BSC7.18	Immediate and Delayed Lymphatic Reconstruction Surgery		
Original Policy Date:	July 1, 2023	**Effective Date:**	July 1, 2023
Section:	7.0 Surgery	**Page:**	Page 1 of 20

Policy Statement

Immediate Lymphatic Reconstruction Surgery

Lymphovenous bypass

I. Lymphovenous bypass may be considered **MEDICALLY NECESSARY** when **BOTH** of the following criteria are met:
   A. Individual meets **BOTH** of the following lymphovenous bypass criteria:
      1. Surgical plan is to undergo axillary lymph node dissection for breast cancer treatment at the time of initial cancer resection; **OR** a surgical plan for radial forearm flap harvesting for planned phalloplasty
      2. Attestation that the individual has demonstrated the ability to tolerate post-surgical compression therapy and physical therapy sessions per the treating lymphedema provider.
   B. Individual has **NONE** of the following:
      1. History of malignant skin cancer of the ipsilateral upper extremity
      2. **Any** of the following uncontrolled comorbidities:
         a. Untreated upper extremity/chest venous disease (superior vena cava syndrome)
         b. Congestive heart failure (CHF)
      3. Pregnancy
      4. Active infection of the affected extremity (cellulitis/erysipelas).

II. Lymphatico-lymphatic bypass is considered **investigational**.

Delayed Lymphatic Reconstruction Surgery

Lymphovenous bypass

III. Lymphovenous bypass may be considered **MEDICALLY NECESSARY** when **ALL** of the following criteria are met:
   A. Individual meets **BOTH** of the following diagnostic criteria:
      1. At least one sign **AND** one symptom consistent with lymphedema **AND** a diagnosis of ≥ stage I lymphedema (International Society of Lymphology or ISL)
         a. Signs: pitting edema **OR** non-pitting edema; hardening and thickening of the skin (fibrosis); limited mobility from swelling
         b. Symptoms: heaviness, achiness, pain, tightness, numbness/tingling, not fitting into clothing or fatigue.
      2. At **least one** of the following positive quantitative measurements for unilateral disease:
         a. Lymphoscintigraphy findings showing a minimum of a one-hour delayed transit time to first-level lymph nodes, axillary lymph nodes (upper extremity lymphedema) or inguinal lymph nodes (lower extremity lymphedema) **OR** dermal back flow
         b. Indocyanine green (ICG) imaging demonstrating obstruction of linear lymphatic channels, with reticular or stardust pattern
         c. Magnetic resonance imaging (MRI) lymphangiography demonstrating obstruction of lymphatic channels or dermal backflow
   B. Individual meets **ALL** of the following lymphovenous bypass eligibility criteria:
      1. Individual has body mass index (BMI) ≤ 35
      2. Individual has engaged and maintained compliance with conservative lymphedema treatment by a certified lymphedema therapist (CLT) for a minimum of 1 month including **BOTH** of the following:

a. Compression therapy (bandaging/garment/gauntlet)
b. **Any** of the following treatment modalities:
i. Manual lymphatic drainage, complete decongestive therapy, use of a pneumatic compression pump
ii. Targeted exercises for lymphedema treatment
3. Individual has demonstrated the ability to tolerate post-surgical compression therapy and physical therapy sessions per treating lymphedema provider.

C. Individual has **NONE** of the following:
1. Transient lymphedema: any swelling that meets diagnostic threshold for lymphedema criteria and resolves naturally within six months after the last oncologic treatment
2. Untreated lipedema or lipedema without lymphatic dysfunction
3. **Any** of the following uncontrolled comorbidities:
a. Untreated venous disease (DVT, superior vena cava or May-Thurner syndrome)
b. Congestive heart failure (CHF)
c. Medication-induced swelling
d. Liver disease including but not limited to cirrhosis, hypoproteinemia
e. Nephropathy including end-stage renal disease
f. Uncontrolled hypothyroidism
g. Venous insufficiency in the affected extremity
4. Pregnancy
5. Active infection of the affected extremity (cellulitis/erysipelas).

IV. Lymphovenous bypass is considered **INVESTIGATIONAL** if above criteria are not met.

Vascularized Lymph Node Transplant

V. Vascularized lymph node transplant may be considered **MEDICALLY NECESSARY** when **ALL** of the following criteria are met:
A. Individual meets **BOTH** of the following diagnostic criteria:
1. At least one sign **AND** one symptom consistent with lymphedema **AND** a diagnosis of ≥ stage I lymphedema (ISL)
a. Signs: pitting edema **OR** non-pitting edema; hardening and thickening of the skin (fibrosis); limited mobility from swelling
b. Symptoms: heaviness, achiness, pain, tightness, numbness/tingling, not fitting into clothing or fatigue.
2. At **least one** of the following positive quantitative measurements:
a. For unilateral disease, **any** of the following:
i. Lymphoscintigraphy findings showing a minimum of a one-hour delayed transit time to first-level lymph nodes, axillary lymph nodes (upper extremity lymphedema) or inguinal lymph nodes (lower extremity lymphedema) **OR** dermal back flow
ii. Indocyanine green (ICG) imaging demonstrating obstruction or absence of linear lymphatic channels, with reticular or stardust pattern
iii. Magnetic resonance imaging (MRI) lymphangiography demonstrating obstruction of lymphatic channels or dermal backflow
b. For bilateral disease, **any** of the following:
i. Lymphoscintigraphy findings showing a minimum of a one-hour delayed transit time to first-level lymph nodes, axillary lymph nodes (upper extremity lymphedema) or inguinal lymph nodes (lower extremity lymphedema) **OR** dermal back flow
ii. Indocyanine green (ICG) imaging demonstrating obstruction or absence of linear lymphatic channels, with reticular or stardust pattern

B. Individual meets **ALL** of the following lymph node transplant eligibility criteria:
1. Individual has body mass index (BMI) ≤ 35

2. Individual has engaged and maintained compliance with conservative lymphedema treatment by a certified lymphedema therapist (CLT) for a minimum of 1 month including **BOTH** of the following:
    a. Compression therapy (bandaging/garment/gauntlet)
    b. **Any** of the following treatment modalities:
        i. Manual lymphatic drainage, complete decongestive therapy, use of a pneumatic compression pump
        ii. Targeted exercises for lymphedema treatment
3. Individual has demonstrated the ability to tolerate post-surgical compression therapy and physical therapy sessions per treating lymphedema provider.

C. Individual has **NONE** of the following:
1. Transient lymphedema: any swelling that meets diagnostic threshold for lymphedema criteria and resolves naturally within six months after the last oncologic treatment
2. Untreated lipedema and lipedema without lymphatic dysfunction
3. **Any** of the following uncontrolled comorbidities:
    a. Untreated venous disease (DVT, superior vena cava or May-Thurner syndrome)
    b. Congestive heart failure (CHF)
    c. Medication-induced swelling
    d. Liver disease including but not limited to cirrhosis, hypoproteinemia
    e. Nephropathy including end-stage renal disease
    f. Uncontrolled hypothyroidism
    g. Venous insufficiency in the affected extremity
4. Pregnancy
5. Active infection of the affected extremity (cellulitis/erysipelas).

VI. Vascularized lymph node transplant is considered **INVESTIGATIONAL** if above criteria are not met.

Reductive Surgery

VII. Reductive surgery includes debulking of a limb with either liposuction or excisional techniques. Reductive surgery may be considered **MEDICALLY NECESSARY** when **ALL** of the following criteria are met:

A. Individual meets **BOTH** of the following diagnostic criteria:
1. At least one sign **AND** one symptom consistent with lymphedema **AND** a diagnosis of ≥ stage II lymphedema (ISL)
    a. Signs: pitting **OR** non-pitting edema; hardening and thickening of the skin (fibrosis); limited mobility from swelling
    b. Symptoms: heaviness, achiness, pain, tightness, numbness/tingling, not fitting into clothing or fatigue.
2. At **least one** of the following positive quantitative measurements:
    a. For unilateral disease, **any** of the following:
        i. Lymphoscintigraphy findings showing a minimum of a one-hour delayed transit time to first-level lymph nodes, axillary lymph nodes (upper extremity lymphedema) or inguinal lymph nodes (lower extremity lymphedema) **OR** dermal back flow
        ii. Volumetry differential (circumferential truncated cone measurements and/or perometry differential) >10% (if affected extremity is the dominant extremity) or >7% if the affected extremity is non-dominant)
        iii. Indocyanine green (ICG) imaging demonstrating obstruction or absence of linear lymphatic channels, with reticular or stardust pattern
        iv. Magnetic resonance imaging (MRI) lymphangiography demonstrating obstruction of lymphatic channels or dermal backflow
    b. For bilateral disease, any of the following:

i. Lymphoscintigraphy findings showing a minimum of a one-hour delayed transit time to first-level lymph nodes, axillary lymph nodes (upper extremity lymphedema) or inguinal lymph nodes (lower extremity lymphedema) **OR** dermal back flow
ii. Indocyanine green (ICG) imaging demonstrating obstruction or absence of linear lymphatic channels, with reticular or stardust pattern

B. Individual meets **ALL** of the reductive surgery eligibility criteria:
1. Individual has body mass index (BMI) ≤ 35
2. Individual has clinical findings documented by treating lymphedema provider consistent with moderate to severe fat hypertrophy
3. Individual has engaged and maintained compliance with conservative lymphedema treatment by a certified lymphedema therapist (CLT) for a minimum of 1 month including **both** of the following:
   a. Lymphedema therapy includes compression therapy (bandaging/garment/gauntlet)
   b. **Any** of the following treatment modalities:
      i. manual lymphatic drainage, complete decongestive therapy, use of a pneumatic compression pump
      ii. targeted exercises for lymphedema treatment
4. Individual has demonstrated the ability to tolerate post-surgical compression therapy and physical therapy sessions per treating lymphedema provider.

C. Individual has **NONE** of the following:
1. Transient lymphedema: any swelling that meets diagnostic threshold for lymphedema criteria and resolved naturally within six months after the last oncologic treatment
2. Untreated lipedema and lipedema without lymphatic dysfunction
3. **Any** of the following uncontrolled comorbidities:
   a. Untreated venous disease (DVT, superior vena cava or May-Thurner syndrome)
   b. Congestive heart failure (CHF)
   c. Medication-induced swelling
   d. Liver disease including but not limited to cirrhosis, hypoproteinemia
   e. Nephropathy including end-stage renal disease
   f. Uncontrolled hypothyroidism
   g. Venous insufficiency in the affected extremity
4. Pregnancy
5. Active infection of the affected extremity (cellulitis/erysipelas).

VIII. Reductive surgery is considered **INVESTIGATIONAL** if above criteria are not met.

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

An immediate procedure is intended to mean one that is done at the time of the initial mastectomy/resection. Staged immediate is when the LVB/LVA is planned to be done within the first week after resection, which is very rare for cancer cases, but could be done for forearm graft harvesting procedures. Typically, anything more than a week after the initial surgery results in scarring that makes the procedure very difficult. For that reason, it is more typical when delayed to then wait to see if lymphedema develops and do a secondary procedure at that time if needed.

Lymphovenous anastomosis is similar to, and for purposes of this policy, is treated the same as lymphovenous bypass.

Autologous lymph node transplantation can be considered to be essentially equivalent to VLNT (Vascularized Lymph Node Transplant).

Lymphatico-lymphatic bypass is no longer common, but might be used during immediate lymphatic reconstruction at the time of lymph node dissection in the axilla or groin instead of lymphovenous bypass.

Axillary lymph node dissection for the purposes of this policy is defined as removal of essentially all axillary lymph nodes. This is typically done by removing a block of tissue including 15-30 nodes and is associated with about a 50% incidence of lymphedema developing. It is not meant to include sentinel lymph node biopsy (of 1-4 nodes), which by itself has a <5% incidence of lymphedema associated with it.

* Table 1 lists International Society of Lymphology (ISL) criteria for staging lymphedema based on "softness" or "firmness" of the limb and the changes with an elevation of the limb. The ISL Staging system is the most widely accepted clinical staging system for lymphedema.

Table 1. ISL Lymphedema Staging	Description
Stage 0	Swelling is not evident despite impaired lymphatic transport on imaging. Individuals may still have other lymphedema symptoms.
Stage I	Accumulation of fluid that subsides (usually within 24 hours) with limb elevation; soft edema that may pit, without evidence of dermal fibrosis
Stage II	Does not resolve with limb elevation alone; limb may no longer pit on examination
Stage III	Lymphostatic elephantiasis; skin has trophic changes

Description

Lymphedema is a chronic and progressive disease secondary to accumulation of lymphatic fluid. The progressive nature of this disease means that accumulation of fluid leads to further lymphatic vessel dysfunction in a cycle that causes failure of the lymphatic vessel systems leading to chronic inflammatory reactions, fibroproliferative changes, fat deposition, skin changes and impaired immune response. Lymphedema causes pain, disfigurement, decreased quality of life, recurrent episodes of infection (cellulitis) that can require prolonged hospitalization or chronic antibiotic therapy and even malignant transformation. These sequelae of lymphedema cause significant morbidity and even mortality.

Primary lymphedema results from congenital lymphatic dysfunction. Secondary lymphedema is more common and is due to injury to some aspect of the lymphatic system. This includes trauma, infection, surgery, other vascular disorders and most commonly, removal of lymph nodes for cancer treatment. In the United States, the primary cause of lymphedema is iatrogenic, in that upper extremity lymphedema secondary to breast cancer treatment prevails. California SB 255 (Health and Safety Code 1367.635, para a3) requires insurance plans to “cover all complications from a mastectomy, including lymphedema.” The Women’s Health and Cancer Rights Act of 1998 requires coverage for “physical complications of mastectomy, including lymphedemas.” Risk factors for upper extremity lymphedema secondary to breast cancer treatment include axillary lymph node dissection (ALND), regional radiation therapy, and elevated BMI. Secondary lymphedema due to cancer treatment can occur in any part of the body including the genitals as well as the head and neck. However, after the upper extremity, lower extremity secondary lymphedema is the most common due to removal of pelvic or groin lymph nodes for cancer treatment.

The mainstay of lymphedema treatment is palliative and focuses on slowing progression of disease and managing symptoms through conservative therapy: complete decongestive therapy (CDT) by Certified lymphedema therapists (CLTs). Complete decongestive therapy includes a decongestion phase of manual lymphatic drainage (MLD), skin and nail care, 24-hour compression bandaging with non-elastic bandages, and compression garments after limb reduction stabilizes. A second maintenance phase utilizes compression garments, continued MLD that can be performed independently by patients, skin and nail care as well as lymphedema exercises. Patient education is an important component of both phases including skin hygiene to prevent infection, diet and exercise. Pneumatic compression pumps are also a component of both phases and are used at home by individuals to force excess fluid out of the affected limb, typically on a nightly basis.

Surgical treatment of lymphedema is aimed to complement conservative therapy as well as slow lymphedema progression and provide additional alleviation of significant lymphedema sequelae including infections requiring prolonged antibiotic therapy, lymphedema symptoms and garment dependence that cause significant functional impairment despite optimized conservative treatment in the form of CDT. Surgical treatments can be divided into physiologic procedures and reductive procedures. Physiologic procedures aim to reduce the amount of fluid buildup and include lymphovenous bypass (LVB) and vascularized lymph node transplant (VLNT). Reductive procedures aim to remove excess fibrofatty deposition and/or skin secondary to lymphedema and include liposuction as well as direct excisional treatments.

Lymphovenous bypass (also referred to as lymphovenous anastomosis) is a physiological surgical procedure for the treatment of primary and/or secondary upper and/or lower extremity lymphedema. Lymphovenous bypass involves surgically cutting blocked lymphatics and connecting them (anastomosing) to nearby veins to effectively re-route fluid around an obstruction and directly into the venous system. This surgery requires use of an operating microscope as lymphatic vessels are typically <1mm in diameter. The surgery is performed through multiple small (typically <3cm) incisions after identifying lymphatic channels to be bypassed preoperatively. The surgery is typically performed under general anesthesia but can also be performed under local anesthesia. It is less invasive than the other forms of surgical treatments and is an outpatient procedure with a quick recovery.

Vascularized lymph node transplant is a physiologic surgical procedure that transplants healthy lymph nodes and tissue from one part of the body to the affected limb using a process of microsurgery to connect small arteries and veins in the transplanted tissue so it can live in the new recipient site. Vascularized lymph node transplants are theorized to act as both a mechanical pump, sucking up lymph fluid through attached lymphatic vessels into the central circulation as well as through a physiologic process of lymphangiogenesis to produce and bridge lymphatic pathways. This treatment option is used for primary and/or secondary upper and/or lower extremity lymphedema. Lymph node tissue can be harvested from different "donor" sites including the groin, chest wall, omentum, submental region and supraclavicular area. These procedures require general anesthesia and typically require a 3 to 7-day hospital stay. Complications include donor-site complications which include a very rare, but potential risk for donor site lymphedema if groin lymph nodes are harvested.

Reductive surgery most commonly refers to lymph-sparing liposuction (also referred to as liposuction, suction-assisted lipectomy or suction-assisted protein lipectomy [SAPL]) for removal of excess fibrofatty tissue accumulation secondary to lymphedema. Physiologic fluid procedures (LVB and VLNT) cannot remove this solid component of lymphedema. Liposuction is performed under general anesthesia and usually with tourniquet control to limit blood loss. Adherence to postoperative compression is paramount to limit post-operative swelling. These procedures are typically outpatient unless large volumes of liposuction are performed (>5 liters).

Immediate lymphatic reconstruction surgery (ILR) refers to immediate reconstruction of the lymphatic channels that are cut at the time of lymph node dissection. This is most typically performed

at the time of axillary node dissection for positive nodal disease in breast cancer treatment. Immediate lymphatic reconstruction involves localizing the cut lymphatics in the surgical wound by injecting dye into the upper extremity (lymphazurin, methylene blue, fluorescein or ICG). These cut lymphatics are then sutured to a nearby vein using a microscope as the vessels are usually <1mm in diameter. If a nearby vein is not available, a vein graft has to be taken (typically from the groin) to bridge the gap between the cut lymphatics and the nearest available vein. The surgery is performed at the same time as the axillary lymph node dissection after the breast surgeon has completed their portion of the procedure. There is no additional recovery from the bypass and individuals typically go home the same day or the following day depending on their recovery from their cancer surgery.

Related Policies

- Axillary Reverse Mapping for Prevention of Breast Cancer-Related Lymphedema
- Bioimpedance Devices for Detection and Management of Lymphedema
- Pneumatic Compression Pumps for Treatment of Lymphedema and Venous Ulcers

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

- N/A

Rationale

Available literature analyzing lymphovenous bypass for surgical treatment of chronic lymphedema includes six systematic reviews and 13 prospective studies. Studies demonstrated a consistent trend in reduction of limb volume and circumferential measurements. All studies reporting on infection frequency also noted a mean decrease in infection frequency after LVB. Gupta et al. (2021) reported on a systematic review of LVB for upper extremity lymphedema. A total of 16 studies were included comprising of 349 individuals of which 14 studies reported objective improvement in limb circumference or volume measurement following LVB with a mean follow-up ranging from 6 months to 8 years. Chang et al. (2021) reported on a systematic review and meta-analysis of 16 studies that included LVB and reported a reduction in limb circumference by a mean of 3.8cm in individuals that underwent LVB plus compression. The literature review by Leung et al. (2015) reported only on breast-cancer related lymphedema (BRCL) and similarly demonstrated an overall 26% mean volume reduction at one year of follow-up. Individual quality of life (QOL) with validated instruments has also been studied. Salgarello et al. (2018) exclusively assessed individual-reported outcomes (PROs) using a validated questionnaire, the LYMQOL, in individuals at multiple time points after LVB and demonstrated improved health-related QOL in individuals with both UE and LE lymphedema across all four LYMQOL domains and overall quality of life. Coriddi et al. (2020) reported on a systematic review of PROs following physiologic surgical treatment of lymphedema with all studies on LVB demonstrating an improvement in QOL. Earlier intervention (physiologic surgery on earlier stages of

lymphedema) has been demonstrated to have better outcomes. The systematic review by Gupta et al. (2021_ supports this as well as the prospective study by Chang et al. which demonstrated early stage lymphedema (MD I-II) had a 61% overall reduction compared to those with later-stage lymphedema (MD III-IV) who had a mean 17% reduction .Complications are reported across certain studies. Basta et al. reported an overall rate of infection of 3.9% and lymphorrea of 4.1%. Systemic reviews by Carl et al. (2017) and Cornelissen et al. (2018) reported rare and minor complications include two cases of skin irritation at contrast injection sites as well superficial wounds and skin separation in one case each.

Available literature analyzing VLNT includes 3 systematic reviews and meta-analyses, 5 systematic reviews and 1 randomized controlled trial (RCT) with some overlap in systematic reviews also reporting on other surgical techniques. There is a significant degree of heterogeneity in the techniques utilized given the multiple donor and recipient sites that can be used for VLNT. Chang et al. (2021) reported a reduction in circumference or volume as well as decreased infection frequency with VLNT and compression. All systematic reviews reporting on objective circumference/volume measurement reported reduction in these outcome parameters after VLNT including studies by Forte et al. (2019), Ozturk et a. (2016) and Leung et al. (2015). The systematic review by Coriddi et al. (2020) demonstrate improvement in QOL in all studies including a range of 84-100% in 3 studies utilizing validated instruments and 83-100% in 3 studies utilizing non-validated instruments. The largest study by Ozturk et al. (2016) (305 individuals) did not report any incidence of donor-site lymphedema and the study by Demiri et al. (2018) reported an incidence of donor-site lymphedema in 1.6% of individuals. In the RCT by Dionyssio et al. (2016), the authors compared 36 individuals with ISL stage II breast-cancer related upper extremity lymphedema that were randomized to either VLNT+therapy or therapy alone groups with assessments of outcomes after 18 months. The authors found a significantly decreased difference in volumes and infection rates in the VLNT group as well as significantly higher subjective quality of life scores in the VLNT group compared to the therapy alone group.

Available literature for liposuction as a reductive surgery in the treatment of lymphedema includes two systematic reviews and meta-analyses and one prospective cohort study. A pooled-analysis of studies by Chang et a. (2021) demonstrated that liposuction and controlled compression therapy (CCT) was significantly superior to CCT alone for reducing volume in individual with ISL stage II upper extremity lymphedema. Carl et al. (2017) reported on a systematic review and meta-analysis of 105 individuals undergoing liposuction for lymphedema and found a weighted excess volume reduction of 96.6%. Brorson et al. (2006) compared individuals undergoing liposuction and postoperative CCT to those receiving only CCT (control). Individuals who had liposuction in addition to compression had significantly greater volume reductions and scored better on all QOL and functional indices. Significantly decreased rates of infection have also been reported after liposuction in series by Lamprou et al. (2017) and Granzow et al. (2014). Additionally, long-term outcomes have also been demonstrated as Hoffner et al. (2018) reported stable and complete volume reduction with postoperative compression in 105 individuals in a 5-year prospective study. The same group demonstrated improved QOL to population norms in sixty individuals after liposuction and compression using a validated questionnaire, the short-form health survey (SF-36).

Available literature of immediate lymphatic reconstruction (ILR) includes a randomized controlled trial and a recent systematic review and meta-analysis. Boccardo et al. (2011) randomized 49 consecutive women undergoing axillary node dissection into immediate lymphatic reconstruction (LYMPHA group) and a control. Lymphedema developed in 4.3% of the treatment group and 30.4% of the control group. A recent systematic review from Johnson et al. (2019) of 3,035 individuals demonstrated a lymphedema rate of 15.6% in individual undergoing nodal dissection and 4.6% in those that underwent nodal dissection and ILR when individuals were not radiated. In cases of radiation, 26.5% of individuals developed lymphedema in the control group compared to 10.6% in those that had ILR.

Primary outcomes for the above surgical procedures include change in limb circumference and volume (compared to the contralateral extremity), symptom reduction, change in infection rate, individual-reported quality of life, and complications. The current available evidence in conjunction with expert opinion demonstrates improved clinical outcomes for individuals who are appropriately diagnosed with lymphatic disease and exhibit symptomatic lymphedema despite optimized conservative treatments.

References

1. Basta MN, Gao LL, Wu LC. Operative treatment of peripheral lymphedema: a systematic meta- analysis of the efficacy and safety of lymphovenous microsurgery and tissue transplantation. Plast Reconstr Surg. 2014;133:905–913.
2. Boccardo FM, Casabona F, Friedman D, et al. Surgical prevention of arm lymphedema after breast cancer treatment. Ann Surg Oncol. 2011;18(9):2500-5
3. Brorson H, Ohlin K, Olsson G, et al. Quality of life following liposuction and conservative treatment of arm lymphedema. Lymphology. 2006;39:8–25.
4. Carl H, Walia G, Bello R, et al. Systematic Review of the Surgical Treatment of Extremity Lymphedema. J Reconstr Microsurg. 2017;33:412-425.
5. Chang DW, Dayan J, Greene AK, et al. Surgical Treatment of Lymphedema: A Systematic Review and Meta-Analysis of Controlled Trials. Results of a Consensus Conference. Plast Reconstr Surg. Apr 01 2021; 147(4): 975-993. PMID 33761519
6. Chang DW, Suami H, Skoracki R. A prospective analysis of 100 consecutive lymphovenous bypass cases for treatment of extremity lymphedema. Plast Reconstr Surg. 2013;132(5):1305-14.
7. Coriddi M, Dayan J, Sobti N, et al. Systematic Review of Patient-Reported Outcomes following Surgical Treatment of Lymphedema. Cancers (Basel). Feb 29 2020; 12(3). PMID 32121343
8. Cornelissen AJM, Beugels J, Ewalds L, et al. Effect of Lymphaticovenous Anastomosis in Breast Cancer-Related Lymphedema: A Review of the Literature. Lymphat Res Biol. 2018;16:426-434.
9. Demiri E, Dionyssiou D, Tsimponis A, et al. Donor-Site Lymphedema Following Lymph Node Transfer for Breast Cancer-Related Lymphedema: A Systematic Review of the Literature. Lymphat Res Biol. Feb 2018; 16(1): 2-8. PMID 29087763
10. Dionyssiou D, Demiri E, Tsimponis A, et al. A randomized control study of treating secondary stage II breast cancer-related lymphoedema with free lymph node transfer. Breast Cancer Res Treat. Feb 2016; 156(1): 73-9. PMID 26895326
11. Forte AJ, Cinotto G, Boczar D, et al. Omental Lymph Node Transfer for Lymphedema Patients: A Systematic Review. Cureus. Nov 25 2019; 11(11): e6227. PMID 31807393
12. Granzow JW, Soderberg JM, Kaji AH, Dauphine C. An effec- tive system of surgical treatment of lymphedema. Ann Surg Oncol. 2014;21:1189–1194.
13. Gupta N, Verhey EM, Torres-Guzman RA, et al. Outcomes of Lymphovenous Anastomosis for Upper Extremity Lymphedema: A Systematic Review. Plast Reconstr Surg Glob Open. 2021;9(8):e3770.
14. Hoffner M, Bagheri S, Hansson E, Manjer J, Troëng T, Brorson H. SF-36 Shows Increased Quality of Life Following Complete Reduction of Postmastectomy Lymphedema with Liposuction. Lymphat Res Biol. 2017 Mar;15(1):87-98.
15. Hoffner M, Ohlin K, Svensson B, Manjer J, Hansson E, Troëng T, Brorson H. Liposuction Gives Complete Reduction of Arm Lymphedema following Breast Cancer Treatment-A 5-year Prospective Study in 105 Patients without Recurrence. Plast Reconstr Surg Glob Open. 2018 Aug 16;6(8):e1912
16. Johnson AR, Kimball S, Epstein S, et al. Lymphedema Incidence After Axillary Lymph Node Dissection: Quantifying the Impact of Radiation and the Lymphatic Microsurgical Preventive Healing Approach. Ann Plast Surg. 2019;82(4S Suppl 3):S234-S41.

17. Lamprou D -a. A, Voesten HGJ, Damstra RJ, et al. Circumferential suction-assisted lipectomy in the treatment of primary and secondary end-stage lymphoedema of the leg. Br J Surg. 2017;104:84–89.
18. Leung N, Furniss D, Giele H. Modern surgical management of breast cancer therapy related upper limb and breast lymphoedema. Maturitas. 2015;80:384-390.
19. Ozturk CN, Ozturk C, Glasgow M, et al. Free vascularized lymph node transfer for treatment of lymphedema: A systematic evidence based review. J Plast Reconstr Aesthet Surg. Sep 2016; 69(9): 1234-47. PMID 27425000
20. Salgarello M, Mangialardi ML, Pino V, et al. A Prospective Evaluation of Health-Related Quality of Life following Lymphaticovenular Anastomosis for Upper and Lower Extremities Lymphedema. J Reconstr Microsurg. 2018;34:701–707.

Documentation for Clinical Review

Please provide the following documentation:

- History and physical and/or consultation notes including:
  - Clinical findings (i.e., pertinent signs and symptoms and duration)
  - Comorbidities
  - Activity and functional limitations
  - Reason for procedure
  - Pertinent past procedural and surgical history
  - Past and present diagnostic testing and results
  - Prior conservative treatments, duration, and response
  - Treatment plan (i.e., surgical intervention)
- Consultation and medical clearance report(s), when applicable
- Prior conservative lymphedema treatments and duration
- Attestation of ability to tolerate post-surgical compression therapy and physical therapy sessions
- Applicable imaging or quantitative measurement reports (e.g., lymphoscintigraphy, volumetric analyses, ICG, etc.)
- Pertinent laboratory results
- Other pertinent multidisciplinary notes/reports: (i.e., psychological or psychiatric evaluation, physical therapy, multidisciplinary pain management, lymphedema provider), when applicable

Post Service (in addition to the above, please include the following):

- Results/reports of tests performed
- Procedure report(s)

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	15757	Free skin flap with microvascular anastomosis
	15758	Free fascial flap with microvascular anastomosis
	15833	Excision, excessive skin and subcutaneous tissue (includes lipectomy); leg
	15836	Excision, excessive skin and subcutaneous tissue (includes lipectomy); arm
	15878	Suction assisted lipectomy; upper extremity
	15879	Suction assisted lipectomy; lower extremity
	35206	Repair blood vessel, direct; upper extremity
	35226	Repair blood vessel, direct; lower extremity
	35236	Repair blood vessel with vein graft; upper extremity
	38790	Injection procedure; lymphangiography
	38999	Unlisted procedure, hemic or lymphatic system
	49329	Unlisted laparoscopy procedure, abdomen, peritoneum and omentum
	49906	Free omental flap with microvascular anastomosis
	69990	Microsurgical techniques, requiring use of operating microscope (List separately in addition to code for primary procedure)
HCPCS	None	

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
07/01/2023	New policy.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT	
BEFORE	**AFTER** Blue font: Verbiage Changes/Additions
New Policy **Policy Statement:** N/A	**Immediate and Delayed Lymphatic Reconstruction Surgery BSC7.18** **Policy Statement:** Immediate Lymphatic Reconstruction Surgery **Lymphovenous bypass** I. Lymphovenous bypass may be considered **MEDICALLY NECESSARY** when **BOTH** of the following criteria are met: A. Individual meets **BOTH** of the following lymphovenous bypass criteria: 1. Surgical plan is to undergo axillary lymph node dissection for breast cancer treatment at the time of initial cancer resection; **OR** a surgical plan for radial forearm flap harvesting for planned phalloplasty 2. Attestation that the individual has demonstrated the ability to tolerate post-surgical compression therapy and physical therapy sessions per the treating lymphedema provider. B. Individual has **NONE** of the following: 1. History of malignant skin cancer of the ipsilateral upper extremity 2. **Any** of the following uncontrolled comorbidities: a. Untreated upper extremity/chest venous disease (superior vena cava syndrome) b. Congestive heart failure (CHF) 3. Pregnancy 4. Active infection of the affected extremity (cellulitis/erysipelas). II. Lymphatico-lymphatic bypass is considered **investigational**. Delayed Lymphatic Reconstruction Surgery **Lymphovenous bypass** III. Lymphovenous bypass may be considered **MEDICALLY NECESSARY** when **ALL** of the following criteria are met: A. Individual meets **BOTH** of the following diagnostic criteria:

POLICY STATEMENT	
BEFORE	**AFTER** **Blue font: Verbiage Changes/Additions**
	1. At least one sign **AND** one symptom consistent with lymphedema **AND** a diagnosis of ≥ stage I lymphedema (International Society of Lymphology or ISL) a. Signs: pitting edema **OR** non-pitting edema; hardening and thickening of the skin (fibrosis); limited mobility from swelling b. Symptoms: heaviness, achiness, pain, tightness, numbness/tingling, not fitting into clothing or fatigue. 2. At **least one** of the following positive quantitative measurements for unilateral disease: a. Lymphoscintigraphy findings showing a minimum of a one-hour delayed transit time to first-level lymph nodes, axillary lymph nodes (upper extremity lymphedema) or inguinal lymph nodes (lower extremity lymphedema) **OR** dermal back flow b. Indocyanine green (ICG) imaging demonstrating obstruction of linear lymphatic channels, with reticular or stardust pattern c. Magnetic resonance imaging (MRI) lymphangiography demonstrating obstruction of lymphatic channels or dermal backflow B. Individual meets **ALL** of the following lymphovenous bypass eligibility criteria: 1. Individual has body mass index (BMI) ≤ 35 2. Individual has engaged and maintained compliance with conservative lymphedema treatment by a certified lymphedema therapist (CLT) for a minimum of 1 month including **BOTH** of the following: a. Compression therapy (bandaging/garment/gauntlet) b. **Any** of the following treatment modalities: i. Manual lymphatic drainage, complete decongestive therapy, use of a pneumatic compression pump ii. Targeted exercises for lymphedema treatment 3. Individual has demonstrated the ability to tolerate post-surgical compression therapy and physical therapy sessions per treating lymphedema provider.

POLICY STATEMENT	
BEFORE	**AFTER** **Blue font: Verbiage Changes/Additions**
	C. Individual has **NONE** of the following: 1. Transient lymphedema: any swelling that meets diagnostic threshold for lymphedema criteria and resolves naturally within six months after the last oncologic treatment 2. Untreated lipedema or lipedema without lymphatic dysfunction 3. **Any** of the following uncontrolled comorbidities: a. Untreated venous disease (DVT, superior vena cava or May-Thurner syndrome) b. Congestive heart failure (CHF) c. Medication-induced swelling d. Liver disease including but not limited to cirrhosis, hypoproteinemia e. Nephropathy including end-stage renal disease f. Uncontrolled hypothyroidism g. Venous insufficiency in the affected extremity 4. Pregnancy 5. Active infection of the affected extremity (cellulitis/erysipelas). IV. Lymphovenous bypass is considered **INVESTIGATIONAL** if above criteria are not met. **Vascularized Lymph Node Transplant** V. Vascularized lymph node transplant may be considered **MEDICALLY NECESSARY** when **ALL** of the following criteria are met: A. Individual meets **BOTH** of the following diagnostic criteria: 1. At least one sign **AND** one symptom consistent with lymphedema **AND** a diagnosis of ≥ stage I lymphedema (ISL) a. Signs: pitting edema **OR** non-pitting edema; hardening and thickening of the skin (fibrosis); limited mobility from swelling b. Symptoms: heaviness, achiness, pain, tightness, numbness/tingling, not fitting into clothing or fatigue.

POLICY STATEMENT	
BEFORE	**AFTER** **Blue font: Verbiage Changes/Additions**
	2. At **least one** of the following positive quantitative measurements: a. For unilateral disease, **any** of the following: i. Lymphoscintigraphy findings showing a minimum of a one-hour delayed transit time to first-level lymph nodes, axillary lymph nodes (upper extremity lymphedema) or inguinal lymph nodes (lower extremity lymphedema) **OR** dermal back flow ii. Indocyanine green (ICG) imaging demonstrating obstruction or absence of linear lymphatic channels, with reticular or stardust pattern iii. Magnetic resonance imaging (MRI) lymphangiography demonstrating obstruction of lymphatic channels or dermal backflow b. For bilateral disease, **any** of the following: i. Lymphoscintigraphy findings showing a minimum of a one-hour delayed transit time to first-level lymph nodes, axillary lymph nodes (upper extremity lymphedema) or inguinal lymph nodes (lower extremity lymphedema) **OR** dermal back flow ii. Indocyanine green (ICG) imaging demonstrating obstruction or absence of linear lymphatic channels, with reticular or stardust pattern B. Individual meets **ALL** of the following lymph node transplant eligibility criteria: 1. Individual has body mass index (BMI) ≤ 35 2. Individual has engaged and maintained compliance with conservative lymphedema treatment by a certified lymphedema therapist (CLT) for a minimum of 1 month including **BOTH** of the following: a. Compression therapy (bandaging/garment/gauntlet) b. **Any** of the following treatment modalities: i. Manual lymphatic drainage, complete decongestive therapy, use of a pneumatic compression pump ii. Targeted exercises for lymphedema treatment

POLICY STATEMENT	
BEFORE	**AFTER** **Blue font: Verbiage Changes/Additions**
	3. Individual has demonstrated the ability to tolerate post-surgical compression therapy and physical therapy sessions per treating lymphedema provider. C. Individual has **NONE** of the following: 1. Transient lymphedema: any swelling that meets diagnostic threshold for lymphedema criteria and resolves naturally within six months after the last oncologic treatment 2. Untreated lipedema and lipedema without lymphatic dysfunction 3. **Any** of the following uncontrolled comorbidities: a. Untreated venous disease (DVT, superior vena cava or May-Thurner syndrome) b. Congestive heart failure (CHF) c. Medication-induced swelling d. Liver disease including but not limited to cirrhosis, hypoproteinemia e. Nephropathy including end-stage renal disease f. Uncontrolled hypothyroidism g. Venous insufficiency in the affected extremity 4. Pregnancy 5. Active infection of the affected extremity (cellulitis/erysipelas). VI. Vascularized lymph node transplant is considered **INVESTIGATIONAL** if above criteria are not met. **Reductive Surgery** VII. Reductive surgery includes debulking of a limb with either liposuction or excisional techniques. Reductive surgery may be considered **MEDICALLY NECESSARY** when **ALL** of the following criteria are met: A. Individual meets **BOTH** of the following diagnostic criteria: 1. At least one sign **AND** one symptom consistent with lymphedema **AND** a diagnosis of ≥ stage II lymphedema (ISL)

POLICY STATEMENT	
BEFORE	**AFTER** **Blue font: Verbiage Changes/Additions**
	a. Signs: pitting **OR** non-pitting edema; hardening and thickening of the skin (fibrosis); limited mobility from swelling b. Symptoms: heaviness, achiness, pain, tightness, numbness/tingling, not fitting into clothing or fatigue. 2. At **least one** of the following positive quantitative measurements: a. For unilateral disease, **any** of the following: i. Lymphoscintigraphy findings showing a minimum of a one-hour delayed transit time to first-level lymph nodes, axillary lymph nodes (upper extremity lymphedema) or inguinal lymph nodes (lower extremity lymphedema) **OR** dermal back flow ii. Volumetry differential (circumferential truncated cone measurements and/or perometry differential) >10% (if affected extremity is the dominant extremity) or >7% if the affected extremity is non-dominant) iii. Indocyanine green (ICG) imaging demonstrating obstruction or absence of linear lymphatic channels, with reticular or stardust pattern iv. Magnetic resonance imaging (MRI) lymphangiography demonstrating obstruction of lymphatic channels or dermal backflow b. For bilateral disease, any of the following: i. Lymphoscintigraphy findings showing a minimum of a one-hour delayed transit time to first-level lymph nodes, axillary lymph nodes (upper extremity lymphedema) or inguinal lymph nodes (lower extremity lymphedema) **OR** dermal back flow ii. Indocyanine green (ICG) imaging demonstrating obstruction or absence of linear lymphatic channels, with reticular or stardust pattern B. Individual meets **ALL** of the reductive surgery eligibility criteria: 1. Individual has body mass index (BMI) ≤ 35

POLICY STATEMENT	
BEFORE	**AFTER** **Blue font: Verbiage Changes/Additions**
	2. Individual has clinical findings documented by treating lymphedema provider consistent with moderate to severe fat hypertrophy 3. Individual has engaged and maintained compliance with conservative lymphedema treatment by a certified lymphedema therapist (CLT) for a minimum of 1 month including **both** of the following: a. Lymphedema therapy includes compression therapy (bandaging/garment/gauntlet) b. **Any** of the following treatment modalities: i. manual lymphatic drainage, complete decongestive therapy, use of a pneumatic compression pump ii. targeted exercises for lymphedema treatment 4. Individual has demonstrated the ability to tolerate post-surgical compression therapy and physical therapy sessions per treating lymphedema provider. C. Individual has **NONE** of the following: 1. Transient lymphedema: any swelling that meets diagnostic threshold for lymphedema criteria and resolved naturally within six months after the last oncologic treatment 2. Untreated lipedema and lipedema without lymphatic dysfunction 3. **Any** of the following uncontrolled comorbidities: a. Untreated venous disease (DVT, superior vena cava or May-Thurner syndrome) b. Congestive heart failure (CHF) c. Medication-induced swelling d. Liver disease including but not limited to cirrhosis, hypoproteinemia e. Nephropathy including end-stage renal disease f. Uncontrolled hypothyroidism g. Venous insufficiency in the affected extremity 4. Pregnancy 5. Active infection of the affected extremity (cellulitis/erysipelas).

POLICY STATEMENT	
BEFORE	**AFTER** **Blue font: Verbiage Changes/Additions**
	VIII. Reductive surgery is considered **INVESTIGATIONAL** if above criteria are not met.