined blue dye and fluorescence, and 1 study combined blue dye with radioisotope. Assessment of lymphedema was measured with volumetrics in 3 studies, and 2 studies used arm circumference measurement. In the 5 included RCTs, the participants had clinical stage II or III. All 5 had a low to moderate risk of bias. The results showed that in the group that received ARM and ALND, 37 patients developed arm lymphedema, and 164 developed lymphedema In the control group (ALND alone). Two studies reported oncological safety (determined by the metastatic rate of ARM nodes) and shoulder movement profiles and both showed no significant differences between the two groups. The authors concluded that while ARM can reduce the risk of BCRL, there is a risk of upper limb lymph node metastasis and further high quality research is needed.

Surgical Treatments

Late stage lymphedema may not respond to standard complex decongestive therapy and several types of surgical interventions are being investigated. These include, liposuction, vascularized lymph node transfer (VLNT) and lymphaticovenous anastomosis (LVA). LVA and VLNT have also been investigated for the prevention of lymphedema, and for that indication, they are done at the time of the index procedure. This is often called lymphatic microsurgical healing approach (LYMPHA). These techniques are very specialized and there is significant variability in patient characteristics and lack of uniformity in outcome measures complicating meta-analyses. High quality studies with longer term follow up is necessary to assess the safety, efficacy and durability of these treatments.

Gaxiola-García et al. (2024) conducted a systematic literature review on the surgical management of primary lymphedema. Data was extracted from 55 articles comprised of 485 patients with primary lymphedema to evaluate the outcomes of lymphaticovenous anastomosis (LVA) and vascularized lymph node transfer (VLNT), and of tissue removal procedures such as suction-assisted lipectomy (SAL) and excision. Treatment and numbers of patients were LVA (177), VLNT (82), SAL (102), and excisional procedures (124). Seven reported results for the upper extremity and 53 reported results for lower extremity lymphedema. The average follow-up was 24.74 months reported in 47 studies. In the results for LVA , 24 studies reported outcomes in 177 patients and showed that the most common stage treated with LVAs was ISL II (130 patients). Surgical outcomes were not homogeneously reported, but in most studies, an improvement of the LE lymphedema index, the QoL, and lymphedema symptoms, as well as a reduction of the cross sectional area, episodes of cellulitis, the need for compression garments, and circumferential measures were described. The overall complication rate was 1%. The most common complications were several episodes of a lymphatic fluid leak in one patient and failure of the anastomosis. There were 12 articles comprised of 82 patients that reported results for VLNT. These results showed inconsistent outcome reporting, with some stating that the average circumference reduction rate ranged from 17.2 to 61%, tonicity was reduced by 6.8% and the episodes of cellulitis decreased by 2.67 to 3 times/year during a follow-up ranging from 16 to 63 months. Most studies reported increased QOL. The overall complication rate was 13% and included

hematoma, venous congestion or thrombosis, and microsurgical revisions. With regard to SAL, the results of 102 patients across 8 studies showed a mean reduction of original excess volume from 71.9% to 94%. Several articles reported a reduction in cellulitis episodes and an improvement in QoL. The overall complication rate was 11% and included limited liposuction in certain areas, skin necrosis, significant blood loss, cellulitis, decubitus ulcers, and temporary peroneal nerve palsy. Fifteen studies reported the outcomes of excisional procedures in 124 patients. These results showed patient with Stage III or advanced disease. Several different excisional techniques were used across studies and the results showed significant reduction in the size of the LE, improvement of symptoms, and a reduction in the episodes of lymphangitis and cellulitis over a follow-up period ranging from 1 to 60 months. Poor cosmetic results were frequently reported and the overall complication rate was 46%. These included injury of the internal saphenous nerve, blood loss requiring transfusion, delayed wound healing, dermatosis, skin graft loss, presence of crevices and pits, chronic ulceration, the need of scar revision and release, seroma, amputation, skin necrosis, hypertrophic scarring, and focal wound tenderness. The authors concluded that primary lymphedema is amenable to surgical treatment and the currently performed procedures have effectively improved symptoms and QoL in this population. This review is limited by a lack of comparison to standard non-surgical treatment as well as inconsistent staging and reporting of some outcomes. Further high quality research is needed to validate these findings.

In a 2021 systematic review and meta-analysis sponsored by the American Association of Plastic Surgeons, Chang et al. examined the published evidence to assess the efficacy and safety of surgical treatment of lymphedema as well as preventing secondary lymphedema of the upper (UE) and lower extremity (LE) lymphedema as well as develop consensus statements and recommendations. Treatment of lymphedema included lymphovenous bypass, vascular lymph node transplantation and liposuction and comparators included surgery and compression therapy. For the prevention of secondary lymphedema, lymphovenous bypass was included with no surgery as the comparator. Studies included randomized controlled trials, observational studies and retrospective cohort and case-controlled publications. Case series that reported relevant pre- and post-operative outcomes were also included. Seventy one articles representing 66 studies were included and of these, 43 were case series. For liposuction, based on very low quality evidence, the results showed that the combination of liposuction and controlled compression therapy reduced limb volume significantly more than controlled compression therapy alone in patients with stage I-III (International Society of Lymphology) UE lymphedema. In studies that compared lymphovenous bypass to compression therapy in the UE and LE, the results showed decreased limb volume when compared to compression therapy alone. Almost half of the 81 patients were able to stop using compression garments, and 3 case series reported a significant reduction in episodes of cellulitis. Vascularized lymph node transfer (VLNT) was reported in 4 studies of 300 patients and compared VLNT to physical therapy. These results showed significant reductions in arm volume, pain, heaviness and overall function in patients who underwent VLNT compared to physical therapy alone. In 5 studies, VLNT combined with compression garments and complex decongestive therapy and the results showed significant reduction in circumference, and incidence of cellulitis was reduced. The authors concluded that there is evidence to support surgical treatments in reducing the severity UE and LE lymphedema, but none are a cure. No consensus was reached on which procedure is more effective, This consensus review is limited by a high degree of heterogeneity among the procedure's studies and combinations thereof. The authors also noted that the meta-analysis has several limitations: Only two randomized controlled trials were included. The majority of included studies were observational studies, which are at high risk of bias, and the conclusions that can be drawn from these studies are limited. Additional well designed research that includes more objective outcome reporting and longer follow up is needed to validate these findings.

Liposuction/Lipectomy

Xin et al. (2022) conducted a retrospective observational study on the therapeutic outcomes of tumescent liposuction for cancer-related lower extremity lymphedema. The study included 62 patients with unilateral cancer related lower extremity with Stage II or Stage III lymphedema who had received liposuction only and wore compression stockings postoperatively and followed for more than 3 months. Half of the participants were in Stage III lymphedema, and a third had a history of recurrent superficial skin infections. The results showed the appearance of the lymphedematous extremity significantly improved by 3 months postoperatively. The preoperative, postoperative, and 3-month follow-up percent volume reduction (PVDs) were 43.2 ±23.7%, 5.5 ±12.2%, and 11.6 ±18.4%, respectively. The PVD at the postoperative and 3-month follow-ups had significantly decreased compared with preoperative measurements, but it significantly increased at the 3-month follow-up compared with that immediately post operatively. At 3 month follow up, patient reported outcomes of feelings of heaviness and fatigue of the affected limb was alleviated, however feelings of stiffness, tenderness, and tightness had worsened. There were no significant differences in pain, numbness and weakness reported. The authors concluded that liposuction has a positive effect on treating cancer related lymphedema of the lower extremity. This study is limited by the retrospective single-arm design, no comparison group, and the short follow up period.

A 2020 Hayes health technology assessment, updated in 2022, reported on the use of liposuction plus compression therapy for reductive treatment of lymphedema of moderate-to-severe, nonpitting, primary or secondary lymphedema of the upper and lower extremities (UEL or LEL) in adult patients, as well as adult patients with head and neck cancer

treatment-related lymphedema. The evidence included studies that reported on the following outcome measures: the efficacy of lymphatic function, limb size and volume reduction, changes in annual skin infections, changes in shoulder joint range of motion as well as patient reported changes. An overall low-quality body of evidence suggests that liposuction plus controlled congestive therapy (CCT) or complex decongestive therapy (CDT) is associated with greater limb size reduction, lower risk of infection, and improved patient-reported outcomes compared with CCT or CDT alone in patients with UEL or LEL that had not responded adequately to conservative therapies. The overall conclusion of this report is that the liposuction plus compression therapy for the reductive surgical treatment of lymphedema has potential but unproven benefit.

In 2019a, Forte et al. conducted a comprehensive systematic review of the results of 13 studies that reported on the outcomes of lipoaspiration followed by controlled compression therapy, as well as the differences in the outcomes in patients treated with compression therapy only, for the treatment of lymphedema of the upper extremity. Ten studies reported outcomes of patients treated with lipoaspiration followed by compressive therapy, and three studies compared this procedure with patients that had only compressive therapy. The majority of patients were at Stage II or Stage III disease. The results showed that all studies showed a potential benefit in volume reduction in patients with chronic lymphedema up to 5 years post-operatively. Two studies showed a decrease in infections and cellulitis. In the 3 studies that compared liposuction with compression to compression alone, the results showed a statistically significant difference in volume reduction at 12 month follow up, with the postoperative reduction for patients with lipoaspiration and controlled compressive therapy 103%, 115%, and 113%, compared to the group treated with controlled compressive therapy alone, which was only were 50%, 54%, and 47%. No studies showed major surgical complications. The authors concluded that lipoaspiration is better suited in later stages of disease (Stage II and III) when controlled compression therapy alone was ineffective. This study is limited by the heterogeneity between studies regarding the measurement tool used, the follow-up of results, and the protocol established.

Forte et al. (2019b) conducted a systematic review of the results of eight studies (case series) that reported on the outcomes of liposuction for the treatment of lymphedema of the lower extremities after compression therapy. A total of 191 patients with primary or secondary lymphedema, most Stage II or III were included. The results showed that all studies reported volume reduction following lipoaspiration. One study reported a difference in volume reduction depending on the cause of lymphedema and showed at 24 months follow up a reduction of 79% in patients with primary lymphedema, and a volume reduction of 101% was found in patients with secondary lymphedema. All studies reported improvement in function, quality of life and decreased infections. The authors concluded that lipoaspiration followed by controlled compression therapy has the potential to improve lymphedema for patients in Stage II or Stage III disease when controlled compression therapy was ineffective. This study is limited by the lack of a comparison group and heterogeneity between studies regarding the measurement tool used, the follow-up of results, and the protocol established.

Microsurgical Procedures

In a 2023 systematic review and meta-analysis, Meuli et al. reported on the outcomes of the two most common microsurgical treatments for lymphedema. One hundred and fifty three articles, comprised of 6,496 patients that documented outcomes following lymphovenous anastomosis (LVA) and vascularized lymph node transfers (VLNTs) in adult patients were included. The most frequently reported outcomes were reductions in circumference and volume and the number of skin infections per year. The results showed that among the 29 studies (1,002 patients) that reported reduced circumference, 20 investigated VLNT, 8 LVA and one investigated a combination of both and showed a 36% reduction. Regarding volume change, 12 studies (587 patients) provided sufficient data and 5 of these 12 studies investigated LVA, 6 investigated VLNT, and 1 investigated a combination of both techniques and showed an overall reduction in excess volume -32.7%. Regarding skin infections, 8 studies contained sufficient data and five out of these eight studies investigated VLNT and three investigated LVA. The overall change in the number of cutaneous infections episode per year for the 248 patients included was -1.9. The authors concluded that LVA and VLT are effective in the treatment for reducing severity of lymphedema. This review is limited by a lack of randomized controlled trials and heterogeneity of results reporting.

Lymphaticovenous Anastomosis (LVA)/Lymphovenous Bypass

Gupta et al. (2021) conducted a systematic review to analyze the outcomes of LVA for primary or secondary upper extremity (UE) lymphedema in various stages. Sixteen studies comprising 349 patients and 244 upper limbs were included. The authors reported on post operative limb circumference/volume reduction and differential, and patient reported improvements in quality of life and symptoms. Studies on filariasis-related lymphedema were excluded. The results showed, among 14 studies that reported on objective improvements, 11 stratified outcomes by UE, and improvements were seen in more than 90% of the patients. Seven studies reported on the results based on the Campisi stage of lymphedema, and 2 reported LVA resulted in better outcomes when done in the earlier stages. The authors

concluded that LVA is a safe and effective emerging treatment for UE lymphedema refractory to decompressive treatment, and large controlled studies are required to validate these findings which are limited by lack of comparison to contemporary comparison groups undergoing a different intervention.

A 2020 Hayes health technology assessment, updated in 2022, regarding lymphovenous anastomosis for the treatment of primary and secondary lymphedema that has not responded adequately to conservative therapies, focused on the effectiveness on lymphatic function, limb size reduction and subjective changes such as decreased infections and changes in the use of compression garments. Based on a moderate sized body of low-quality evidence, it was concluded that LVA appears to be safe with a low risk of complications. There was an overall positive impact on baseline limb circumference, excess volume and patient reported outcomes such as the use of compression garments and infections. There is insufficient evidence to come to a conclusion regarding the efficacy compared to other surgical procedures or non-surgical procedures. This suggests the potential benefit of LVA, and prospective comparative or randomized controlled trials are warranted. The report overall conclusion is that this technique has potential but unproven benefit.

Vascularized Lymph Node Transfer (VLNT)

Li et al. (2021) completed a systematic literature review and meta-analysis on intra-abdominal vascularized lymph node transfer for the treatment of lymphedema. Primary outcomes were circumference/volume reduction, episodes of cellulitis reduction and lymph flow assessment. Secondary outcomes included donor and recipient site complications. Twenty-one studies (one non-randomized controlled trial, 3 retrospective cohort studies, 5 prospective case series, and 12 retrospective case series) with omental/gastroepiploic, jejunal, ileocecal, and appendicular donor sites totaling 594 patients met the inclusion criteria. The results showed a mean reduction in circumference and volume rate ranged from 0.38% to 70.8%. Significant reduction in infectious episodes was reported in 10 studies. The pooled donor-site complication rate was 1.4%, and the pooled recipient-site complication rate was 3.2%. No donor site lymph disfunction was reported. The authors concluded that low quality evidence suggests there is improvement in lymphedema following intra-abdominal VLNT. However, they also note that these results were of low quality with great heterogeneity across almost all data. Further research with high quality randomized trials are needed to confirm these findings.

In a 2021 systematic review and meta-analysis, Ward et al. evaluated the effectiveness of VLNT in reducing UE and LE volume, and cellulitis episodes in patients with cancer treatment related lymphedema (CTRL). Thirty-one studies totaling 581 patients in which VLNT was the sole therapeutic procedure for CTRL, and reported limb volume, frequency of infection episodes and/or lymphedema specific quality-of-life data, were included. The results showed for the UE, after VLNT the pooled circumferential reduction rates (CRRs) were 42.7% above elbow, and 34.1% below elbow. For the LE, there was a CCR of 46.8% above knee and 54.6% below knee. In addition, patients experienced approximately 2 fewer cellulitis episodes per year, and had improved lymphoedema-Specific Quality of Life scores. The authors concluded that VLNT reduces limb volume and cellulitis and improves quality of life, however most studies analyzed were of low quality, and had limited to small numbers of participants and lacked long term follow up. Furthermore, there was an overall high degree of heterogeneity across all studies as it related to VLNT, and further methodologically rigorous RCTs that include standardization of reporting are required.

A 2020 Hayes health technology assessment (updated in 2022) on lymph tissue transfer for the physiological microsurgical treatment of lymphedema concluded than an overall low quality body of evidence, LNT and VLNT is associated with better limb size reduction and improved patient reported outcomes when compared with other modalities. However, most of the limitations in the evidence are to be expected given the difficulties of conducting RCTs of complex, individualized microsurgical procedures in a highly heterogenous condition such as lymphedema. Despite the lack of well-designed controlled trials and the weaknesses in the design of the available studies, the current evidence suggests a benefit of LNT in selected patients with lymphedema who have not responded adequately to standard nonsurgical therapies.

Preventive Microsurgical Procedures/Immediate Lymphatic Reconstruction/ Lymphatic Microsurgical Preventive Healing Approach (LYMPHA)

In a 2024 retrospective review, Levy et al. reported the 4 year outcomes of patients treated with LYMPHA as lymphedema prophylaxis within their institution (Columbia University Irving Medical Center). Two groups were compared, those who received LYMPHA (45) and those who did not (45). All study participants were women, and the LYMPHA and the non-LYMPHA groups had a similar mean age, BMI and obesity rates. Patients received ALND along with either complete mastectomy or breast-conserving therapy for breast cancer. A similar number of lymph nodes were removed in both groups. Follow up times were 57 and 63 months in the LYMPHA and non-LYMPHA groups respectively. Non-LYMPHA patients underwent complete mastectomy more frequently than LYMPHA patients but had a similar number of nodes removed during ALND. The results showed that overall, lymphedema incidence was 31.1% in the LYMPHA group and 33.3% in the non-LYMPHA group with no significant differences in lymphedema incidences were observed between the

LYMPHA and non-LYMPHA groups for patients with obesity, patients who received radiation therapy, or patients with obesity who also received radiation therapy. The authors concluded that this procedure may not prevent lymphedema long-term in patients who undergo ALND. Additional long-term studies are needed to determine the true potential of LYMPHA for the prevention of lymphedema.

Chungsiriwattana et al. (2023) conducted a retrospective data review of 29 patients with melanoma or non-melanoma of the lower extremities that underwent tumor resection with Inguinal lymph node dissection (ILND), and compared long term incidence of lymphedema and oncological outcomes in patients that received lymphaticovenous anastomosis (LVA) at the time of surgery with those that only has surgery. Seven patients underwent immediate LVA at the groin after the ILND (intervention) and the remaining 22 patients underwent resection of the tumor and ILND (control). Outcomes were followed for up to seven years. The results showed 12 cases of lymphedema in the control group and 3 in the LVA group and. The intervention group had a longer median time to lymphedema occurrence than the control group (70 vs. 17 months). Oncological outcomes showed that tumors recurred in 71.4% of patients in the intervention group compared to 31.8% in the control group. Metastases occurred in 5 cases in the intervention group compared to 8 in the control group. The overall median survival time was 44 months. For the intervention group, The intervention group had significantly shorter 2 and 5-year recurrence free survival (RFS) and metastatic free survival (MFS) rates. The median survival time was 26 months and 82 months in the intervention and control groups respectively. The authors concluded that while this procedure appears feasible, there was no statistically significant difference in lymphedema occurrence rates. Furthermore, there are significant concerns that LVA results in systematic spread of the original cancer via the lymphatic pathway. This study is limited by a small number of participants and longer term studies are needed to further evaluate LVA at the groin following ILND for preventing lymphedema of the lower extremities.

Ciudad et al. (2022) conducted a systematic review and meta-analysis of the current evidence on the use of preventive lymphatic surgery (PLS) for reducing the risk of cancer related lymphedema (CRL). Twenty-four studies comprising 830 LVA procedures on 1,547 patients fulfilled the inclusion criteria. Eighteen studies were observational studies, two were randomized control studies, one was a case series, and three were abstracts or conference presentations. 1,247 patients (80.6%) underwent axillary lymph node dissection (ALND), three-hundred patients (19.4%) underwent ilioinguinal, para-aortic, inguinofemoral lymph node dissection, and/or wide tissue excision of the inguinal region (the type of cancer was highly heterogenous). The results showed in single-cohort studies, the pooled cumulative rate of upper extremity lymphedema after ALND and PLS was 5.15% with no significant heterogeneity across studies. The pooled cumulative rate of lower extremity lymphedema after oncological surgical treatment and PLS was 6.66%. In double-arm studies for upper limb lymphedema, the pooled analysis showed that PLS reduced the rate of lymphedema after ALND by 18.7 per 100 patients' heterogeneity was substantial and had significant clinical relevance. For lower limb lymphedema the pooled analysis showed that PLS reduced the rate of lymphedema after ilioinguinal lymph node dissection by 30.3 per 100 patients treated with no significant heterogeneity across the studies. The authors concluded that PLS is a promising treatment for the prevention of lymphedema following cancer related lymph node dissection. This systematic review is limited by the highly heterogenous nature of the included studies. This includes different diagnostic methods, levels and regions of LND, type of LVA, different follow up periods, and patient characteristics such as past radiation therapy. High-quality studies are necessary to determine the outcomes and determine recommendations regarding the use of preventive lymphatic surgery.

In a 2022 single-arm meta-analysis, Chun et al. evaluated the effectiveness of immediate lymphatic reconstruction (ILR) to prevent secondary lymphedema and provide suggestions for using the LYMPHA approach. This meta-analysis included 789 patients across 13 studies, and included upper and lower limb ILR, 10 studies address ILR for breast cancer axillary lymph node dissection (ALND) and 3 addressed malignant melanoma inguinal lymphadenectomy. The results showed for upper extremity lymphedema, the pooled analysis indicated that 2.75% of patients developed lymphedema after ALND with ILR. The average pooled follow up time was 11.6 months and that the incidence of lymphedema started to increase immediately post operatively at 0.92%, 2.19% at 6 months and 2.50% at 12 months, and continued to increase beyond 12 months with the highest incident rate between one and two years. For lower extremity following lymphadenectomy, the results showed 3.6% of patients developed lymphedema after inguinal lymphadenectomy with ILR for malignant melanoma treatment. The authors acknowledge there is a limitation to LYMPHA for lower extremity ILR due to the availability of recipient veins with appropriate size, arc of rotation, and venous valvular sufficiency. The authors concluded that ILR is a promising technique to mitigate lymphedema. Future research should address standardization of techniques and focusing on specific patient populations and show the short-term efficacy and long-term outcomes. The findings are limited by lack of comparison group.

In a 2022 systematic review and meta-analysis, Hill et al. analyzed the current evidence on the effects of immediate lymphatic reconstruction (ILR) on the incidence of breast cancer-related lymphedema (BCRL) following ALND. Eleven studies totaling 417 breast cancer patients met the inclusion criteria. These studies included one randomized control trial, and ten observational studies. Four of the 11 studies with control groups could be included in a meta-analysis. The results

showed 24 of 417 (5.7%) patients developed BCRL following ILR. Meta-analysis revealed that in the ILR group, 6 of 90 patients (6.7%) developed lymphedema, whereas in the control group, 17 of 50 patients (34%) developed lymphedema. Patients in the ILR group had a risk ratio of 0.22 (CI, 0.09 -0.52) of lymphedema with a number needed to treat (NNT) of four. The authors concluded that ILR can prevent BCRL, however the findings are limited by lack of randomization. Randomized control trials are underway to validate these findings. ILR may prove to be a beneficial intervention for improving the quality of life of breast cancer survivors.

In a 2020 ECRI clinical evidence assessment regarding LYMPHA for Preventing Lymphedema, it was concluded that based on low-quality but consistent evidence from one systematic review (SR) with meta-analysis and one nonrandomized comparative study, LYMPHA procedures performed during axillary lymph node dissection (ALND) reduce lymphedema rates compared to ALND alone in patients with breast cancer, and larger, prospective controlled studies are needed to verify these findings and to determine whether it improves outcomes for patients with other cancer types who undergo lymph node dissection.

In a 2019 Cochrane systematic review of randomized controlled trials, Markkula et al. assessed and compared the efficacy of surgical interventions for the prevention of lymphedema in the arm after breast cancer treatment and to assess and compare to the treatment of existing lymphedema. Two studies involving 95 participants reported on the effectiveness of lymphaticovenular anastomosis for the prevention of breast cancer related lymphedema compared to non-surgical management and showed that LVA appears to result in a reduction in the incidence of lymphedema. Both studies had an unclear risk of bias and did not report secondary outcomes. The overall certainty of the evidence was low. One study involving 36 participants reported on the effectiveness of vascularized lymph node transfer for the treatment of existing lymphedema compared to no treatment, and showed that for participants with stage 2 lymphedema, there were reductions in limb volume, pain scores, heaviness sensation and overall function. Overall, the evidence was very low. The authors concluded that there is currently not enough high-quality evidence to support the widespread adoption of lymphaticovenular anastomosis or vascularized lymph node transfer techniques for the prevention or treatment of lymphedema. Well-designed randomized controlled trials that compare the effectiveness of surgical treatments to each other, and against the current gold standard non-surgical treatments are needed.

A 2019 Hayes health technology assessment, updated in 2022 regarding microsurgery for primary prevention of breast cancer related lymphedema, evaluated the LYMPHA procedure for efficacy and safety. It was concluded that based on an overall low-quality body of evidence, the LYMPHA procedure appears to have a positive impact on the prevention of lymphedema resulting in a relatively low incidence of transient or persistent lymphedema. There is a reasonable degree of uncertainty with this finding, given the lack of comparative evidence and retrospective nature of many studies. Future research should focus on long-term safety and efficacy of LYMPHA, determination of which patients are most likely to benefit from this preventative microsurgical approach, experimental study designs that support the earlier trial evidence, the impact of the procedure on additional conventional preventive therapies, patient quality of life, and related adverse events. The report overall conclusion is that this technique has potential but unproven benefit.

Head and Neck Cancer Treatment-Related Lymphedema

A 2020 Hayes health technology assessment, updated in 2022, reported on the use of liposuction plus compression therapy for the reductive surgical treatment of lymphedema of moderate-to-severe, nonpitting, primary or secondary lymphedema of the upper and lower extremities (UEL or LEL) in adult patients, as well as adult patients with head and neck cancer treatment-related lymphedema. A very small body of low-quality evidence in patients with head and neck cancer-related lymphedema suggests that liposuction compared with no liposuction does have a positive impact on patient-reported subjective outcomes assessed 6 months after surgery.

Tyker et al. (2019) conducted a systematic review to evaluate all established treatment modalities for lymphedema resulting from head and neck cancer treatment. The authors concluded that the overall poor study quality limited the ability to draw conclusions regarding the benefit of these treatments. All studies had limitations of short follow-up times, lack of blinding and randomization of participants, heterogenous patient populations, and low numbers of participants. Large multicenter RCTs which directly compare treatment modalities are required.

Alamoudi et al. (2018) conducted a randomized controlled trial at an oncology center in tertiary hospital setting to review the outcomes of submental liposuction in head and neck cancer patients with post treatment lymphedema and to compare the outcomes with a control group. Twenty one patients met the inclusion criteria, however, one died before completing post operative evaluation and was excluded in the final results. All participants had completed radiation therapy and eleven underwent neck dissection and radiation with or without chemotherapy, had been disease free for one year and had no previous facial plastic surgery procedures. Outcome measures included patient reported results in the form of two validated surveys, the Derriford Appearance Scale (DAS59) which objectively measures psychological symptoms associated with aesthetic disfigurement and deformities, and the Modified Blepharoplasty Outcome Evaluation (MBOE)

which was modified from the Blepharoplasty Outcome Evaluation to meet the needs of the submental region. The surveys were completed preoperatively, at the time of surgery, and six months or more postoperatively. The results showed for both the DAS59 and MBOE scores, overall there was a statistically significant improvement in the intervention group compared to the control group. The authors concluded that submental liposuction is safe and effective and improves QOL and self-perception in patients with lymphedema secondary to head and neck radiation therapy. This study is limited by the lack of a comparison group to non-surgical therapies as well as a lack of objective assessment by blinded reviewers. Further research comparing liposuction in the submental region to established treatment as well as long term outcomes is required to validate these findings.

Clinical Practice Guidelines

American Association of Plastic Surgeons (AAPS)

In the 2021 consensus guidelines on surgical treatment of lymphedema (Chang et al.) the AAPS concluded the following:

LVA and VLNT:

- There is evidence to support that lymphaticovenous anastomosis can be effective in reducing severity of lymphedema (Grade 1C) with a large number of studies demonstrating better outcomes in patients with earlier stage of disease.
- There is evidence to support that vascularized lymph node transfer can be effective in reducing the severity of lymphedema (Grade 1B).
- There is no consensus on which procedure is more effective.
- Neither procedure is a cure for lymphedema.

Prophylactic lymphovenous bypass:

- Few studies show this procedure reduces the incidence of lymphedema and further studies with longer follow up are required (Grade 1B).

Liposuction

- Debulking procedures such as liposuction are effective in addressing the nonfluid component such as fat involving lymphedema (Grade 1C).
- There is a role for liposuction combined with physiologic procedures (physical therapy and compression), although the timing of each procedure is currently unresolved (Grade 1C).

This guideline also states that lymphatic procedures are highly complex and surgery should be performed at a high volume center with training in microsurgery to lower the incidence of complications.

Additional consensus recommendations:

- A consensus on staging of lymphedema and preoperative and postoperative evaluations is needed.
- More quantitative methods for measuring fat, fluid, and physiologic measures and immunologic function are required.
- There is a need for better designed studies that include more objective reporting of outcomes and longer follow-up.

National Comprehensive Cancer Network (NCCN)

The 2024 NCCN Survivorship guideline contains a section on lymphedema diagnosis and management and lists treatment options as compression garments, manual lymphatic drainage and supervised progressive resistance and range of motion training. It does not mention liposuction or microsurgical treatments. It also states that for select patients, consider referral to a lymphedema surgeon, in consultation with a certified lymphedema therapist and/or physiatrist specializing in lymphedema.

American Venous Forum (AVF), American Vein and Lymphatic Society (AVLS), and Society for Vascular Medicine (SVM)

In 2022, the AVF created a work group to develop a consensus statement regarding current practices on the diagnosis and treatment of lymphedema (Lurie et al.). The criteria for consensus panel participation included publications and presentations on lymphedema, participation with a specialty society, and significant representation of lymphedema patients in the expert's clinical practice. Participants included academic, private and hospital-based practice settings, as well as an international panel of experts. It was acknowledged that there is high variability in lymphedema care among experts in the field. Consensus was reached for the following treatments:

- The regular use of compression garments reduces progression of lymphedema.
- Sequential pneumatic compression (SPC) should be recommended.
- Manual lymphatic Drainage (MLD) should be a mandatory component of the management of patients with lymphedema.

There was no consensus reached regarding surgical treatments.

International Society of Lymphology (ISL)

In a 2020 consensus document on the diagnosis and treatment of peripheral lymphedema, the ISL states the following:

- No treatment has undergone rigorous, randomized, stratified, long-term, controlled studies, and there remains some degree of uncertainty, ambiguity, and flexibility along with dissatisfaction with current lymphedema diagnosis and management.
- In carefully selected patients following full evaluation, microsurgical and super microsurgical procedures are an adjunct to CDT or when CDT has clearly been unsuccessful.
- Liposuction, lymphaticovenous anastomosis and lymph node transfer operations coupled with appropriate lymphedema therapy and compression are effective when used to treat properly selected lymphedema patients and performed by an experienced lymphedema surgeon.
- Debulking is mainly for the treatment of the most severe forms of fibrosclerotic lymphedema (elephantiasis) and in cases of advanced genital lymphedema.

National Institute for Health and Care Excellence (NICE)

In a 2022 interventional procedures guidance document, NICE states that the evidence regarding the safety and efficacy of liposuction for chronic lymphedema is adequate and should only be used for patients with lymphedema that has been non-responsive to conventional treatments. Patient selection must be done by a multidisciplinary team that specializes in managing lymphedema and should only be done in specialist centers with training and expertise in this procedure. The procedure is not curative, and effectiveness relies on lifelong wearing of compression garments.

American Society of Breast Surgeons (ASBrS)

In a 2022 consensus statement the ASBrS states that newer surgical techniques, such as axillary reverse mapping, lymphatic transfer, and lympho-venous anastomosis are promising both for prevention and for treatment of established lymphedema. However, well-designed prospective studies with uniform criteria for patient selection, procedure, and outcome assessment are needed. In institutions where these techniques are available, they should be considered whenever ALND is required.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

The FDA has approved a number of devices for use for liposuction. Refer to the following website for more information (use product codes MUU): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed July 16, 2024)

The FDA has approved a number of near infrared fluorescence imaging systems. Refer to the following website for more information using product codes IZI or device name: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. Accessed July 17, 2024.

Indocyanine green is an FDA approved injectable drug frequently used with near infrared fluorescence imaging systems. Further information can be found at the following website:
https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=040811.
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Policy History/Revision Information

Date	Summary of Changes
06/01/2025	• New Medical Policy

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. The UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.