# MEDICAL POLICY

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| **Medical Policy Title** | **Bioimpedance Devices for Detection and Management of Lymphedema** |
| **Policy Number** | **2.01.52** |
| **Current Effective Date** | May 22, 2025 |
| **Next Review Date** | May 2026 |

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

## POLICY STATEMENT(S)

Bioimpedance devices (bioelectrical impedance spectroscopy), is considered **investigational** for use in the diagnosis, surveillance, or treatment of patients with lymphedema, including use in subclinical secondary lymphedema.

## RELATED POLICIES

Corporate Medical Policy

11.01.03 Experimental or Investigational Services

## POLICY GUIDELINE(S)

Not Applicable

## DESCRIPTION

Lymphedema is the abnormal accumulation of lymph fluid in the subcutaneous tissues of an affected body part due to an obstruction of the lymphatic flow. Primary lymphedema is present at birth, while secondary lymphedema is a disorder of lymphatic flow that is caused by some other disease or condition. Secondary lymphedema is more common than primary lymphedema. Secondary lymphedema is most commonly caused by surgery, especially lymph node dissection for breast cancer, radiation therapy (axillary, supraclavicular, cervical, or inguinal lymph node system), trauma, lymphatic obstruction by a tumor, or lymphatic filariasis. Secondary lymphedema may also result from compression of the lymphatic and venous channels, resulting from leakage of fluid into interstitial tissues in patients with chronic venous insufficiency. In the United States, breast cancer treatment is the most common cause of lymphedema.

Lymphedema is diagnosed based upon a patient's history and physical examination, which is staged by observing the patient's physical condition. One challenge, especially in women with breast cancer after surgery, is identifying the presence of clinically significant limb swelling through simple noninvasive methods. Volume displacement is considered the "gold standard" for lymphedema diagnosis. Measurements obtained by volume displacement have been shown to be reproducible, with an error rate of less than 1%. Arm volume measurements with water displacement are performed by comparing the volume of water displaced between the affected and unaffected limb, then reported as an interlimb volume difference. Another widely accepted measure of lymphedema is

limb circumference compared with that of the unaffected limb or compared with that of the same limb before the interventions or events that led to lymphedema. Patient education regarding the signs and symptoms of developing lymphedema, as well as early identification and treatment of lymphedema, when it is reversible, is believed to yield better patient outcomes.

One approach suggested for the management of lymphedema is treatment of subclinical (Stage 0) disease. Subclinical lymphedema occurs when there are early changes within the tissues without obvious noticeable swelling or symptoms. Subclinical lymphedema may exist for months or years before overt edema is noted and detection of lymphedema at this stage is difficult. Bioimpedance Spectroscopy (BIS) has been proposed as a diagnostic test for detection of subclinical lymphedema.

Bioimpedance involves applying a very mild electrical current to the body. To detect lymphedema in the upper extremity, the current is applied to the arm. As the current travels through the arm there is resistance. The level of impedance or resistance of a patient's arm to the current can be measured and converted into clinically useful measurements. If an increase in extracellular fluid in the arm (lymphedema) is present, the bioimpedance measurement will increase. Measurement of the extracellular fluid in the patient's upper limb over time allows for tracking fluid changes in the arm and assessing for early signs of lymphedema. Bioimpedance measurements are taken prior to surgery and then at regular follow-up intervals post-surgery. Patients are instructed to avoid caffeine, exercise two hours prior to the measurement being taken, and to avoid alcohol for at least 12 hours prior to the measurement being taken.

## SUPPORTIVE LITERATURE

Ridner et al. (2019 and 2022) conducted a multicenter, international, randomized controlled trial (RCT) [PREVENT RCT] comparing bioimpedance (n=263 at interim, 482 at final) to volume measurements calculated from arm circumference using a tape measure (n=245 at interim, 481 at final). The primary aim of the study was to determine if subclinical detection of extracellular fluid accumulation via BIS and subsequent early intervention reduces the rate of progression to clinical lymphedema relative to the rates seen using standard tape measurements. Included participants were women over 18 years of age with newly diagnosed breast cancer who received surgical treatment including one or more of the following: mastectomy, axillary treatment, regional node irradiation, or taxane-based chemotherapy. Patients requiring early intervention were prescribed a compression sleeve and gauntlet for 4 weeks and then re-evaluated. Predetermined thresholds were used to trigger early intervention. The implementation threshold for patients in the bioimpedance group was initially a change that was ≥10 L-Dex units (3 standard deviations) higher than the presurgical baseline measure, but the protocol was changed in 2016 to include all patients with ≥6 L-Dex units. Patients in the tape measure group triggered when they had a volume change in the at-risk arm that was between >5 and <10% above the presurgical baselines. Progression to clinical lymphedema was defined as a 10% or greater increase in tape measure volume from baseline in the at-risk arm.

At interim analysis, 109 of 508 (21.9%) patients received early intervention due to reaching the pre-determined threshold. Patients randomized to bioimpedance had a lower rate of trigger and longer times to trigger. A total of 12 triggering patients progressed to clinical lymphedema (10 in the tape

measure group [14.7%] and 2 in the BIS group [4.9%]). The difference between groups was not statistically significant (p=.130) and did not meet stopping criteria specified in the study protocol. At final analysis (median of 32.9 months follow-up), BIS triggered an intervention at a lower rate than TM patients (20.1% vs 27.5%; p=.011); however, fewer patients in the BIS group progressed compared with tape measure (7.9% vs 19.2%; relative risk, 0.41; 95% CI, 2.8-4.5; p=.001).

This study had several limitations, including an open-label design, which may have introduced bias in outcome assessment, treatments, or the decision to trigger an intervention. Important health outcomes such as patient-reported symptoms, quality of life (QOL), and function were not assessed. Additionally, 39 patients who progressed prior to an intervention being triggered were excluded from the analysis.

Multiple uncontrolled observational studies have reported rates of lymphedema identified through surveillance with bioimpedance in women at high-risk following breast cancer treatment (Laidley A 2016, Koelmeyer LA 2019, Kilgore LJ 2018, Whitworth PW 2018a, Erdogan Iyigun Z 2015, Shah C 2013, Lim SM 2019, Kaufman DI 2017, Whitworth PW 2018b, Jeffers EJ 2023). Because these studies did not include a comparison group of women who received usual care or alternative methods of screening, they do not provide evidence to draw conclusions about the clinical utility of bioimpedance.

Results of available studies do not provide consistent evidence that bioimpedance is any more reliable than current methods for detection of lymphedema. In addition, there is a lack of clinical studies demonstrating that incorporation of bioimpedance into lymphedema management improves clinical outcomes. Long-term studies demonstrating the effectiveness of bioimpedance testing over conventional monitoring techniques for lymphedema are needed.

## PROFESSIONAL GUIDELINE(S)

The National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology: Breast Cancer (V3.2025) state that lymphedema is a potential side effect after the treatment of axillary lymph node surgery resulting from damage to the lymphatic system. Factors associated with increased risk of lymphedema include extent of axillary surgery, axillary radiation, infection, and patient obesity. The panel recommends educating patients on lymphedema, monitoring for lymphedema, and referring for lymphedema management as needed. The NCCN Clinical Practice Guidelines on Survivorship (V2.2024) recommend that survivors at risk for lymphedema should be regularly screened for lymphedema by symptom assessment, clinical exam, and, if available, bioimpedance spectroscopy. Early detection/diagnosis of lymphedema is key for optimal management because stages 0 and 1 are reversible, while stages 2 and 3 are less responsive to treatment.

The Agency for Healthcare Research and Quality (AHRQ) published a technology assessment for the diagnosis and treatment of secondary lymphedema (Oremus 2010). The AHRQ assessment identified 8 studies that reported the sensitivity and specificity of tests to diagnose secondary lymphedema. Two of the 8 selected studies evaluated BIS devices. They state there is consistent evidence to indicate that lymphedema can be reliably measured using circumferential measures or volume displacement. There is too little evidence to draw conclusion about the reliability of other tests such as tonometry, ultrasound, lymphoscintigraphy, or bioimpedance.

## REGULATORY STATUS

A selection of devices has 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. Among the FDA-approved bioimpedance devices are SOZO (ImpediMed), MoistureMeterD (Delfin Technologies), and the L-Dex U400 (ImpediMed). The L-Dex U400 was discontinued by its manufacturer in November 2018.

## CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

### CPT Codes

| Code | Description |
|---|---|
| 93702 (E/I) | Bioimpedance spectroscopy (BIS), extracellular fluid analysis for lymphedema assessment(s) |



### HCPCS Codes

| Code | Description |
|---|---|
| | No specific code(s) |

### ICD10 Codes

| Code | Description |
|---|---|
| I89.0 - I89.9 | Other noninfective disorders of lymphatic vessels and lymph nodes (code range) |
| I97.2 | Postmastectomy lymphedema syndrome |

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## SEARCH TERMS

Bioimpedance, bioelectrical impedance spectroscopy

## CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Based on our review, bioimpedance devices for the detection and management of lymphedema is not addressed in National or Regional Medicare coverage determinations or policies.

## PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.
- If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

## POLICY HISTORY/REVISION

| Committee Approval Dates |
|---|
| 08/17/17, 05/17/18, 05/16/19, 05/21/20, 05/20/21, 05/19/22, 05/18/23, 05/16/24, 05/22/25 |

| Date | Summary of Changes |
|---|---|
| 05/22/25 | • Annual review, policy intent unchanged. |
| 01/01/25 | • Summary of changes tracking implemented. |
| 08/17/17 | • Original effective date |