

**2.01.82 Bioimpedance Devices for Detection and Management of Lymphedema**

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<b>Section:</b>	2.0 Medicine	<b>Page:</b>	Page 1 of 14

**Policy Statement**

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.

**NOTE:** Refer to [Appendix A](#) to see the policy statement changes (if any) from the previous version.

**Policy Guidelines****Coding**

There is a CPT code for bioelectrical impedance testing:

- **93702:** Bioimpedance spectroscopy (BIS), extracellular fluid analysis for lymphedema assessment(s)

**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.

**Related Policies**

- Pneumatic Compression Pumps for Treatment of Lymphedema and Venous Ulcers
- Surgical Treatments for Breast Cancer-Related Lymphedema

**Benefit Application**

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

**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 1.

**Table 1. 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.
2007	ImpediMed L-Dex™ U400	ImpediMed (Carlsbad, CA)	K050415	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.

## Rationale

### Background 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=29612 women), DiSipio et al (2013) reported that approximately 1 in 5 women who survive breast cancer will develop arm lymphedema.<sup>1</sup> 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 2 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.<sup>2</sup>

**Table 2. Recommendations for Staging Lymphedema**

Stage	Description
<b>Stage 0 (subclinical)</b>	Swelling is not evident and most patients are asymptomatic despite impaired lymphatic transport

Stage	Description
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 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.

### Literature Review

Evidence reviews 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. Evidence reviews assess the evidence on whether a test is clinically valid and clinically useful. Technical reliability is outside the scope of these reviews, and credible information on technical reliability is available from other sources.

### Bioimpedance Spectroscopy in Patients With Known or Suspected Lymphedema

#### Clinical Context and Test Purpose

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

The question addressed in this evidence review is: Does the use of BIS devices detect lymphedema in individuals with known or suspected lymphedema?

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

### **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.<sup>3</sup> 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 patient 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.<sup>4</sup> 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 bioimpedance devices.<sup>5,6</sup> 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.

### Observational Studies

After the AHRQ review, several other studies have evaluated the diagnostic performance of bioimpedance 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.<sup>7</sup> 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 LDex, 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 LDex 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.<sup>8</sup> 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.

### Section Summary: Clinically Valid

A 2010 AHRQ technology assessment identified few studies on bioimpedance analysis for diagnosing lymphedema. A few prospective studies, published after the AHRQ review, found suboptimal correlations between bioimpedance analysis and the reference standard. In the study that reported measures of diagnostic accuracy, bioimpedance analysis had low sensitivity and specificity for predicting lymphedema development.

### Clinically Useful

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 patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

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

### Randomized Controlled Trial

One RCT compared bioimpedance to volume measurements calculated from arm circumference using a tape measure (Table 3). The study is ongoing but preliminary results on the first 508 patients have been published.<sup>2</sup> The interim analysis was preplanned to be performed when at least 500 participants reached at least 12 months of follow-up. The primary aim of the study was to determine if subclinical detection of extracellular fluid accumulation via bioimpedance 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 a change that was  $\geq 10$  L-Dex units (3 standard deviations) higher than the presurgical baseline measure. Patients in the tape measure group triggered when they had a volume change in the at-risk arm that was between  $\geq 5$  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 are summarized in Table 4. Overall, 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 ( $p=0.130$ ) and did not meet stopping criteria specified in the study protocol. The study is expected to be completed in December 2020 with a total of 1100 patients.

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, 10 patients who progressed prior to an intervention being triggered were excluded from the analysis.

**Table 3. Summary of Key RCT Characteristics**

Study; Trial	Country	Sites	Dates	Participants	Interventions	
					Active	Comparator
Ridner et al (2019) <sup>2</sup> -PREVENT-NCT02167659	U.S.	10	2014-2018	Presurgical: Women >18 years of age with histologically confirmed breast cancer (invasive or ductal carcinoma in situ with planned surgery. Postsurgical: stage I-III invasive breast cancer or DCIS who received mastectomy, axillary treatment, and/or taxane-based chemotherapy	Bioimpedance N=263	Tape measure N=245

RCT: randomized controlled trial; DCIS: ductal carcinoma in situ; NCT: national clinical trial; PREVENT: Bioimpedance Spectroscopy Versus Tape Measure in Prevention of Lymphedema.

**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
<b>Ridner et al (2019)<sup>2</sup></b>				
<b>Bioimpedance</b>	41/259 (15.8%)	2.8 (0.6–5.6)	2/41 (4.9%)	6.0 (1.4, 16.9)
<b>Tape measure</b>	68/239 (28.5%)	4.0 (1.0–11.2)	10/68 (14.7%)	6.0 (0.8, 16.9)
<b>P-value</b>	0.001	0.002	0.130	0.389

RCT: randomized controlled trial; IQR: interquartile range.

**Table 5. Study Relevance Limitations**

Study	Population <sup>a</sup>	Intervention <sup>b</sup>	Comparator <sup>c</sup>	Outcomes <sup>d</sup>	Duration of Follow-Up <sup>e</sup>
<b>Ridner et al (2019)</b>				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.

<sup>a</sup> 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.

<sup>b</sup> Intervention key: 1. Classification thresholds not defined; 2. Version used unclear; 3. Not intervention of interest.

<sup>c</sup> 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.

<sup>d</sup> 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).

<sup>e</sup> 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 <sup>a</sup>	Blinding <sup>b</sup>	Delivery of Test <sup>c</sup>	Selective Reporting <sup>d</sup>	Data Completeness <sup>e</sup>	Statistical <sup>f</sup>
<b>Ridner et al (2019)</b>		1. Open-label			2. 10 patients who progressed prior to triggered intervention were excluded	1. Confidence intervals not reported

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

<sup>a</sup> Selection key: 1. Selection not described; 2. Selection not random or consecutive (i.e., convenience).

<sup>b</sup> Blinding key: 1. Not blinded to results of reference or other comparator tests.

<sup>c</sup> 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.

<sup>d</sup> Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.

<sup>e</sup> 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. <sup>f</sup> 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.<sup>10</sup> 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.<sup>11-19</sup> 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.

### Section Summary: Clinically Useful

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 predetermined 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. One prospective comparative study has compared rates of clinical lymphedema in women managed with and without bioimpedance analysis. This study 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. The authors reported a significantly lower rate of clinical lymphedema in patients managed with bioimpedance analysis and who received treatment for subclinical lymphedema. An additional retrospective analysis suggested that postoperative bioimpedance monitoring is feasible but provided limited information on its efficacy. Additional studies to confirm these findings are needed, especially RCTs and trials that include an alternative method for early or subclinical lymphedema detection.

### Summary of Evidence

For individuals who have known or suspected lymphedema who receive bioimpedance spectroscopy, the evidence includes a systematic review, 1 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). 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 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.

### **Supplemental Information**

The purpose of the remaining sections in Supplemental Information is to provide reference material regarding existing practice guidelines and position statements, U.S. Preventive Services Task Force Recommendations and Medicare National Coverage Decisions and registered, ongoing clinical trials. Inclusion in the Supplemental Information does not imply endorsement and information may not necessarily be used in formulating the evidence review conclusions.

### **Clinical Input From Physician Specialty Societies and Academic Medical Centers**

While the various physician specialty societies and academic medical centers may collaborate and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests from Blue Cross Blue Shield Association, input was received from 2 specialty societies and 2 academic medical centers in 2011. Three of 4 reviewers agreed that bioimpedance devices are considered investigational for diagnosis, surveillance, and treatment of patients with lymphedema. The fourth reviewer, from an academic medical center, considered the use of the technology a reasonable alternative, especially in situations in which minor lymphedema can have a large impact on a patient. One specialty society supported further research into the effectiveness of this technology and recommended reimbursement in the context of relevant clinical trials.

### **Practice Guidelines and Position Statements**

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

National Comprehensive Cancer Network Clinical Practice Guidelines on Survivorship (v.3.2021)<sup>20</sup> and Breast Cancer (v.1.2022)<sup>21</sup> recommend education, monitoring, and referral for lymphedema management as needed. Neither guideline mentions bioimpedance.

### **U.S. Preventive Services Task Force Recommendations**

Not applicable.

### **Medicare National Coverage**

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

### **Ongoing and Unpublished Clinical Trials**

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

**Table 7. Summary of Key Trials**

NCT No.	Trial Name	Planned Enrollment	Completion Date
<b>Ongoing</b>			
NCT03978754	Assessment of Breast Cancer-Related Arm Lymphedema— Comparison of Traditional Measurement Methods and Indocyanine Green (ICG) Lymphography	300	Jan 2022 (recruiting as of Jun 2019)
NCT02743858	A Prospective Surveillance Program for Assessment and Treatment of Breast Cancer-Related Lymphedema After Axillary Lymph Node Dissection	850	Apr 2023 (Active, but not recruiting as of Nov 2021 )
<b>Unpublished</b>			
NCT01544335	Evaluation of the Validity of BIS as a Tool for Quantification of Lymphedema Through Comparison With Perometry and Self-Report	270	Sept 2020

BIS: bioimpedance spectroscopy; NCT: national clinical trial.

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## Documentation for Clinical Review

- No records required

## Coding

*This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.*

*The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.*

Type	Code	Description
CPT®	93702	Bioimpedance spectroscopy (BIS), extracellular fluid analysis for lymphedema assessment(s)
HCPCS	None	

### Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
07/02/2010	BCBSA Medical Policy adoption
08/04/2010	Administrative Review
10/07/2011	Administrative Review
07/24/2013	Policy revision without position change Policy placed on No Further Routine Literature Review status
01/30/2015	Policy title change from Bioimpedance for Assessment of Lymphedema Policy revision without position change Coding Update
03/01/2016	Policy revision without position change
08/01/2017	Policy revision without position change
03/01/2018	Policy revision without position change
04/01/2019	Policy revision without position change
03/01/2020	Annual review. No change to policy statement. Literature review updated.
03/01/2021	Annual review. No change to policy statement. Literature review updated.
03/01/2022	Annual review. No change to policy statement. Literature review updated.

### Definitions of Decision Determinations

**Medically Necessary:** Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

**Investigational/Experimental:** A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

### Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an

authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at [www.blueshieldca.com/provider](http://www.blueshieldca.com/provider).

*Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.*

**Appendix A**

POLICY STATEMENT (No changes)	
BEFORE	AFTER
<p><b>Bioimpedance Devices for Detection and Management of Lymphedema 2.01.82</b></p> <p><b>Policy Statement:</b> Devices using bioimpedance (bioelectrical impedance spectroscopy) are considered <b>investigational</b> for use in the diagnosis, surveillance, or treatment of patients with lymphedema, including use in subclinical secondary lymphedema.</p>	<p><b>Bioimpedance Devices for Detection and Management of Lymphedema 2.01.82</b></p> <p><b>Policy Statement:</b> Devices using bioimpedance (bioelectrical impedance spectroscopy) are considered <b>investigational</b> for use in the diagnosis, surveillance, or treatment of patients with lymphedema, including use in subclinical secondary lymphedema.</p>