# VHA Office of Integrated Veteran Care
# Clinical Determination and Indication
# Bioimpedance Devices for Detection of Lymphedema

**CDI Number: 00019**

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## I. Disclaimer

This document is currently in draft and is intended to be used as a reference for non-VA providers and not intended to replace clinical judgment when determining care pathways. These guidelines do not guarantee benefits or constitute medical advice.

## II. Clinical Determinations and Indications

### a. Indications for Bioimpedance Devices for Detection of Lymphedema

Bioimpedance devices for the detection or surveillance of lymphedema are considered investigational and experimental. There is insufficient evidence from peer-reviewed medical literature to support the safety and efficacy of this treatment. Therefore, bioimpedance devices for the detection or surveillance of lymphedema are considered not medically necessary.

## III. Background and Supporting Information

The following information is for reference purposes only in accordance with the medical benefits package outlined in 38 C.F.R. § 17.38 (b). Each subsection supports VA's determination for medical necessity and alignment with generally accepted standards of medical practice.

### a. Background Information

#### Lymphedema

The lymphatic system is part of the immune system, but complementary to the circulatory system. It is an extensive network of vessels that carry fluid throughout the body. Lymphedema is defined as tissue swelling caused by a pooling of fluid that is normally drained through the body's lymphatic system. It is a chronic condition that is most often seen in the arms or legs, but can also occur in the chest wall, abdomen, neck, and genitals. The swelling is a result of disruption to the lymphatic system (e.g., blockage) likely due to some dysfunction (e.g., lymph node was removed).

There are two types of lymphedema. Primary lymphedema is caused by congenital or inherited abnormalities in the lymphatic system. Secondary

lymphedema is a result of damage to the lymphatic system and is the most common type of lymphedema. Damage to the lymphatic system can occur from surgery, cancer treatment such as radiation therapy, or the removal of lymph nodes. Lymph nodes are an important part of the lymphatic system, responsible for filtering the lymph fluid, which is a clear liquid that carries waste, toxins, and immune cells from the body's tissues.

### Diagnosing and Staging Lymphedema

Secondary lymphedema is diagnosed through a review of patient history and physical examination. For example, history of procedures that may have damaged or resulted in the removal of lymph nodes with current signs and symptoms of limb swelling. Magnetic Resonance Imaging (MRI), Computed Tomography (CT), ultrasound, or lymphography may be necessary to diagnose lymphedema, if the cause of lymphedema is not obvious. If secondary causes are ruled out, it will be diagnosed as primary lymphedema.

Lymphedema is staged based on its characteristics. The stages according to the International Society of Lymphology are:

- **Stage 0 (subclinical)**: No signs or symptoms, despite impaired lymphatic transport
- **Stage I (mild)**: Accumulation of fluid with swelling. Swelling resolves with limb elevation. Soft edema that may leave a dent when pressed upon
- **Stage II (moderate)**: Permanent swelling that does not resolve with elevation. Pressing on the area no longer leaves a dent. Changes in the skin with scarring and thickening
- **Stage III (severe)**: Elephantiasis (large, deformed limb), skin thickening with "wart-like" growth and extensive scarring

Bioimpedance devices are noninvasive technology used to diagnosis lymphedema. The device measures the patient's total body water volume by using resistance to electrical current. Bioimpedance measurements are taken by sending a painless electrical current through the body and measuring the body's resistance and reactance to the electrical current. These measurements are then used to compare the composition of fluids within the patient's interstitial tissue in areas of upper or lower extremity swelling. Bioimpedance devices can be used to diagnose lymphedema and track patient progress with treatments over time.

Treatment for lymphedema depends on the severity and extent of the condition. Prevention and controlling lymphedema are the primary goals for lymphedema management since there is no cure.

### b. Research, Clinical Trials, and Evidence Summaries

Bioimpedance devices or bioelectrical spectroscopy (BIS) have not been proven to be more effective than conservative measures for the detection of lymphedema. Bioimpedance devices have been found to be accurate as a diagnostic tool for pre-existing lymphedema, however they have not been validated for early detection of lymphedema. The National Comprehensive Cancer Network (NCCN) guidelines on breast cancer recommend patient education on lymphedema and monitoring for the condition, however, the use of BIS is not specifically mentioned.

Shah et al. (2023) conducted a literature review to compare the effectiveness of BIS to tape measurement assessment for the assessment of breast cancer related lymphedema (BCRL). A randomized trial called the PREVENT trial compared BCRL evaluation with BIS to evaluation with a tape measure. Early intervention was triggered by either evaluation method. Results demonstrated that surveillance with BIS coupled with early intervention was associated with an 11.3% absolute reduction in complex decongestive physiotherapy (CDP) or chronic BCRL. Authors concluded that based on the randomized nature, size of the study, and long-term follow-up, the PREVENT trial provides level I evidence to support prospective surveillance with BIS in conjunction with early intervention to reduce chronic BCRL.

Qin et al. (2018) conducted a single-center, retrospective case series study to test the sensitivity, specificity, and diagnostic accuracy of BIS in diagnosing lymphedema. In this study, 58 participants had positive lymphography results, which is considered the most accurate diagnostic modality for diagnosing lymphedema. When tested using BIS, 21 of the 58 participants had normal BIS readings, which represented a 36% false positive rate. The 21 participants with false-negative results were patients with early-stage disease. Authors concluded that BIS carries an excessively high rate of false-negative results to be reliably used as a diagnostic modality for lymphedema.

Fu et al. (2013) conducted a study to examine the reliability, sensitivity, and specificity of cross-sectional assessment of bioelectrical impedance analysis (BIA) in detecting lymphedema. The study examined the relationship between BIA and sequential circumferential tape measurement using the most accepted definition of lymphedema as a 200-mL difference in limb volume when comparing the affected and unaffected limb. The study included 250 adult females, with different representations of lymphedema, including three study groups: 60 healthy female adults, 42 breast cancer survivors who had been previously diagnosed with lymphedema, and 148 breast cancer survivors who were at risk for lymphedema. The BIA using Lymphedema Index Score (L-Dex) ratio measurements was observed to increase with elevated body mass index (BMI) values indicating additional research is

necessary to better clarify the relationship between BMI and L-Dex ratio by BIA. Results showed a significant correlation between BIA and interlimb volume ratio by sequential circumferential tape measurements. This finding indicates that both objective measures of interlimb volume difference and lymph fluid change by BIA can be used to detect lymphedema objectively in clinical practice.

Spitz et al. (2019) conducted a study to evaluate the accuracy of BIS measurements using the L-Dex compared to circumference measurements for the diagnosis of breast cancer-related lymphedema. A retrospective review of a prospectively maintained database was performed of patients who had surgical treatment for breast cancer. Eligible patients included those who had preoperative and postoperative evaluations for potential lymphedema by limb circumference measurements and bioimpedance. The ability of bioimpedance to diagnose lymphedema based on the manufacturer's criteria proved low sensitivity, equal to 7.5% when lymphedema was defined as an absolute L-Dex value greater than 10, and 24.6% when defined as a relative change of >10 between preoperative and postoperative measurements. Based on the results of the study, the authors concluded it is not recommended to use bioimpedance as a screening tool or for measurement of breast cancer-related lymphedema.

Kilgore et al. (2018) sought to determine if baseline measurement with BIS and postoperative assessments provide early detection amenable to conventional interventions that reduce BCRL. Early detection with patient-directed interventions improved patient outcomes and decreased the risk of persistent BCRL. The study included 146 patients who were high-risk for BCRL. Patients received preoperative baseline measurements with BIS followed by postoperative measurements with at least two follow-up visits. Results demonstrated that early conservative intervention for patients at high risk for BCRL, who were prospectively monitored by using bioimpedance spectroscopy, significantly lowers rates of BCRL. The findings support early prospective screening and intervention for BCRL.

### c. Medicare Coverage Determinations

There are no available Medicare coverage determinations for bioimpedance devices for the detection of lymphedema. VA and Medicare are governed by separate laws and regulations; thus, VA coverage determinations may be different.

## IV. Definitions

| Term | Definition |
|---|---|
| Bioimpedance | A technique that measures how electrical signals move through the body's tissues, often used to detect fluid buildup |
| Extracellular | In the space surrounding a cell or collection of cells |
| Intercellular | Between or among cells |
| Lymphedema Index Score | Measurement system that is used to measure both arms (or legs) to see if one arm (or leg) is collecting excess fluid |
| Lymphatic System | A network of vessels, nodes, and ducts that pass through most bodily tissues allowing circulation of a fluid called lymph |
| Lymphedem | Accumulation of lymphatic fluid in the interstitial tissues of the body, usually due to a blockage of the lymph vessels |
| Lymphography | Imaging test that captures pictures of the lymphatic system |
| Neoadjuvant Chemotherapy | Chemotherapy given to breast cancer patients before surgery with the goal of reducing tumor size and improving overall survival by treating undetected micro metastasis |
| Perometer | Infrared instrument designed to measure the volume of human extremities or, if desired, the whole trunk |
| Perometry | A noninvasive technique involving a Perometer, which uses infrared light to scan a limb and obtain measurements of the limb's circumference |

## V. References

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## VI. CDI History/Revision Information

- Explanation of changes to the CDI

| Revision Type | Date of Revision | Update(s) Made to CDI |
|---|---|---|
| | MM/DD/YYYY | |
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