

MEDICAL POLICY

POLICY TITLE	BIOIMPEDANCE DEVICES FOR DETECTION AND MANAGEMENT OF LYMPHEDEMA
POLICY NUMBER	MP 2.190

Effective Date:	5/1/2023
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[POLICY RATIONALE](#)
[DISCLAIMER](#)
[POLICY HISTORY](#)

[PRODUCT VARIATIONS](#)
[DEFINITIONS](#)
[CODING INFORMATION](#)

[DESCRIPTION/BACKGROUND](#)
[BENEFIT VARIATIONS](#)
[REFERENCES](#)

I. POLICY

Devices using bioimpedance (bioelectrical impedance spectroscopy) are considered **investigational** for use in the diagnosis, surveillance, or treatment of individuals with lymphedema, including use in subclinical secondary lymphedema. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

The National Comprehensive Cancer Network (NCCN) is a nonprofit alliance of cancer centers throughout the United States. NCCN develops the Clinical Practice Guidelines in Oncology which are recommendations aimed to help health care professionals diagnose, treat and manage patients with cancer. Guidelines evolve continuously as new treatments and diagnostics emerge and may be used by Capital Blue Cross when determining medical necessity according to this policy.

Cross-reference:

MP 6.013 Pneumatic Compression Devices for the Treatment of Lymphedema and Venous Insufficiency

POLICY GUIDELINES

National Comprehensive Cancer Network

In the most recent breast cancer guidelines, the NCCN addressed lymphedema directly. “Lymphedema is a potential side effect after the treatment of axillary lymph node surgery resulting from damage to the lymphatic system. Consider pretreatment measurement in both arms as a baseline for patient’s with risk factors for lymphedema.” They also address their Survivorship guidelines. These state “pretreatment limb measurement of both sides should be performed as a baseline for survivors with treatment related or individual-risk factors, preferably by a trained lymphedema specialist.”

National Lymphedema Network

“There is now a body of evidence emerging demonstrating that waiting to treat breast cancer-related lymphedema when it becomes visible and symptomatic may not be optimal. Just as with breast cancer itself, lymphedema can be detected at early, even a subclinical, latent stage amenable to treatment and that may reverse the progression to chronic, irreversible lymphedema.”

MEDICAL POLICY

POLICY TITLE	BIOIMPEDANCE DEVICES FOR DETECTION AND MANAGEMENT OF LYMPHEDEMA
POLICY NUMBER	MP 2.190

“All patients diagnosed with breast cancer have pre-treatment measurements on both arms. They may be given a record of this information that can be shared by them with treatment providers.”

II. PRODUCT VARIATIONS

[TOP](#)

This policy is only applicable to certain programs and products administered by Capital Blue Cross please see additional information below, and subject to benefit variations as discussed in Section VI 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-guidelines/medical-policies>.

III. DESCRIPTION/BACKGROUND

[TOP](#)

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). 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 et al (2013) reported that approximately 1 in 5 women who survive breast cancer will develop arm lymphedema. 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.

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 MRI, 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

MEDICAL POLICY

POLICY TITLE	BIOIMPEDANCE DEVICES FOR DETECTION AND MANAGEMENT OF LYMPHEDEMA
POLICY NUMBER	MP 2.190

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

Management and Treatment

Lymphedema is treated using elevation, compression, and exercise. 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.

Bioimpedance Spectroscopy

Bioimpedance spectroscopy is based on the theory that the level of opposition to flow of electric current (impedance) through the body is inversely proportional to the volume of fluid in the tissue. In lymphedema, with the accumulation of excess interstitial fluid, tissue impedance decreases.

Bioimpedance has been proposed as a diagnostic test for this condition. In usual care, lymphedema is recognized clinically or via limb measurements. However, management via bioelectrical impedance spectroscopy has been proposed as a way to implement early treatment of subclinical lymphedema to potentially reduce its severity.

Regulatory Status

Devices that have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process to aid in the assessment of lymphedema are summarized in Table 1.

Table 1. FDA Cleared Bioimpedance Spectroscopy Devices for Lymphedema

Year	Device:	510(k) number	Manufacturer	Indication

MEDICAL POLICY

POLICY TITLE	BIOIMPEDANCE DEVICES FOR DETECTION AND MANAGEMENT OF LYMPHEDEMA
POLICY NUMBER	MP 2.190

2018	SOZO	K180126	ImpediMed (Carlsbad, CA)	For adults at risk of lymphedema. Supports the measurement of extracellular fluid volume differences between the limbs and is presented to the clinician on an L-Dex scale as an aid to their clinical assessment of lymphedema. The device is only indicated for patients who will have or who have had lymph nodes, from the axillary and/or pelvic regions, either removed, damaged, or irradiated.
2015	Moisture-MeterD	K143310	Delfin Technologies (Stamford, CT)	Supports local assessment of tissue water differences between affected and contralateral non-affected arm tissues to aid in forming a clinical judgment of unilateral lymphedema in women. The device is not intended to make diagnosis or predict arm lymphedema.
2007	ImpediMed L-Dex™ U400	K050415	ImpediMed (Carlsbad, CA)	Supports the measurement of extracellular fluid volume differences between the arms to aid in the clinical assessment of unilateral lymphedema of the arm in women. This device is not intended to diagnose or predict lymphedema of an extremity.

FDA product code: OBH.

IV. RATIONALE

[TOP](#)

Summary of Evidence

For individuals who have known or suspected lymphedema who receive bioimpedance spectroscopy, the evidence includes a systematic review, one RCT, one prospective comparative observational study, and multiple uncontrolled observational studies. The relevant outcomes are test validity, symptoms, and quality of life. Diagnostic accuracy studies have found a poor correlation between bioimpedance analysis and the reference standard (volume displacement or circumferential measurement). Interim results from an ongoing RCT comparing bioimpedance with standard tape measure following treatment for breast cancer have been published. Overall, 109 of 508 (21.5%) patients received early treatment due to reaching a pre-determined threshold to trigger an intervention. A total of 12 triggering patients progressed to clinical lymphedema (2 in the bioimpedance group [4.9%] and 10 in the tape measure group [14.7%]; P=0.130). The RCT was limited by its open-label design and lack of reporting of important health outcomes. The single prospective comparative study found a significantly lower rate of clinical lymphedema in patients managed with bioimpedance devices but had several limitations, including nonrandomized design, lack of blinding, lack of complete data on a substantial proportion of enrolled patients, and lack of a systematic method for diagnosing lymphedema in the control group. Retrospective studies suggested that postoperative

MEDICAL POLICY

POLICY TITLE	BIOIMPEDANCE DEVICES FOR DETECTION AND MANAGEMENT OF LYMPHEDEMA
POLICY NUMBER	MP 2.190

bioimpedance monitoring is feasible but provide limited information about its efficacy. As more studies emerge, there may be stronger evidence to suggest the benefits of this technology. However, there is currently insufficient to determine the effects of the technology on health outcomes.

V. DEFINITIONS

[TOP](#)

NA

VI. BENEFIT VARIATIONS

[TOP](#)

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 should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

[TOP](#)

Capital Blue Cross's medical policies are developed to assist in administering a member's benefits, 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.

VIII. CODING INFORMATION

[TOP](#)

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.

Investigational:

Procedure Codes							
93702							

MEDICAL POLICY

POLICY TITLE	BIOIMPEDANCE DEVICES FOR DETECTION AND MANAGEMENT OF LYMPHEDEMA
POLICY NUMBER	MP 2.190

IX. REFERENCES

[TOP](#)

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MEDICAL POLICY

POLICY TITLE	BIOIMPEDANCE DEVICES FOR DETECTION AND MANAGEMENT OF LYMPHEDEMA
POLICY NUMBER	MP 2.190

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MEDICAL POLICY

POLICY TITLE	BIOIMPEDANCE DEVICES FOR DETECTION AND MANAGEMENT OF LYMPHEDEMA
POLICY NUMBER	MP 2.190

X. POLICY HISTORY

[TOP](#)

MP 2.190	CAC 7/21/15 New policy. New investigational policy statement added indicating devices using bioimpedance (bioelectrical impedance spectroscopy) are considered investigational for use in the diagnosis, surveillance, or treatment of patients with lymphedema, including use in subclinical secondary lymphedema. Coding added.
	CAC 7/26/2016 Consensus Review. No changes to the policy statements. References and rationale updated. Coding reviewed.
	Administrative Update 11/23/16 Variations reformatted
	CAC 9/26/17 Consensus review. Policy statement unchanged. Description/Background, Rationale, and Reference sections updated. Coding reviewed.
	6/5/18 Consensus review. No change to policy statements. References updated. Rationale condensed to include summary only.
	4/15/19 Consensus review. No change to policy statements.
	4/16/20 Consensus review. No change to policy statement. References added. Description/Background and Rationale sections updated. FEP policy removed. Coding reviewed.
	2/18/21 Consensus review. Policy statement unchanged. References updated.
	2/3/22 Consensus review. Policy statement unchanged. References updated.
	02/07/23 Consensus review. Policy statement unchanged. NCCN statement added. Added policy guidelines. Literature review and updated references.

[Top](#)

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