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Bioimpedance Devices for Detection and Management of Lymphedema

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None

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Coverage

Bioimpedance spectroscopy **may be considered medically necessary** to confirm a diagnosis of lymphedema in the following clinical scenario:

- The individual is asymptomatic with history of surgery, radiotherapy, or trauma impacting the lymphatic system, and testing would guide decisions regarding early intervention (e.g., physical therapy, complete decongestive therapy).

Bioimpedance spectroscopy **may be considered medically necessary** for surveillance of lymphedema in the following clinical scenarios:

- The individual is asymptomatic with history of surgery, radiotherapy, or trauma impacting the lymphatic system, and testing would guide decisions regarding early intervention (e.g., physical therapy, complete decongestive therapy); OR
- The individual remains symptomatic following a course of conservative therapy for lymphedema, and testing would guide decisions regarding escalation of therapy (e.g., liposuction, surgery) (see Policy Guidelines).

Bioimpedance spectroscopy **is considered experimental, investigational and/or unproven** outside of the aforementioned clinical scenarios.

Policy Guidelines

For individuals with clinically diagnosed and/or symptomatic lymphedema, bioimpedance spectroscopy provides limited incremental utility for the optimization of decongestive therapy - but may confirm maximal expected benefit from conservative therapies and thus inform decisions concerning treatment escalation.

An optimal surveillance frequency in individuals at high-risk for the development of secondary lymphedema has not been established. Lymphedema experts generally recommend assessments every 3-6 months for a minimum of 3 years after cancer treatment on the basis of the PREVENT randomized controlled trial.

Description

Secondary lymphedema may develop following treatment for breast cancer. Bioimpedance, which uses resistance to electrical current to compare the composition of fluid compartments, could be used as a tool to diagnose lymphedema.

Background

Lymphedema

Lymphedema is an accumulation of fluid due to disruption of lymphatic drainage. It is characterized by nonpitting swelling of an extremity or trunk, and is associated with wound healing impairment, recurrent skin infections, and decreased quality of life. 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 (surgical removal of lymph nodes and radiotherapy) is one of the most common causes of secondary lymphedema. In a systematic review of 72 studies (N=29,612 women), DiSipio et al. (2013) reported that nearly 20% of breast cancer survivors will develop arm lymphedema. (1) The risk factors with robust evidence for the development of lymphedema included extensive surgical procedures (such as axillary lymph node dissection, a higher number of lymph nodes removed, and mastectomy) as well as 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 (2023) based on "softness" or "firmness" of the limb and the changes with an elevation of the limb. (2)

Table 1. Recommendations for Staging Lymphedema

Stage	Description
Stage 0 (latent or subclinical)	Swelling is not evident despite impaired lymph transport, subtle alterations in tissue fluid/composition, and changes in subjective symptoms. It can be transitory and may exist months or years before overt edema occurs (Stages I-lll).
Stage 1 (mild)	Early accumulation of fluid relatively high in protein content (e.g., in comparison with "venous" edema) which subsides with limb elevation. Pitting may occur. An increase in various types of proliferating cells may also be seen.
Stage II (moderate)	Involves the permanent accumulation of pathologic solids such as fat and proteins and limb elevation alone rarely reduces tissue swelling, and pitting is manifest. Later in this stage, the limb may not pit as excess subcutaneous fat and fibrosis develop.
Stage III (severe)	Encompasses lymphostatic elephantiasis where pitting can be absent and trophic skin changes such as acanthosis, alterations in skin character and thickness, further deposition of fat and fibrosis, and warty overgrowths have developed. It should be noted that a limb may exhibit more than one stage, which may reflect alterations in different lymphatic territories.

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. Individuals 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 affected individuals 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 individuals who have difficulty performing self-manual lymphatic drainage. In individuals 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 the 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

A selection of 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 2. 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.

Table 2. FDA Cleared Bioimpedance Spectroscopy Devices for Lymphedema

Year	Device	Manufacturer	510(k) Number	Indication
2018	SOZO	ImpediMed (Carlsbad, CA)	K180126	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	MoistureMeterD	Delfin Technologies (Stamford, CT)	K143310	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.

FDA: U.S. Food and Drug Administration.

FDA product code: OBH.

Rationale

Medical policies assess whether a medical test is clinically useful. A useful test provides information to make a clinical management decision that improves the net health outcome. That is, the balance of benefits and harms is better when the test is used to manage the condition than when another test or no test is used to manage the condition.

The first step in assessing a medical test is to formulate the clinical context and purpose of the test. The test must be technically reliable, clinically valid, and clinically useful for that purpose. Medical policies assess the evidence on whether a test is clinically valid and clinically useful. Technical reliability is outside the scope of these policies, and credible information on technical reliability is available from other sources.

Bioimpedance Spectroscopy in Individuals with Known or Suspected Lymphedema

Clinical Context and Test Purpose

The purpose of using bioimpedance spectroscopy (BIS) in individuals who have known, or suspected lymphedema, is to inform a diagnosis of subclinical lymphedema to initiate treatment sooner than with other diagnostic methods.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals with known or suspected lymphedema.

Interventions

The relevant intervention of interest is BIS.

Management via BIS has been proposed as a way to implement early treatment of subclinical lymphedema to potentially reduce its severity.

Comparators

The relevant comparators of interest are volume displacement and circumferential measurement.

In usual care, lymphedema is recognized clinically or via limb measurements.

Volume is measured using different methods; e.g., tape measurements with geometry formulas, perometry, and water displacement.

Outcomes

Objective outcomes of interest include a reduction in limb circumference and/or volume and reduction in the rates of infections (e.g., cellulitis, lymphangitis).

Patient-reported outcomes (PROs) of interest include symptoms, quality of life (QOL), and functional measures. A systematic review of PRO instruments and outcomes used to assess QOL

in breast cancer patients with lymphedema, Pusic et al. (2013) found that most studies included generic PRO instruments or oncology PRO instruments. (3) Lymphedema-specific instruments are occasionally used; specifically, the Upper Limb Lymphedema 27 was found to have strong psychometric properties.

There does not appear to be a consensus on minimally clinically important change for either objective outcomes such as changes in arm volume or subjective measures such as changes to an individual's symptoms or QOL.

The time frame for outcomes varies from months to years after the onset of lymphedema symptoms.

Study Selection Criteria

For evaluation of clinical validity of bioimpedance testing, studies that meet the following eligibility criteria were considered:

- Reported on the accuracy of the marketed version of the technology (including any algorithms used to calculate scores).
- Included a suitable reference standard.
- Patient/sample clinical characteristics were described.
- Patient/sample selection criteria were described.

For evaluation of clinical utility, comparative controlled prospective trials, with preference for RCTs were considered. In the absence of such trials, comparative observational studies, with preference for prospective studies were considered.

Clinically Valid

A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

Systematic Review

A technology assessment on the diagnosis and treatment of secondary lymphedema, performed for the Agency for Healthcare Research and Quality (AHRQ), was published in 2010. (4) The AHRQ assessment identified 8 studies that reported the sensitivity and specificity of tests to diagnose secondary lymphedema. Reviewers noted there is no true criterion standard to grade severity of lymphedema and that limb volume and circumference are used as de facto criterion standards. Two of the 8 selected studies evaluated BIS devices. (5, 6) Overall, reviewers concluded that, due largely to heterogeneity among studies, the evidence did not permit conclusions on the optimal diagnostic test for detection of secondary lymphedema.

A systematic review by Whitworth et al. (2022) evaluated strategies for screening and early intervention in breast cancer patients at risk for lymphedema. (7) A total of 12 studies (N=2907) were included. Although 4 RCTs were included, only 1 RCT evaluated BIS (see Ridner et al. below). Of the 7 prospective, observational studies identified, 5 evaluated BIS. Although these

studies generally point to BIS as a sensitive surveillance technique, this analysis did not synthesize data from the included studies and no quality or bias risk was assessed.

Observational Studies
After the AHRQ review, several other studies have evaluated the diagnostic performance of BIS devices for detecting lymphedema. Prospective studies that compared bioelectrical impedance analysis to a reference standard are described next.

A study by Barrio et al. (2015) enrolled 223 women with newly diagnosed breast cancer and a plan for unilateral axillary surgery. (8) Thirty-seven patients were excluded due to ineligibility or withdrawal, leaving a sample size of 186. Prior to surgery, participants received baseline volumetric measurements with a bioimpedance device (L-Dex) and volume displacement (the reference standard). Patients then had follow-up volumetric measurements every 3 to 6 months for 3 years. At the last follow-up (median, 18.2 months), 152 (82%) patients had no lymphedema, 21 (11%) had an abnormal L-Dex and no lymphedema by volume displacement, 4 (2%) had an abnormal L-Dex and lymphedema by volume displacement, and 9 (5%) had lymphedema without prior L-Dex abnormality. In an analysis including only patients with at least 6 months of follow-up, L-Dex had a sensitivity of 31% (4/13) and a specificity of 88% (129/147) for predicting subsequent lymphedema development. Also, the correlation between changes in volume displacement and changes in L-Dex results were in the low-to-moderate range at 3 months (r=0.31) and 6 months (r=0.21). However, at the time of lymphedema diagnosis, the L-Dex ratio was abnormal in 12 of 13 patients (diagnostic sensitivity, 92%).

Blaney et al. (2015) reported on a prospective study with 126 women with stage I, II, or III unilateral breast cancer. (9) A total of 115 women underwent baseline assessment with an L-Dex and circumferential measurement. The circumferential measurement was used as the reference standard, although the authors noted the test is an imperfect criterion standard. Postsurgical follow-up assessments were planned every 3 months for a year. The number of women completing these assessments was 109 (95%) at 3 months, 89 (77%) at 6 months, 79 (69%) at 9 months, and 71 (62%) at 12 months. Over 12 months, 31 participants were identified as having lymphedema by at least 1 of the assessment methods. Twenty-eight (90%) of 31 were identified by circumferential measurement and 11 (35%) by BIS. There was no statistically significant correlation between bioimpedance analysis and circumferential measurement.

<u>Clinically Useful</u>
A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if individuals receive correct therapy, or more effective therapy, or avoid unnecessary therapy or testing.

The ideal study design is an RCT comparing health outcomes in individuals managed with and without the use of bioimpedance devices.

Randomized Controlled Trial

One multicenter, international, RCT conducted by Ridner et al. (2019 and 2022) [PREVENT RCT] compared bioimpedance to volume measurements calculated from arm circumference using a tape measure (Table 3). (10, 11) 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. 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 (TM) 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.

Results of the interim analysis and final analysis are summarized in Table 4. (10, 11) 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 TM 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 (see Tables 5 and 6), 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, QOL, and function were not assessed. Additionally, 39 patients who progressed prior to an intervention being triggered were excluded from the analysis.

Shah et al. (2024) conducted a secondary analysis on data from the PREVENT RCT to investigate the onset and progression of subclinical breast cancer-related lymphedema (sBCRL) and clinical breast cancer-related lymphedema (cBCRL). (12) The aim was to provide guidance on the optimal screening frequency and duration for BCRL. Women at risk of cBCRL (N=919) were regularly screened for up to 36 months post breast cancer treatment using either bioimpedance or TM. In total, 209 patients (23%) developed sBCRL (bioimpedance: n=89, TM: n=120) and were eligible for intervention. Subsequently, 30 patients progressed to cBCRL post-intervention (BIS: 7, TM: 23). More than half of the patients exhibited measurements consistent with sBCRL within 9 months of breast cancer treatment. Initial detections of sBCRL persisted, regardless of the screening method used, with rates remaining stable in the second and third years (p>0.24) post-surgery. Furthermore, 39 patients progressed to cBCRL without previously developing sBCRL or receiving intervention over the 3-year period. The timing of sBCRL

detection highlights that patients remain at risk years after treatment and may continue to progress to cBCRL long after surgery. Early detection of sBCRL facilitates timely intervention, thereby reducing the likelihood of progression to cBCRL. Consequently, patients should be diligently monitored for a minimum of 3 years following the completion of cancer treatment, with particular emphasis on focused and targeted monitoring during the initial 9-month period.

Table 3. Summary of Key RCT Characteristics

Study, Trial	County	Sites	Dates	Participants	Interventions	
					Active	**Comparator**
Ridner et al. (2019 and 2022) (10, 11) PREVENT-NCT02167659	U.S. and Australia	13	2014-2018	Presurgical: Women >18 years of age with histologically confirmed, newly diagnosed, breast cancer (invasive or DCIS) with planned surgery. Postsurgical: stage I–III invasive breast cancer or DCIS who received ≥1 of the following: mastectomy, axillary treatment, regional node irradiation, or taxane-based chemotherapy	BIS: N=263 at interim; 482 at final	Tape measure: N=245 at interim; 481 at final

BIS: bioimpedance spectroscopy; DCIS: ductal carcinoma in situ; NCT: national clinical trial; PREVENT: Bioimpedance Spectroscopy Versus Tape Measure in Prevention of Lymphedema; RCT: randomized controlled trial; U.S.: United States.

Table 4. Summary of Key RCT Results

Study	Intervention Triggered	Median (IQR) months to Intervention triggered	Progression to clinical lymphedema	Median (range) months to progression to clinical lymphedema
Ridner et al. (2019) (10)				
BIS	41/259 (15.8%)	2.8 (0.6-5.6)	2/41 (4.9%)	6.0 (1.4, 16.9)
Tape measure	68/239 (28.5%)	4.0 (1.0-11.2)	10/68 (14.7%)	6.0 (0.8, 16.9)
p-value	0.001	0.002	0.130	0.389
Ridner et al. (2022) (11)				
BIS	89/442 (20.1%)	9.7 (3.6-18.2)	7/89 (7.9%)	4.9 (0.7-15.2)
Tape measure	120/437 (27.5%)	3.9 (1.0-11.6)	23/120 (19.2%)	10.7 (1.4-31.9)

p-value	0.011	0.001	0.016	0.100

BIS: bioimpedance spectroscopy; IQR: interquartile range; RCT: randomized controlled trial.

Table 5. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-Up[e]
Ridner et al. (2019 and 2022) (10, 11)				1. Patient-reported outcomes not assessed	

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.

[b] Intervention key: 1. Classification thresholds not defined; 2. Version used unclear; 3. Not intervention of interest.

[c] Comparator key: 1. Classification thresholds not defined; 2. Not compared to credible reference standard; 3. Not compared to other tests in use for same purpose.

[d] Outcomes key: 1. Study does not directly assess a key health outcome; 2. Evidence chain or decision model not explicated; 3. Key clinical validity outcomes not reported (sensitivity, specificity, and predictive values); 4. Reclassification of diagnostic or risk categories not reported; 5. Adverse events of the test not described (excluding minor discomforts and inconvenience of venipuncture or noninvasive tests).

[e] Follow-Up key: 1. Follow-up duration not sufficient with respect to natural history of disease (true-positives, true-negatives, false-positives, false-negatives cannot be determined).

Table 6. Study Design and Conduct Limitations

Study	Selection[a]	Blinding[b]	Delivery of Test[c]	Selective Reporting[d]	Data Completeness[e]	Statistical[f]
Ridner et al. (2019 and 2022) (10, 11)		1. Open label			2. 10 patients who progressed prior to triggered intervention were excluded from interim and 39 from final analysis	

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

[a] Selection key: 1. Selection not described; 2. Selection not random or consecutive (i.e., convenience).

[b] Blinding key: 1. Not blinded to results of reference or other comparator tests.

[c] Test Delivery key: 1. Timing of delivery of index or reference test not described; 2. Timing of index and comparator tests not same; 3. Procedure for interpreting tests not described; 4. Expertise of evaluators

not described.
[d] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[e] Data Completeness key: 1. Inadequate description of indeterminate and missing samples; 2. High number of samples excluded; 3. High loss to follow-up or missing data.
[f] Statistical key: 1. Confidence intervals and/or p values not reported; 2. Comparison with other tests not reported.

Observational Studies
One prospective observational study compared clinical lymphedema rates in patients managed with and without bioimpedance analysis. This study, by Soran et al. (2014), involved prospective detection of subclinical lymphedema in 186 women with breast cancer managed with L-Dex or tape measurement of limb circumference. (13) Measurements were obtained at baseline and 3- to 6-month intervals for 5 years. Subclinical lymphedema was defined as an L-Dex value outside the normal range, or that increased at least 10 units from baseline. Patients diagnosed with subclinical lymphedema were treated with, e.g., short-term physical therapy, compression garments, and received education on exercise and limb elevation. A total of 180 women were included in the analysis. Seventy-two women had both preoperative and postoperative bioimpedance and tape measurements (preoperative group). Forty-four women had preoperative bioimpedance and tape measurements but only had tape measurements postoperatively (control group). The remaining 64 women had postoperative bioimpedance and tape measurements, but no preoperative measurements (no preoperative group). The authors compared the demographic and clinical characteristics of the preoperative and control groups and the preoperative and postoperative groups; they did not identify any statistically significant differences.

In the preoperative group, 28 (36%) of 72 women were diagnosed with subclinical lymphedema and referred for treatment; 2 women progressed to clinical lymphedema. In the control group, 16 women (36%) developed clinical lymphedema during follow-up. Limitations of the study included a lack of an alternative method for detecting subclinical lymphedema in women in the control group so that they could receive treatment early; a lack of randomization to a treatment group; and incomplete data on pre- and postoperative measures of lymphedema except in a subset of the total population.

Multiple uncontrolled observational studies have reported rates of lymphedema identified through surveillance with bioimpedance in women at high-risk following breast cancer treatment. (14-23) 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.

<u>Section Summary: Bioimpedance Spectroscopy in Individuals With Known or Suspected Lymphedema</u>
Diagnostic accuracy studies have found a poor correlation between bioimpedance analysis and the reference standard (volume displacement or circumferential measurement). Results from

the PREVENT RCT (2019, 2022) comparing BIS with standard tape measure following treatment for breast cancer have been published. At a median follow-up of 32.9 months, BIS patients triggered intervention at a lower rate than tape measure patients (20.1% vs 27.5%) and fewer patients progressed in this group (7.9% vs 19.2%). 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 BIS 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 bioimpedance monitoring is feasible but provide limited information about its efficacy. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Summary of Evidence

For individuals who have known or suspected lymphedema who receive bioimpedance spectroscopy (BIS), the evidence includes systematic reviews, 1 randomized controlled trial (RCT), 1 prospective comparative observational study, and multiple uncontrolled observational studies. 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). Results from the PREVENT RCT comparing bioimpedance with standard tape measure following treatment for breast cancer have been published. At a median follow-up of 32.9 months, BIS patients triggered intervention at a lower rate than tape measured patients (20.1% vs 27.5%) and fewer patients progressed in this group (7.9% vs 19.2%). 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 BIS 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 bioimpedance monitoring is feasible but provide limited information about its efficacy. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Clinical Input

For individuals with known or suspected (i.e., clinically diagnosed or symptomatic) lymphedema, 2025 clinical input supports that use of bioimpedance spectroscopy is consistent with generally accepted medical practice. Feedback on whether this use results in a clinically meaningful improvement in net health outcome was mixed, with the primary benefit limited to situations where confirmation of maximal benefit from conservative measures such as decongestive therapy can help inform decisions around escalation of therapy. For individuals who are asymptomatic but are at elevated risk for lymphedema due to prior radiation, surgery, or trauma impacting the lymphatic system, clinical input supports that use of bioimpedance spectroscopy is consistent with generally accepted medical practice and that its clinical use is expected to provide a clinically meaningful improvement in net health outcome. Bioimpedance

spectroscopy in this high-risk, surveillance context can prompt early intervention and limit progression to chronic, irreversible lymphedema with fibrosis.

Practice Guidelines and Position Statements

National Comprehensive Cancer Network

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines on Survivorship (v.2.2025) recommends that survivors at risk for lymphedema should be regularly screened for lymphedema by symptom assessment, clinical exam, and, if available, bioimpedance spectroscopy. (24) NCCN notes that survivors who had surgery, radiation, or chemoradiation to the axillary, supraclavicular, cervical, or pelvic inguinal lymph node system are at risk. While sentinel node biopsy also increases risk of lymphedema, it poses less risk than complete dissection. Other factors increasing risk of lymphedema development include BMI ≥ 30 kg/m^2, localized infection, increased number of nodes removed, and higher initial extent of disease.

NCCN Clinical Practice Guidelines on Breast Cancer (v.4.2025) recommend education, monitoring, and referral for lymphedema management as needed. For further information, they refer the reader to the Survivorship Guidelines. (25)

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this policy are listed in Table 7.

Table 7. Summary of Key Trials

NCT Number	Trial Name	Planned Enrollment	Completion Date
NCT01521741	Prospective Screening for Breast Cancer-related Lymphedema: Analysis of Objective Measurements, Symptoms, Functionality, and Quality of Life Questionnaires to Evaluate Lymphedema in Patients Following Treatment for Breast Cancer.	10000	Dec 2026
NCT03292198[a]	Treatment Indications for Breast Cancer-related Subclinical Lymphedema Identified Through a Bioimpedance Surveillance Model	267	Dec 2025
NCT02743858	A Prospective Surveillance Program for Assessment and Treatment of Breast Cancer-Related Lymphedema After Axillary Lymph Node Dissection	1250	Apr 2026
NCT03978754	Assessment of Breast Cancer-Related Arm Lymphedema-Comparison of Traditional Measurement Methods	1600	Jan 2022 (status unknown)

	and Indocyanine Green (ICG) Lymphography		

BIS: bioimpedance spectroscopy; NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	93702
HCPCS Codes	None

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
10/15/2025	Document updated with literature review. The following changes were made to Coverage: 1) Conditional criteria added for the use of bioimpedance spectroscopy to confirm the diagnosis of lymphedema and for the surveillance of lymphedema in select clinical scenarios; and 2) Bioimpedance spectroscopy is considered experimental, investigational and/or unproven outside of the aforementioned clinical scenarios. Reference 12 added; others updated.
02/01/2025	Document updated with literature review. Coverage unchanged. Added/updated references 2, 7, 10, 22, 23, and 24.
09/15/2023	Document updated with literature review. Coverage unchanged. No new references; some updated.
04/15/2022	Reviewed. No changes.
09/15/2021	Document updated with literature review. Coverage unchanged. References 1-3 and 12-19 added, 20-21 updated; others removed.
08/15/2020	Reviewed. No changes.

10/15/2019	Document updated with literature review. Coverage unchanged. Reference 9 added; none removed.
10/01/2018	Document updated with literature review. Coverage unchanged. References 1 and 8 added; several references removed.
10/15/2017	Reviewed. No changes.
06/01/2016	Document updated with literature review. Coverage unchanged. Rationale significantly revised with updated References.
03/15/2015	Reviewed. No changes.
04/15/2014	Document updated with literature review. Coverage unchanged.
07/15/2010	New medical document. Devices using bioimpedance (bioelectrical impedance spectroscopy) are considered experimental, investigational and unproven for use in the diagnosis, surveillance, or treatment of patients with lymphedema, including use in subclinical secondary lymphedema. (Coverage is unchanged. This topic was previously addressed on MED202.018, Plethysmography.)