

| POLICY TITLE | SURGICAL TREATMENTS FOR BREAST CANCER RELATED LYMPHEDEMA | | |
|---------------|--|--|--|
| POLICY NUMBER | MP 1.161 | | |

| CLINICAL BENEFIT | ☐ MINIMIZE SAFETY RISK OR CONCERN. | | |
|------------------|--|--|--|
| | ☑ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. | | |
| | ☐ ASSURE APPROPRIATE LEVEL OF CARE. | | |
| | ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. | | |
| | ☐ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. | | |
| | ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE. | | |
| Effective Date: | 4/1/2025 | | |

POLICY PRODUCT VARIATIONS DESCRIPTION BACKGROUND

RATIONALE <u>DEFINITIONS</u> <u>BENEFIT VARIATIONS</u>

DISCLAIMER CODING INFORMATION REFERENCES

POLICY HISTORY

I. POLICY

Lymphatic physiologic microsurgery to treat lymphedema (including, but not limited to, lymphatico-lymphatic bypass, lymphovenous bypass, lymphaticovenous anastomosis, autologous lymph node transplantation, and vascularized lymph node transfer) in individuals who have been treated for breast cancer is considered **investigational**.

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 insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with these procedures.

Cross-reference:

MP 6.013 Compression Devices for Treatment of Lymphedema and Peripheral Disease

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI. Please see additional information below

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at:

https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-quidelines/medical-policies .



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III. DESCRIPTION/BACKGROUND

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LYMPHEDEMA

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).

Diagnosis and Staging

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 other causes of edema in diagnostically challenging cases.

Table 1 lists International Society of Lymphology guidance for staging lymphedema based on "softness" or "firmness" of the limb and the changes with an elevation of the limb.

Table 1. Recommendations for Staging Lymphedema

| Stage | Description | | |
|-----------------------|---|--|--|
| Stage 0 (subclinical) | Swelling is not evident, and most patients are asymptomatic | | |
| | despite impaired lymphatic transport | | |
| Stage I (mild) | Accumulation of fluid that subsides (usually within 24 hours) with | | |
| | limb elevation; soft edema that may pit, without evidence of dermal | | |
| | fibrosis | | |
| Stage II (moderate) | Does not resolve with limb elevation alone; limb may no longer pit | | |
| | on examination | | |
| Stage III (severe) | Lymphostatic elephantiasis; pitting can be absent; skin has trophic | | |
| | changes | | |

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 of lymphedema in patients with breast cancer.

In a systematic review of 72 studies (N=29,612 women), DiSipio et al (2013) reported that approximately 1 in 5 women who survive breast cancer will develop arm lymphedema. 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,



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mastectomy) and being overweight or obese. The incidence of breast cancer-related lymphedema was found by DiSipio et al as well as other authors to be up to 30% at 3 years after treatment.

Studies have also suggested that Black breast cancer survivors are nearly 2.2 times more likely to develop breast cancer-related lymphedema compared to White breast cancer survivors. These observations may be linked to racial disparities with regards to access to treatment and the types of treatments received. Black women are more likely than White women to undergo axillary lymph node dissection, which is associated with greater morbidity than the less invasive sentinel lymph node biopsy. While this may be explained in part by Black individuals having a higher likelihood of being diagnosed with more aggressive tumors, there is evidence that even when adjusting for stage and grade of tumors, Black women are more likely to undergo axillary lymph node dissection, putting Black women at greater risk of breast cancer-related lymphedema. Additionally, Black breast cancer survivors, on average, have higher body mass indexes than White breast cancer survivors, which could contribute to development of lymphedema in this setting as well.

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.

IV. RATIONALE TOP

For individuals who have breast cancer-related secondary lymphedema who receive physiologic microsurgery to treat lymphedema along with continued conservative therapy, the evidence includes a randomized controlled trial (RCT), observational studies, and systematic reviews. Relevant outcomes are symptoms, morbid events, functional outcomes, health status measures, quality of life, resource utilization, and treatment-related morbidity. Several physiologic microsurgeries have been developed; examples include lymphaticovenular anastomosis and vascularized lymph node transfer (VLNT). No RCTs of lymphaticovenular anastomosis or similar surgeries involving the venous system were identified. One RCT of VLNT with 36 participants has been conducted. Systematic reviews have indicated that the preponderance of the available evidence comes from single-arm clinical series from individual institutions. Surgical technique, outcomes metrics, and follow-up time have varied across these studies. These types of studies might be used for preliminary estimates of the amount of volume reduction expected from surgery,



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MEDICAL POLICY

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the durability of the reduction in volume, and the rates of adverse events. However, these studies are not adequate for determining the comparative efficacy of physiologic microsurgery versus conservative treatment or decongestive therapy, or the comparative efficacy of different microsurgery techniques. Randomized controlled trials are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are undergoing lymphadenectomy for breast cancer who receive physiologic microsurgery to prevent lymphedema, the evidence includes a RCT, observational studies, and systematic reviews. Relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. Lymphatic Microsurgical Preventing Healing Approach (LYMPHA) is a preventive lymphaticovenular anastomosis performed during nodal dissection. One RCT including 46 patients has been conducted. 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. However, because the cumulative incidence of lymphedema after breast cancer treatment approximates 30% at 3 years, longer follow-up is needed to assess the durability of the procedure. The trial methods of randomization and allocation concealment were not described and there was no blinding, potentially introducing bias. The remaining evidence consists of uncontrolled studies and systematic reviews of these studies. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

V. BENEFIT VARIATIONS

The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations are based on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VI. DISCLAIMER TOP

Capital Blue Cross' medical policies are developed to assist in administering a member's benefits. These medical policies do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.



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VII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement. The codes need to be in numerical order.

Considered investigational for lymphatic physiologic microsurgery and therefore not covered.

| Procedure Codes | | | | | | | |
|-----------------|--|--|--|--|--|--|--|
| 38999 | | | | | | | |

| ICD-10-CM Diagnosis Code | Description |
|-----------------------------|---|
| 189.0 | Lymphedema, not elsewhere classified |
| 189.1 | Lymphangitis |
| 189.8 | Other specified noninfective disorders of lymphatic vessels and lymph nodes |
| 189.9 | Noninfective disorder of lymphatic vessels and lymph nodes, unspecified |
| 197.2 | Post-mastectomy lymphedema syndrome |

VIII. REFERENCES TOP

- International Society of Lymphology Executive Committee. The Diagnosis and Treatment of Peripheral Lymphedema: 2016 Consensus Document of the International Society of Lymphology. 2016;
- 2. DiSipio T, Rye S, Newman B, et al. Incidence of unilateral arm lymphoedema after breast cancer: a systematic review and meta-analysis. Lancet Oncol. May 2013; 14(6): 500-15. PMID 23540561
- 3. Ribeiro Pereira ACP, Koifman RJ, Bergmann A. Incidence and risk factors of lymphedema after breast cancer treatment: 10 years of follow-up. Breast. Dec 2017; 36: 67-73. PMID 28992556
- 4. Zou L, Liu FH, Shen PP, et al. The incidence and risk factors of related lymphedema for breast cancer survivors post-operation: a 2-year follow-up prospective cohort study. Breast Cancer. May 2018; 25(3): 309-314. PMID 29397555
- 5. Dean LT, Kumar A, Kim T, et al. Race or Resource? BMI, Race, and Other Social Factors as Risk Factors for Interlimb Differences among Overweight Breast Cancer Survivors with Lymphedema. J Obes. 2016; 2016: 8241710. PMID 27433356
- 6. Pusic AL, Cemal Y, Albornoz C, et al. Quality of life among breast cancer patients with lymphedema: a systematic review of patient-reported outcome instruments and outcomes. J Cancer Surviv. Mar 2013; 7(1): 83-92. PMID 23212603

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- 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. Leung N, Furniss D, Giele H. Modern surgical management of breast cancer therapy related upper limb and breast lymphoedema. Maturitas. Apr 2015; 80(4): 384-90. PMID 25747119
- 9. 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. Oct 2018; 16(5): 426-434. PMID 29356596
- 10. Scaglioni MF, Fontein DBY, Arvanitakis M, et al. Systematic review of lymphovenous anastomosis (LVA) for the treatment of lymphedema. Microsurgery. Nov 2017; 37(8): 947-953. PMID 28972280
- 11. Carl HM, Walia G, Bello R, et al. Systematic Review of the Surgical Treatment of Extremity Lymphedema. J Reconstr Microsurg. Jul 2017; 33(6): 412-425. PMID 28235214
- 12. 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
- 13. 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. Nov 2018; 34(9): 701-707. PMID 29689576
- 14. 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
- 15. 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
- Li Y, Dong R, Li Z, et al. Intra-abdominal vascularized lymph node transfer for treatment of lymphedema: A systematic literature review and meta-analysis. Microsurgery. Nov 2021; 41(8): 802-815. PMID 34562039
- 17. 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
- 18. 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
- 19. Nguyen AT, Suami H, Hanasono MM, et al. Long-term outcomes of the minimally invasive free vascularized omental lymphatic flap for the treatment of lymphedema. J Surg Oncol. Jan 2017; 115(1): 84-89. PMID 27439587
- 20. Ciudad P, Agko M, Perez Coca JJ, et al. Comparison of long-term clinical outcomes among different vascularized lymph node transfers: 6-year experience of a single center's approach to the treatment of lymphedema. J Surg Oncol. Nov 2017; 116(6): 671-682. PMID 28695707
- 21. Gennaro P, Gabriele G, Salini C, et al. Our supramicrosurgical experience of lymphaticovenular anastomosis in lymphoedema patients to prevent cellulitis. Eur Rev Med Pharmacol Sci. Feb 2017; 21(4): 674-679. PMID 28272717

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- 22. Drobot A, Bez M, Abu Shakra I, et al. Microsurgery for management of primary and secondary lymphedema. J Vasc Surg Venous Lymphat Disord. Jan 2021; 9(1): 226-233.e1. PMID 32446874
- 23. Cemal Y, Pusic A, Mehrara BJ. Preventative measures for lymphedema: separating fact from fiction. J Am Coll Surg. Oct 2011; 213(4): 543-51. PMID 21802319
- 24. Armer JM. The problem of post-breast cancer lymphedema: impact and measurement issues. Cancer Invest. 2005; 23(1): 76-83. PMID 15779870
- 25. Armer JM, Stewart BR. A comparison of four diagnostic criteria for lymphedema in a postbreast cancer population. Lymphat Res Biol. 2005; 3(4): 208-17. PMID 16379589
- 26. Jørgensen MG, Toyserkani NM, Sørensen JA. The effect of prophylactic lymphovenous anastomosis and shunts for preventing cancer-related lymphedema: a systematic review and meta-analysis. Microsurgery. Jul 2018; 38(5): 576-585. PMID 28370317
- 27. Ciudad P, Escandón JM, Bustos VP, et al. Primary Prevention of Cancer-Related Lymphedema Using Preventive Lymphatic Surgery: Systematic Review and Meta-analysis. Indian J Plast Surg. Feb 2022; 55(1): 18-25. PMID 35444756
- 28. Boccardo FM, Casabona F, Friedman D, et al. Surgical prevention of arm lymphedema after breast cancer treatment. Ann Surg Oncol. Sep 2011; 18(9): 2500-5. PMID 21369739
- 29. Hahamoff M, Gupta N, Munoz D, et al. A Lymphedema Surveillance Program for Breast Cancer Patients Reveals the Promise of Surgical Prevention. J Surg Res. Dec 2019; 244: 604-611. PMID 29397949
- 30. McLaughlin SA, DeSnyder SM, Klimberg S, et al. Considerations for Clinicians in the Diagnosis, Prevention, and Treatment of Breast Cancer-Related Lymphedema, Recommendations from an Expert Panel: Part 2: Preventive and Therapeutic Options. Ann Surg Oncol. Oct 2017; 24(10): 2827-2835. PMID 28766218
- 31. Executive Committee of the International Society of Lymphology. The diagnosis and treatment of peripheral lymphedema: 2020 Consensus Document of the International Society of Lymphology. Lymphology. 2020; 53(1): 3-19. PMID 32521126
- 32. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Survivorship. Version 1.2023.
- 33. National Lymphedema Network Medical Advisory Comittee. The Diagnosis and Treatment of Lymphedema. Position Statement of the National Lymphedema Network 2011.
- 34. Blue Cross Blue Shield Association Medical Policy Reference Manual. 7.01.162. Surgical Treatments for Breast Cancer Related Lymphedema. September 2023.

| IX. POLICY HISTORY | <u>Top</u> |
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| MP 1.161 | 07/24/2024 Major Review. New policy adoption. |
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