Regence

NOTE: This policy is not effective until January 1, 2027

Medical Policy Manual Surgery, Policy No. 220

Surgical Treatments for Lymphedema and Lipedema

Effective: January 1, 2027

Next Review: June 2027
Last Review: September 2026

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Lymphedema is an accumulation of fluid due to disruption of lymphatic drainage. Lymphedema can be caused by congenital or inherited abnormalities in the lymphatic system (primary lymphedema) but is most often caused by acquired damage to the lymphatic system (secondary lymphedema). Lipedema is a rare condition where increased fat tissue accumulates under the skin which causes non-pitting, bilateral swelling in the extremities.

MEDICAL POLICY CRITERIA

Notes:

- Member contracts for covered services vary. Member contract language takes precedence over medical policy.
- Clinical documentation to support criteria is required (See Required Documentation).
- Reporting 15839 for body parts represented by other specific codes (e.g., thigh, leg) is not appropriate.

Medically Necessary

I. Liposuction or lipectomy to treat lipedema of the extremities may be considered **medically necessary** when all of the following are met (A.-H.):

A. Surgical interventions are performed by hospital credentialed, board certified plastic surgeon; and

B. The individual has a diagnosis of lipedema including all of the following clinical exam findings documented during an in-person exam:

1. Bilateral symmetric adiposity that is disproportionately affecting the extremities when compared to the trunk, neck, chest, abdomen, and/or pelvis with minimal involvement of the hands and feet; and
2. Non-pitting edema of all extremities included in the planned procedure; and
3. Pain and tenderness on palpation of all affected areas included in the planned procedure; and
4. Negative Stemmer sign on all extremities included in the planned procedure; and
5. Submission of photographs documenting bilateral symmetric adiposity disproportionately affecting the extremities when compared to the trunk, unaffected hands and feet, and appearance of the extremities consistent with the diagnosis of lipedema; and

C. There is documentation of significant physical functional impairment (e.g., difficulty ambulating or performing activities of daily living); and

D. The individual has not responded to at least six consecutive months of optimal medical management including complex decongestive therapy and compression therapy; and

E. For individuals with BMI greater than 35 kg/m^2, there has been a lack of effect on lipedema-affected areas of medically supervised weight loss measures as documented in the medical records through nutrition and/or medical interventions with clinic visits over six consecutive months; and

F. The plan of care postoperatively is to continue to wear compression garments as instructed to maintain the benefits of treatment; and

G. The area requested to be treated has not previously been treated with liposuction or lipectomy; and

H. The surgical plan indicates a maximum of 5 liters of aspirate to be removed.

Investigational

II. Liposuction or lipectomy to treat lipedema for areas other than extremities (e.g., trunk or back) is considered **investigational**.

III. Liposuction or lipectomy when Criterion I. is not met is considered **investigational.**

IV. Lymphatic physiologic surgery with or without a microscope to treat lymphedema (including, but not limited to, lymphatico-lymphatic bypass, lymphatic-venous-lymphatic plasty, lymphovenous bypass, lymphaticovenous anastomosis, autologous lymph node

transplantation, lysis of vein adhesions, and vascularized lymph node, omental, or other tissue transfer) is considered **investigational.**

V. Lymphatic physiologic surgery with or without a microscope performed during nodal dissection (e.g. axillary or groin) or breast reconstruction to prevent lymphedema (including, but not limited to, the Lymphatic Microsurgical Preventing Healing Approach) in individuals who are being treated for breast cancer is considered **investigational**.

VI. Liposuction or lipectomy to treat lymphedema (including, but not limited to, lipectomy, suction-assisted protein lipectomy, lipisuction, and lymph-sparing liposuction) is considered **investigational.**

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

REQUIRED DOCUMENTATION

It is critical that the list of information below is submitted for review to determine if the policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome.

- History and physical/chart notes
- Documentation that surgery will be performed by hospital credentialed, board certified plastic surgeon
- Documentation supporting diagnosis of lipedema as defined by the policy criterion I.B.
- Documentation of specific significant physical functional impairment(s) including specific ADLs (e.g., walking, feeding, dressing/grooming, toileting, bathing, transferring)
- Documentation of no response to a minimum of six months of conservative therapy including compression therapy and complex decongestive therapy (CDT), which combines several approaches including manual lymph drainage (a massage technique), compression therapy, and physical mobilization
- If the individual has a BMI greater than 35 kg/m^2, documentation of lack of effect of medically supervised weight loss on lipedema-affected areas through nutrition and/or medical interventions with clinic visits over six consecutive months
- Documentation of post-operative plan to include compression therapy
- Documentation of the amount of aspirate to be removed

CROSS REFERENCES

None

BACKGROUND

LYMPHEDEMA

A diagnosis of secondary lymphedema is based on history (e.g., cancer treatment, trauma) and physical examination (localized, progressive edema and asymmetric limb measurements) when other causes of edema can be excluded. Imaging, such as magnetic resonance imaging, computed tomography, ultrasound, or lymphoscintigraphy, may be used to differentiate lymphedema from others causes of edema in diagnostically challenging cases.

Breast Cancer-Related Lymphedema

Breast cancer treatment is one of the most common causes of secondary lymphedema. Both the surgical removal of lymph nodes and radiotherapy are associated with development lymphedema in patients with breast cancer.

In a systematic review of 72 studies (N=29,612 women), DiSipio (2013) reported that approximately 1 in 5 women who survive breast cancer will develop arm lymphedema.[1] Reviewers reported that risk factors for development of lymphedema that had a strong level of evidence were extensive surgery (i.e., axillary-lymph-node dissection, greater number of lymph nodes dissected, mastectomy) and being overweight or obese.

Management and Treatment

Early and ongoing treatment of lymphedema is necessary. Conservative therapy may consist of several features depending on the severity of the lymphedema. Patients are educated on the importance of self-care including hygiene practices to prevent infection, maintaining ideal body weight through diet and exercise, and limb elevation. Compression therapy consists of repeatedly applying padding and bandages or compression garments. Manual lymphatic drainage is a light pressure massage performed by trained physical therapists or by patients designed to move fluid from obstructed areas into functioning lymph vessels and lymph nodes. Complete decongestive therapy is a multiphase treatment program involving all of the previously mentioned conservative treatment components at different intensities. Pneumatic compression pumps may also be considered as an adjunct to conservative therapy or as an alternative to self-manual lymphatic drainage in patients who have difficulty performing self-manual lymphatic drainage. In patients with more advanced lymphedema after fat deposition and tissue fibrosis has occurred, palliative surgery using reductive techniques such as liposuction may be performed.

LIPEDEMA

Lipedema is a rare condition primarily seen in women where increased fat tissue accumulates under the skin which causes non-pitting, bilateral swelling typically seen in the lower extremities. Lipedema can also be seen in the upper extremities. The condition usually worsens gradually, although in some cases minor lipedema may stabilize. Lipedema is often painful and may be accompanied by easy bruising and joint problems. There is no known cause for lipedema. Lipedema is often misdiagnosed as obesity or lymphedema and conservative management and weight loss measures in certain subpopulations help differentiate a diagnosis or demonstrate the need for surgical intervention.

Management and Treatment

Management of lipedema is complex and distinct from lymphedema. The proposed main conservative treatment is complete or complex decongestive therapy (CDT). CDT combines several approaches including manual lymph drainage (a massage technique), compression therapy, and physical mobilization. Liposuction has been proposed as an alternative treatment option for lipedema.

EVIDENCE SUMMARY

SURGICAL TREATMENT FOR LYMPHEDEMA

The purpose of physiologic microsurgery treatments and liposuction for lymphedema is to provide a treatment option that is an improvement on existing therapies such as conservative therapy with compression garments or bandages, manual lymph drainage or pneumatic pumps, and decongestive therapy. Both surgical treatment and radiotherapy for breast cancer can lead to lymphedema and is one of the most common causes of secondary peripheral lymphedema.

Multiple Techniques

Systematic Reviews

Meuli (2023) published an updated systematic review which included 150 studies with 6496 patients who received LVA or LVNT.[2] A qualitative summary was conducted initially to determine the three most frequently reported outcomes for which a pooled analysis was then conducted. The authors reported an overall pooled change in excess limb circumference of -35.6%, change in excess volume of -32.7%, and a change in the number of cutaneous infection episodes per year of -1.9. Although the authors reported positive findings in reducing volume, circumference, and infection, the included studies suffer from significant quality and study design limitations. There exists significant heterogeneity in sampling, outcomes, and staging in the included studies which further limits possible conclusions.

Coriddi (2020) reported on a systematic review of PROs following surgical treatment of lymphedema, including lymphovenous bypass and vascularized lymph node transfer (VLNT).[3] Overall, 32 studies were identified (details regarding study design were not reported) with follow-up ranging from approximately 4 months to 43 months. The number of patients with breast cancer-related lymphedema was not described. The study reported findings for both validated and non-validated instruments assessing quality of life; however, only 18 studies (n=717 patients) reported individual patient data to permit quantitative assessment of the proportion of patients experiencing quality of life improvements. All studies showed an improvement in QOL ranging from 50% to 100%. Only one study used a validated instrument which demonstrated a 50% improvement in QOL.

Markkula (2019) published a Cochrane systematic review to assess and compare the efficacy of surgical interventions for the prevention of the development of lymphedema (LE) in the arm after breast cancer treatment and to assess and compare the efficacy of surgical interventions for the treatment of established LE in the arm after breast cancer treatment.[4] Reductive and reconstructive techniques were considered including liposuction, lymphaticovenular anastomoses (LVA), lymphatico-lymphatic bypass (LLB), and vascularized lymph node transfer (VLNT). Three studies which included two studies assessing the effectiveness of LVA as part of preventive management protocols in the prevention of breast cancer-related lymphedema and one study addressing the effectiveness of VLNT in the treatment of established breast cancer-related lymphedema. The authors concluded that there is not enough evidence to support the widespread adoption of liposuction, LVA, or VLNT techniques and that high-quality RCTs are needed.

A 2019 systematic review by Tyker aimed to evaluate the efficacy of a variety of surgical treatments for patients with lymphedema following head and neck cancer therapy.[5] 26 studies met the inclusion criteria including 14 cohort studies, seven case reports, two RCTs, two systematic reviews, and one narrative review. Manual lymph drainage had the largest number of studies and participants and there was limited evidence evaluating the efficacy of liposuction and microsurgery techniques. The authors concluded that there is limited data from high-

quality studies including RCTs and that more research is needed to understand the long-term efficacy of other treatment modalities.

A 2017 systematic review by Carl aimed to develop a treatment algorithm based on highest-quality lymphedema research.[6] The SR addressed lymphovenous anastomosis (LVA), vascularized lymph node transfer (VLNT), liposuction, excision, and combination surgical approaches for the treatment of lymphedema. Sixty-nine articles met inclusion criteria and were included in the review. In studies measuring excess volume reduction, the mean reduction was 96.6% for liposuction, 33.1% for LVA, and 26.4% for VLNT. Included excision articles did not report excess volume reduction. The authors stated that further studies with a focus on follow up after treatment will improve the validity of lymphedema surgery research. There was significant heterogeneity of the included studies in terms of lymphedema stage and etiology, method of assessing surgical outcomes, and inconsistent reporting of complications and quality of life outcomes. Additional trials are needed that compare surgical treatments to conservative therapies which may help define the most appropriate interventions for patients according to their clinical stage.

Additional single-arm studies have been published on liposuction for the treatment of lymphedema.[7, 8] However, these studies suffer from the same limitations as the studies included in the systematic reviews and do not capture longer periods of follow up and/or larger populations than the existing studies. Therefore, they are not discussed further.

Surgeries That Reconstruct or Bypass Using Donor Lymph Vessels

Leung (2015) reported on a systematic review of the surgical management of breast cancer-related lymphedema.[9] The search included studies reporting on the efficacy of surgical techniques used for the prevention or treatment of breast cancer-related lymphedema published between 2000 and 2014. Only one study on lymphatico-lymphatic bypass was identified and published since 2000. The study included seven patients followed for 2.6 years. One patient had "complete recovery" as measured by the circumference of the affected limb and the remaining six patients had a "reasonable outcome". Postsurgery complications were cellulitis, donor-site lymphorrhea, and transient edema of donor leg.

Surgeries That Reconstruct or Bypass Using the Venous System

Systematic Reviews

Several systematic reviews specifically evaluating microsurgical procedures using the venous system (lymphaticovenular anastomosis [LVA], lymphovenous bypass) have been reported.[10, 11] Two broader systematic reviews of treatments for lymphedema including several microsurgical procedures have also been reported.[6, 9] Corneilissen (2018) and Leung (2015) were limited to studies of breast cancer-related lymphedema but the remaining reviews were not.

Chang (2021) reported on a systematic review and meta-analysis of LVA and vascularized lymph node transfer (VLNT) for treatment of lymphedema.[12] Overall, 66 total studies were included, with 16 studies included on LVA. Follow-up ranged from approximately 6 to 68 months. The number of patients with breast cancer-related lymphedema was not described. In addition, studies evaluating use of these procedures for both upper and lower extremity lymphedema were included. The results of the study showed both a reduction in limb circumference and a reduction in the number of cellulitis infections before and after surgery.

Cornelissen (2018) reported on a systematic review assessing the effect of LVA in breast cancer-related lymphedema.[10] Fifteen observational studies were identified (11 prospective, 4 retrospective) with follow-up times ranging from two months to eight years. Although LVA surgery was performed in the included studies, the technical procedure differed among studies: six studies used only end-to-end anastomoses; four studies used both end-to-end and end-to-side anastomoses; one study used the ‘‘Octopus technique''; and four studies did not report the LVA technique used. Only two studies included a control group (bandaging, decongestive therapy).

Scaglioni (2017) reported on a systematic review of LVA for the treatment of lymphedema.[11] Reviewers noted significant variations in surgical techniques, numbers of anastomoses, and supplementary interventions (i.e., compressive therapy, additional debulking surgery). Nine studies included secondary lymphedema alone, while eight studies included patients with both primary and secondary lymphedemas. The number of patients with breast cancer-related lymphedema was not described. As mentioned, the Carl (2017) and Leung (2015) reviews included multiple surgical techniques. Leung (2015) was limited to breast cancer-related lymphedema while Carl (2017) was not.

Basta (2014) published a systematic review which included 27 studies evaluating the efficacy and safety of microsurgical treatments for lymphedema.[13] Lymphovenous shunt procedures were used in 22 studies and lymph node transfer was used in the remaining five studies. The primary endpoint was reduction in excess volume or circumference. The authors reported an excess circumference reduction of 48.8% and an absolute circumference reduction of 3.3 cm. The studies that reported excess volume reduction show a reduction of 56.6%. The rate of no improvement in the included studies was 11.8% and complications included infection, lymphorrhea, reexploration for flag congestion, and reoperation.

Randomized Controlled Trials

No RCTs were identified.

Nonrandomized Studies

Maruccia (2019) published a retrospective study comparing vascularized lymph node transfer (VLNT) to combined VLNT and axillary scar release.[14] Thirty-nine patients were included and all had stage II or III breast cancer-related lymphedema. Primary outcomes were limb circumference and lymphedema-related quality of life. A significant difference between the circumference reduction rates at above elbow level was observed at three and six months of follow-up comparing the two groups, with higher values in the combined treatment group than VLNT alone. No significant difference was detected comparing reduction rate values at above and below elbow at 12 and 24 months postoperatively. Quality of life metrics showed significantly better scores in all domains at all follow-up appointments in the combined group.

Agko (2018) published a nonrandomized, noncomparative prospective study including 12 patients with lymphedema who received vascularized lymph node transfer followed by lipectomy.[15] The primary outcomes were limb size and number of infectious episodes in addition to an evaluation of compression garment utilization. The authors reported a limb circumference reduction rate of 37.9% after the VLNT procedure and this was increased to a reduction rate of 96.4% after the lipectomy procedure. Only one patient reported an infectious episode after either of the treatments. It was noted that all patients were able to eventually

discontinue the use of compression garments. Limitations of this study include the lack of a comparator group, small sample size, and no long-term follow-up.

Additional single-arm studies have been published since the systematic reviews.[16] However, these studies suffer from the same limitations as the studies included in the systematic reviews and do not capture longer periods of follow-up and/or larger populations than the existing studies. Therefore, they are not discussed further.

Subsection Summary: Surgeries That Reconstruct or Bypass Using the Venous System

No controlled trials were identified evaluating the physiologic microsurgeries using techniques such as lymphovenous bypass or LVA that reconstruct or bypass the obstructed lymphatic vessels using the venous system. Systematic reviews have indicated that most of the available evidence for these procedures comes from uncontrolled studies including fewer than 40 participants each, most of which lack adequate descriptions of how patients were selected for inclusion. Surgical technique, the severity of lymphedema, outcomes metrics, and follow-up times varied across studies making it difficult to synthesize the evidence. Surgical complications have been inconsistently reported but appear to be rare. RCTs of physiologic microsurgeries that bypass the obstructed lymphatic vessels using the venous system plus conservative therapy vs conservative therapy alone are needed.

SURGERIES THAT TRANSFER LYMPH TISSUE

Systematic Reviews

Systematic reviews evaluating microsurgical procedures that transfer lymph tissue (autologous lymph node transfer, vascularized lymph node transfer [VLNT]) have been reported. Ozturk (2016) reported on a systematic review of VLNT for treatment of lymphedema.[17] They included treatment for both primary and secondary lymphedema and as such comprised a heterogeneous population. However, 191 of 305 of the surgeries were for breast cancer-related lymphedema. Eighteen studies were identified (3 prospective, 15 retrospective). For breast cancer-related lymphedema, VLNT with a skin island or VLNT with an autologous flap was used. There was inconsistent reporting of the staging of lymphedema. Reviewers did not state whether any of the studies included a control group. Two systematic reviews of various surgical methods previously described also included a review of lymph node transfer.[6, 9]

In addition to the systematic reviews of efficacy, Demiri (2018) reported on a systematic review of donor-site complications following autologous lymph node transfer for breast cancer-related lymphedema.[18]

Risk of bias was assessed in Ozturk (2016) using a checklist from the American Society of Plastic Surgeons guidelines for therapeutic studies. A summary of the assessment follows:

- 12 of 18 studies did not report whether patients were selected consecutively and one did not include consecutive patients;
- 13 of 18 studies had insufficient information on the surgical team;
- 3 of 18 studies had an insufficient follow-up to observe outcomes (ie, <1 year).

Randomized Controlled Trials

Dionyssiou (2016) reported on an RCT that evaluated VLNT plus physical therapy vs physical therapy alone for lymphedema in 36 women with stage II breast cancer-related

lymphedema.[19] At 18 months, the reduction in the excess volume of the affected limb as a percentage of the intact limb was 57% in the VLNT group and 18% in the physical therapy group (treatment effect not reported, p<0.001). The mean number of lymphedema-related infections per patient per year was lower in the VLNT group (0.28 vs 1.16; treatment effect not reported, p=0.001). The trial had several limitations described in Tables 9 and 10. Notably, there was no description of allocation concealment and the trial was not blinded, possibly introducing both selection and ascertainment bias. The reporting did not describe the power calculations or justify a clinically important difference for the reported outcomes. The trial was not registered, so selective reporting cannot be ruled out.

Nonrandomized Studies

Additional single-arm studies have been published since the systematic reviews.[20-25] However, these studies suffer from the same limitations as the studies included in the systematic reviews and do not capture longer periods of follow-up and/or larger populations than the existing studies. Therefore, they are not discussed further.

Subsection Summary: Surgeries That Transfer Lymph Tissue

One RCT with 36 participants was identified evaluating VLNT that uses lymph tissue transfer in patients with breast cancer-related lymphedema. The trial reported reductions in the excess volume of the affected limb and rates of lymphedema-related infections for VLNT plus physical therapy compared with physical therapy alone. Systematic reviews have indicated that most of the remaining available evidence for these procedures comes from uncontrolled studies including fewer than 50 participants each, most of which lacked adequate descriptions of how patients were selected for inclusion. Surgical techniques, the severity of lymphedema, outcomes metrics, and follow-up times varied across studies. Although surgical complications were inconsistently reported, a systematic review of complications estimated that donor-site lymphedema occurs in approximately 2% of surgeries and seroma occurs in approximately 4%. Additional RCTs of physiologic microsurgeries that use lymph tissue transfer with conservative therapy vs conservative therapy alone are needed.

PHYSIOLOGIC MICROSURGERY TO PREVENT LYMPHEDEMA

The purpose of lymphatic physiologic microsurgery simultaneous to lymphadenectomy for breast cancer (e.g., the Lymphatic Microsurgical Preventing Healing Approach [LYMPHA]) is to prevent lymphedema in individuals who are being treated for breast cancer. While recommendations on preventive measures for lymphedema exist, such as avoiding needle sticks, limb constriction, and air travel, most recommendations are based on clinical opinion. A systematic review of preventive measures for lymphedema by Cemal (2011) found strong scientific evidence only for the recommendations to maintain a normal body weight or avoid weight gain and to participate in a supervised exercise regimen.[26]

LYMPHA is a preventive LVA procedure performed during nodal dissection or reconstructive surgery that involves anastomosing arm lymphatics to a collateral branch of an axillary vein.

Systematic Reviews

Pagliara (2024) published a systematic review of prophylactic lymphatic surgery (PLS) of 18 studies including 11 without control groups and seven with control groups.[27] A total of 15 of 342 patients involved in the uncontrolled studies developed lymphedema at least six months after PLS (4.59%). The seven studies with a control group included 569 patients, 328 cases

and 241 controls. Among the cases, 36 (10%) developed lymphedema whereas the incidence of lymphedema in the controls was 40%. These results are significantly limited by the low quality of the included studies and randomized controlled trials with long-term follow-up are necessary to draw affirmative conclusions or develop evidence-based recommendations.

Jorgensen (2017) reported on a systematic review of prophylactic LVA and shunts for preventing cancer-related lymphedema, not limited to breast cancer.[28] Twelve articles were included in the qualitative analysis (5 specific to breast cancer) and four of those studies (2 specific to breast cancer) were included in a meta-analysis. Jorgensen (2017) performed a meta-analysis of the incidence of lymphedema that included 4 studies (2 specific to breast cancer) with a control group consisting of patients without prophylactic LVA. The relative risk for incident lymphedema was 0.33 (95% CI, 0.19 to 0.56) favoring prophylactic LVA vs control; however, because the incidence of lymphedema varies over time and the follow-up times varied across studies, it is not clear whether it would be appropriate to pool the risk including all time points.

Jorgensen (2017) also performed a risk of bias assessment of the included studies. They noted the following:

- None of the studies had allocation concealment or blinding;
- Only 1 study was randomized;
- None of the studies were registered;
- Only 4 studies had a control group. Selection of the control groups was unclear or a potential source of bias in all 4 controlled studies.

Randomized Controlled Trials

Boccardo (2011) reported on results of an RCT including 46 women referred for axillary dissection for breast cancer treatment between 2008 and 2009 who were randomized to LYMPHA or no preventive surgery (control).[29] All LVA procedures were performed by the same surgeon, reported to be skilled in lymphatic microsurgery. The LVA surgeon was not the same surgeon who performed lymph node dissection. The same axillary dissection treatment was performed in the 2 treatment groups. Lymphedema was diagnosed as a difference in excess volume of at least 100 mL compared with preoperative volume measurements. Lymphedema was diagnosed in 1 (4%) woman in the LYMPHA group and 7 women (30 %) in the control group by 18 months of follow-up. The change in volume with respect to baseline was reportedly higher in the control group than in the LYMPHA group at 1, 3, 6, 12, and 18 months (all $p<0.01$). The trial had several limitations described in Tables 15 and 16. Notably, the follow-up duration was only 18 months. Methods of randomization and allocation concealment were not described and there was no justification of the sample size. The patients and investigators were not blinded (ie, no sham procedure was performed) and there was no discussion of whether outcome assessors were blinded.

Nonrandomized Studies

Additional single-arm studies have been published since the systematic reviews.[30] However, these studies suffer from the same limitations as the studies included in the systematic reviews and do not capture longer periods of follow up and/or larger populations than the existing studies. Therefore, they are not discussed further.

Section Summary: Physiologic Microsurgery to Prevent Lymphedema

One RCT was identified evaluating LYMPHA to prevent lymphedema in 49 patients referred for axillary dissection for breast cancer. The trial reported that lymphedema developed in 4% of women in the LYMPHA group and 30% in the control group by 18 months of follow-up. Longer follow-up is needed to observe incident lymphedema occurring after 18 months and assess the durability of the procedure. The trial had limitations that could have introduced bias: methods of randomization and allocation concealment were not described, and there was no sham procedure or blinding. Systematic reviews have indicated that most of the remaining available evidence for LYMPHA comes from uncontrolled studies, although two controlled observational studies in women with breast cancer have been performed. Selection of the control group was identified as a potential source of bias in both controlled studies. Outcomes metrics and follow-up times varied across studies. Additional RCTs of LYMPHA are needed and 1 such trial is underway (see NCT03428581).

SURGICAL TREATMENT FOR LIPEDEMA

The purpose of liposuction treatments for lipedema is to provide a treatment option that is an improvement on existing therapies such as complete decongestive therapy.

Systematic Reviews

Amato (2024) published a meta-analysis on the efficacy of liposuction for the treatment of lipedema.[31] Seven studies were included in the final analysis, six from Germany and one from Australia and no randomized trials were included. The authors reported that the results showed significant post-operative improvements in spontaneous pain, edema, bruising, mobility, and quality of life among lipedema patients undergoing liposuction. Over half of the patients still required conservative therapy after surgery. The authors caution these results due to lipedema's complexity, significant reliance on self-reported data, and limitations of the studies reviewed. Finally, the authors suggest that liposuction may offer symptomatic relief, it should be considered an adjunct, experimental therapy rather than a definitive cure, emphasizing the need for a comprehensive approach to care.

The Canadian Agency for Drugs and Technology in Health (CADTH) published a rapid response report summarizing the evidence on liposuction for the treatment of lipedema.[32]

The report consists of five nonrandomized, uncontrolled studies that suggest liposuction may be effective in reducing extremity size and complaints related to lipedema. Complaints related to lipedema included spontaneous pain, easy bruising, sensitivity to pressure, impairment in quality of life, restrictions to mobility, edema, feeling of tension, and general impairment. Outcome data was collected via patient self-assessment using tools that have not been validated for lipedema related complaints. Additionally, all studies included were noncomparative, nonrandomized studies and did not include long-term follow up.

Randomized Controlled Trials

No RCTs were identified.

Nonrandomized Studies

Baumgartner (2021) reported the results of a single center study of 60 patients to monitor the 12-year success of liposuction for treating lipedema from the patients' perspective using self-reported outcomes.[33] Prior to liposuction, 18 patients had Stage I lipedema, and 42 had Stage II. Self-reported outcomes included responses from patients that were asked to indicate to

what extent they are currently experiencing the following: spontaneous pain, sensitivity to pressure, edema, bruising, restriction of movement, cosmetic impairment, reduction in quality of life. The results showed significant improvement in scores across all indicators, as well as overall impairment score. There were 37 of the 60 patients that underwent combined decongestive therapy (CDT) with manual lymph drainage (MLD) plus compression garments before surgery. A subgroup analysis was conducted on these patients in order to assess treatment success, and the results showed seven patients required fewer conservative treatments and 10 no longer needed conservative treatment. The authors concluded that these results demonstrate a permanent improvement in lipedema symptoms for patients with Stage I and II lipedema. This study did not include Stage III lipedema patients and relies exclusively on self-reported outcomes.

Section Summary: Surgical Treatment for Lipedema

The existing literature addressing liposuction techniques for the treatment of lipedema only includes nonrandomized, uncontrolled studies with no comparator group. The evidence is lacking and further research with longer-term outcomes and patient selection criteria are needed. High quality randomized trials or comparative studies are needed.

PRACTICE GUIDELINE SUMMARY

NATIONAL LYMPHEDEMA NETWORK

The National Lymphedema Network published a position paper on the diagnosis and treatment of lymphedema in 2011.[34] The paper stated the following on microsurgical procedures:

"Microsurgical and supramicrosurgical (much smaller vessels) techniques have been developed to move lymph vessels to congested areas to try to improve lymphatic drainage. Surgeries involve connecting lymph vessels and veins, lymph nodes and veins, or lymph vessels to lymph vessels. Reductions in limb volume have been reported and a number of preliminary studies have been done, but there are no long-term studies of the effectiveness of these techniques."

INTERNATIONAL SOCIETY OF LYMPHOLOGY

International Society of Lymphology published a consensus document on the diagnosis and treatment of peripheral lymphedema in 2016.[35] The document stated the following on lymphaticovenous (or lymphovenous) anastomoses (LVA):

"LVA are currently in use at multiple centers around the world. These procedures have undergone confirmation of long-term patency (in some cases more than 20 years) and some demonstration of improved lymphatic transport (by objective physiologic measurements of long-term efficacy)."

NATIONAL CANCER INSTITUTE

The NCI Health Professional Version on lymphedema states:[36]

> “Surgery is rarely performed on patients who have cancer-related lymphedema. The primary surgical method for treating lymphedema consists of removing the subcutaneous fat and fibrous tissue with or without creation of a dermal flap within the muscle to encourage superficial-to-deep lymphatic anastomoses. These methods have

not been evaluated in prospective trials, with adequate results for only 30% of patients in one retrospective review. In addition, many patients face complications such as skin necrosis, infection, and sensory abnormalities. The oncology patient is usually not a candidate for these procedures. Other surgical options include the following: Microsurgical lymphaticovenous anastomoses in which the lymph is drained into the venous circulation or the lymphatic collectors above the area of lymphatic obstruction; liposuction; superficial lymphangiectomy; fasciotomy".

SUMMARY

Medically Necessary

There is enough research to show that liposuction (including, but not limited to, lipectomy, suction-assisted protein lipectomy, and lymph-sparing liposuction) to treat lipedema may improve health outcomes in certain populations. Therefore, liposuction (including, but not limited to, lipectomy, suction-assisted protein lipectomy, and lymph-sparing liposuction) may be considered medically necessary when policy criteria are met.

Investigational

There is not enough research to show that liposuction (including, but not limited to, lipectomy, suction-assisted protein lipectomy, and lymph-sparing liposuction) to treat lipedema improves health outcomes when policy criteria are not met. Therefore, liposuction (including, but not limited to, lipectomy, suction-assisted protein lipectomy, and lymph-sparing liposuction) is considered investigational for patients with lipedema when policy criteria are not met.

There is not enough research to show that liposuction (including, but not limited to, lipectomy, suction-assisted protein lipectomy, and lymph-sparing liposuction) to treat lipedema in areas other than extremities improves health outcomes. Therefore, liposuction (including but not limited to lipectomy, suction-assisted protein lipectomy, and lymph-sparing liposuction) is considered investigational.

There is not enough research to show that physiologic microsurgeries including, but not limited to, lymphatico-lymphatic bypass, lymphatic-venous-lymphatic plasty, lymphovenous bypass, lymphaticovenous anastomosis, autologous lymph node transplantation, and vascularized lymph node transfer improve health outcomes for people with lymphedema. Therefore, physiologic microsurgeries including, but not limited to, lymphatico-lymphatic bypass, lymphatic-venous-lymphatic plasty, lymphovenous bypass, lymphaticovenous anastomosis, autologous lymph node transplantation, and vascularized lymph node transfer is considered investigational for all indications, including but not limited to lymphedema.

There is not enough research to show that lymphatic physiologic microsurgery performed during nodal dissection or breast reconstruction to prevent lymphedema (including, but not limited to, the Lymphatic Microsurgical Preventing Healing Approach) in individuals who are being treated for breast cancer improves health outcomes. Therefore, lymphatic physiologic microsurgery performed during nodal dissection or breast reconstruction to prevent lymphedema (including, but not limited to, the Lymphatic Microsurgical Preventing Healing Approach) in individuals who are being treated for breast cancer is considered investigational.

There is not enough research to show that liposuction (including, but not limited to, lipectomy, suction-assisted protein lipectomy, and lymph-sparing liposuction) to treat lymphedema improves health outcomes. No clinical guidelines based on research recommend liposuction for the treatment of lymphedema. Therefore, liposuction (including, but not limited to, lipectomy, suction-assisted protein lipectomy, and lymph-sparing liposuction) is considered investigational for patients with lymphedema.

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CODES

NOTE: Reporting 38999 for the treatment of lipedema is not appropriate as it is not a disease of the lymphatic system. Reporting 15839 for body parts represented by other specific codes (e.g., thigh, leg) is not appropriate.

Codes	Number	Description
CPT	1019T	Lymphovenous bypass, including robotic assistance, when performed, per extremity
	1081T	Microvascular anastomosis between a lymph node and a vein, including robot assistance, when performed; initial anastomosis
	1082T	Microvascular anastomosis between a lymph node and a vein, including robot assistance, when performed; each additional anastomosis (List separately in addition to code for primary procedure)
	15832	Excision, excessive skin and subcutaneous tissue (includes lipectomy); thigh
	15833	;leg
	15834	;hip
	15835	;buttock
	15836	;arm
	15837	;forearm or hand
	15838	;submental fat pad
	15839	;other area
	15876	Suction assisted lipectomy; head and neck
	15877	;trunk

Codes	Number	Description
	15878	;upper extremity
	15879	;lower extremity
	38999	Unlisted procedure, hemic or lymphatic system
HCPCS	None	

Date of Origin: *June 2020*