Medical Coverage Policy

Effective Date.....07/15/2024
Next Review Date.....07/15/2025
Coverage Policy Number..... 0571

Bioimpedance Spectroscopy

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Lymphedema and Lipedema Surgical Treatments

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy

will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This Coverage Policy addresses bioimpedance spectroscopy to measure extracellular fluid differences between limbs (CPT Code 93702).

Coverage Policy

Bioimpedance spectroscopy is considered medically necessary for measurement of extracellular fluid volume in an individual at risk for developing lymphedema (e.g., undergoing breast cancer treatment, lymph node biopsy, regional lymphadenectomy, and/or radiation therapy for other non-breast malignancies).

Health Equity Considerations

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing, transportation, and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

General Background

Bioelectrical impedance analysis is a noninvasive technique measures the body's response to electrical current. Current flows along the path of least resistance through the body and thus follows tissues with the highest water content, allowing measurement of edema. Bioimpedance spectroscopy has been proposed as a tool to detect early-stage lymphedema.

Lymphedema is a pathological condition resulting from an accumulation of protein-rich fluid in the interstitial space because of congenital or acquired damage to the lymphatic system. Acquired or secondary lymphedema may be caused by disease, trauma, or an iatrogenic process such as surgery or radiation (Agency for Healthcare Research and Quality [AHRQ], 2010). Lymphedema is generally staged by observation of the individual's physical condition (i.e., stage 0-3) and is typically diagnosed by clinical history and physical examination. AHRQ notes that it is difficult to detect stage 0 or subclinical lymphedema with current methods. According to a technology assessment by AHRQ (2010) serial measurement of limb volume and or circumference are de facto gold standards for diagnosing secondary edema; however, no single method of assessment has emerged as the standard comparator for randomized clinical trials.

U.S. Food and Drug Administration (FDA)

Impedimed L-Dex U400 ExtraCellular Fluid analyzer received FDA 510(k) approval on October 3, 2008 with approval of an expansion of indications on November 4, 2011. According to the approval summary it is "indicated for use on adult human patients, utilizing impedance ratios that are displayed as an L-Dex ratio that supports the measurement of extracellular fluid volume between the limbs and is presented to the clinician as an aid to their clinical assessment of unilateral lymphedema of the arm and leg in woman and the leg in men.

The ImpediMed SOZO® device received 510(k) approval on January 12, 2018.The SOZO Body Fluid Analyzer has the following uses for adult human patients at risk of lymphedema:

- A bioimpedance spectroscopy device for use on adult human patients, utilizing impedance ratios that are displayed as an L-Dex ratio that supports the measurement of extracellular 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 use of the device to obtain an L-Dex score 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.

The SOZO® device received 510(k) approval on April 19, 2021 (K203473) for use in heart failure patients. The SOZO Body Fluid Analyzer is intended for use, under the direction of a physician, for the noninvasive monitoring of patients with fluid management problems suffering from heart failure. Data from the device should be considered in conjunction with other clinical data.

The SOZO Pro® (ImpediMed Limited) received approval on May 4, 2023 (K230530/S001). Indications for Use: For adult human patient at risk of lymphedema. The use of the device to obtain an L-dex score 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.

Literature Review

Whitworth et al. (2024) conducted a systematic review of the literature searching for published randomized and prospective data evaluating prospective breast cancer-related lymphedema (BCRL) surveillance with early intervention. A total of 12 studies (2907 patients) including 4 randomized trials (1203 patients) and 8 prospective studies (1704 patients) were included. The authors found that randomized data consistently demonstrate that early intervention reduces rates of progression to chronic BCRL with multiple paradigms and diagnostic modalities utilized; the strongest data comes from the randomized PREVENT trial (Ridner, 2022). The authors stated that breast cancer patients at risk for BCRL should undergo prospective surveillance as part of survivorship. The authors noted "Because level 1 data demonstrate that BIS is superior to conventional tape measure, it should be included as the standard BCRL diagnostic modality unless an equally effective modality is employed".

Ridner et al. (2022) reported results from a multicenter, randomized clinical trial that compared bioimpedance spectroscopy (BIS) and tape measure (TM) measurements for breast cancer-related lymphedema (BCRL) surveillance among newly diagnosed breast cancer patients. Median follow-up was 32.9 months. A total of 963 (BIS n = 482; TM n = 481) patients were randomized and 879 analyzed (BIS n = 442; TM n = 437). The authors concluded that use of BIS as part of prospective BCRL surveillance, coupled with early compression sleeve and gauntlet intervention, significantly reduced chronic BCRL (progression to complex decongestive physiotherapy [CDP]), (7.9% vs. 19.2%, p = 0.016) compared to TM.

Shah et al. (2021) conducted a meta-analysis to evaluate the impact of monitoring techniques on the incidence of chronic breast cancer-related lymphedema (BCRL) among patients monitored by bioimpedance spectroscopy (BIS) and circumference. Incidence rates from 50 studies (>67,000

women) were classified by BCRL monitoring method: background (no standardized BIS or circumference assessments), BIS or circumference. Authors concluded that monitoring with BIS allowing for early intervention significantly reduces the relative risk of chronic BCRL with a 69% and 81% reduction compared to background and circumference, respectively.

Jeffers et al. (2023) retrospectively reviewed prospectively collected data to provide long-term follow-up on early detection with bioimpedance spectroscopy (BIS). In total, 148 female patients with breast cancer who had axillary lymph node dissection (ALND) were analyzed. Baseline BIS measurements and postoperative follow-up occurred every 3 months for 1 year, biannual for 1 year, and then annually. An elevated BIS triggered evaluation and initiation of at-home interventions with reassessment for resolution versus persistent breast cancer-related lymphedema (BCRL, pBCRL). Mean follow-up was 55 months, and 65 (44%) patients had an abnormal BIS. Of these, 54 (82%) resolved with home intervention. The overall pBCRL rate was 8%. Average time to first abnormal BIS was 11.7 months. None of the stage 0 patients (0/34) and only 5/25 (20%) of stage 1 patients had pBCRL. All of stage 2 and stage 3 patients (7/7) had pBCRL. The authors recommend prospective surveillance programs using BIS to identify patients with subclinical BCRL. A limitation of this study is that it is a single institution retrospective review.

da Silva Tozzo et al. (2023) prospectively evaluated the accuracy of BIS in the diagnosis of BCRL in a Brazilian population, comparing it with water displacement volumetry (direct volumetry). The participants underwent lymphoedema evaluation by BIS, volumetry, perimetry and self-report The 462 women had previous surgical treatment of the breast; surgical treatment of the axilla, i.e., axillary lymphadenectomy or SLN biopsy; and completion of radiotherapy in a period equal to or greater than 12 months.

- When comparing patients with lymphoedema diagnosed by direct volumetry with those diagnosed by BIS with L-DEX ≥ 10, BIS did not diagnose lymphoedema in 52 of the 93 patients with a volume difference ≥200 mL in the upper limbs. For L-DEX ≥ 10, the sensitivity and specificity of BIS were 44.1% and 95.4%, respectively.
- When comparing patients with lymphoedema diagnosed by direct volumetry with those diagnosed by BIS with L-DEX ≥ 6.5, 40 of the 93 patients with lymphoedema had L-DEX < 6.5. For L-DEX ≥ 6.5, the sensitivity and specificity of BIS were 57% and 88.5%, respectively.

The main limitation of this study is a cross-sectional evaluation. As all patients had already undergone cancer treatment, a pretreatment L-DEX was not collected. Another limitation of our study is that we did not collect information on previous lymphoedema, such as the time of lymphoedema, whether the patient had undergone or was undergoing treatment, and the type of lymphoedema treatment performed.

Borman et al. (2022) prospectively comparatively determine the frequency of subclinical/clinical lymphedema by using prospective monitoring with bioimpedance spectroscopy (BIS) and circumferential measurements in a group of 82 patients who underwent breast cancer surgery. Extremity volumes by circumferential and BIS measurements were performed after surgery (baseline) and monitorizations were carried out at third and sixth months, in order to determine the frequency of subclinical/clinical lymphedema. The authors reported their findings demonstrated that prospective surveillance using BIS can detect subclinical and/or clinical BCRL more sensitively than circumferential volume measurements at the sixth month follow up. BIS identified 36.5% and 25.6% of patients with subclinical/ clinical lymphedema at the third and sixth month of follow up, respectively, while 21.9% and 23.1% of patients had subclinical/ clinical lymphedema by circumferential measurements at third and sixth months, respectively. The study is limited by small sample size and relatively short follow-up.

Cho et al. (2020) reported on a prospective cohort study to evaluate the use of bioimpedance analysis (BIA) as a tool to measure lymphedema before and after treatment. The study included

29 patients with cancer treatment-related lymphedema (CTRL) who were admitted to a secondary university hospital for complex decongestive therapy (CDT) (12 upper- and 17 lower-extremity CTRL). Circumferential measure (CM) and BIA were used to evaluate lymphedema at admission (initial) and before discharge (follow-up, FU). The authors concluded that BIA data correlates significantly with clinical measurement, and therefore can be a practical tool in monitoring outcome measure after lymphedema treatment. The study was limited by the small number of participants and lack of randomization.

Asklöf et al. (2018) conducted a systematic review to summarize the current knowledge of non-invasive bioelectrical impedance analysis (BIA) used with gynecological surgical patients in regard to postoperative development of lymphedema and determination of perioperative fluid balance, and as a prognostic factor in cancer mortality and a predictor of postoperative complications. Two of the articles were retrospective; five had a cross-sectional, and nine were prospective. Three different methods of BIA were used: single frequency-BIA, multifrequency-BIA and bioimpedance spectroscopy. BIA was found to detect lymphedema with a sensitivity of 73% and a specificity of 84%. The authors note that there is a need for further studies within gynecological surgery focusing on early detection of lower limb lymphedema, perioperative fluid balance, and postoperative complications in order to establish the value of BIA in clinical praxis.

Hidding et al. (2016) conducted a systematic review with the purpose to provide best evidence regarding which measurement instruments are most appropriate in measuring lymphedema in its different stages. Inclusion criteria included prognostic, cross-sectional, and case-control studies assessing measurement properties of clinical measurement instruments for lymphedema with at least two repeated measurements with one instrument and studies describing comparisons between two or more measurement instruments were included and the review included 30 studies. Measurement instruments that were described in the studies included: water volumeter, tape measure, perometer, bioimpedance spectroscope (BIS), MoistureMeter, and tonometer. The authors noted limitations of the study included: no uniform definition of lymphedema was available, and a gold standard as a reference test was lacking. The items concerning risk of bias included study design, patient selection, description of lymphedema, blinding of test outcomes, and number of included participants. The authors found that measurement instruments with evidence for good reliability and validity were BIS, water volumetry, tape measurement, and perometry, where BIS can detect alterations in extracellular fluid in stage 1 lymphedema and the other measurement instruments can detect alterations in volume starting from stage 2.

Barrio et al. (2015) reported on a prospective study that compared bioimpedance (L-Dex) and volume displacement (VD) measurements in a prospective cohort of 186 breast cancer patients at risk for lymphedema. Patients received baseline VD and L-Dex; with follow-up measurements performed at three-six months intervals for three years. The authors concluded that VD and bioimpedance demonstrated poor correlation with inconsistent overlap of measurements considered abnormal. It was found that of patients with an abnormal L-Dex, few progressed to lymphedema; with most patients with lymphedema not having a prior L-Dex abnormality. The authors noted that further studies are needed to understand the clinical significance of bioimpedance.

A technology review by AHRQ (2010) notes there is consistent evidence to indicate that lymphedema can be reliably measured using circumferential measurements or volume displacement. Additionally, the assessment noted that there is insufficient evidence to draw conclusions about the reliability of other measures including tonometry, ultrasound, lymphoscintigraphy, or bioimpedance. The authors reviewed 41 studies related to diagnosis of lymphedema. In one study included in the technology assessment the test of interest involved differences in the sum of arm circumference between treated and untreated arms in persons with breast cancer. Circumferential differences to diagnose lymphedema were established at ≥5cm and

≥10cm. For differences of ≥5cm versus bioimpedance, sensitivity was 35% and specificity was 89%. For a difference of ≥10cm versus bioimpedance, sensitivity was 5% and specificity was 100%. For self-report compared to bioimpedance, sensitivity was 65%, specificity was 77%. In another included study bioimpedance was used diagnostically in 102 persons with breast cancer. The sensitivity of bioimpedance compared to limb volume was 10% and specificity was 98%. Two included studies involved bioimpedance alone. The first study found that mean and median bioimpedance measures were greater in the arms of women with lymphedema who survived breast cancer. In the other study single frequency bioimpedance was highly correlated to bioimpedance spectroscopy (r=.99). The authors noted the tests did not drive the choice of treatment or outcome.

Professional Societies/Organizations

The NCCN® Practice Guidelines in Oncology (NCCN Guidelines®) Survivorship (Version 1.2024 — March 29, 2024 states under Principles of Lymphedema:

- Early detection/diagnosis and early referral are key for optimal lymphedema management because stages 0 and 1 are reversible, whereas stages 2 and 3 are less responsive to treatment. Therefore, survivors at risk for lymphedema should be regularly screened for lymphedema by symptom assessment, clinical exam, and, if available, bioimpedance spectroscopy. Patients should be educated about early symptoms and signs of lymphedema including fullness, tightness, heaviness, and pain (page SLYMPH-2).

On page SLYMPH-3, the algorithm for Screening of Survivor at risk for lymphedema includes:

- Perform clinical examination, which may include, but is not limited to:
  - Range of motion
  - Muscle performance
  - Circulation
  - Sensation
  - Hemodynamic functioning
  - Functional mobility
  - If available, obtain objective measurements to identify early signs of lymphedema; tools may include bioimpedance spectroscopy

The NCCN® Practice Guidelines in Oncology (NCCN Guidelines®) Breast Cancer (Version 2.2024 — March 11, 2024 states:

- Lymphedema is a potential side effect after the treatment of axillary lymph node surgery resulting from damage to the lymphatic system. Early detection/diagnosis of lymphedema is key for optimal management. Consider pretreatment measurement of both arms as a baseline for patients with risk factors for lymphedema (BIVV-E).

The Multinational Association in Supportive Care in Cancer (MASCC) Oncodermatology and Survivorship study groups conducted a literature search and international Delphi consensus process to compile opinions of 55 experts involved in the care and research of breast cancer and lymphoedema on such interventions.

- The expert panel recommended that prospective surveillance should be implemented where feasible and resources allow. Bioimpedance spectroscopy (BIS) was recommended as an option for early lymphoedema detection before more prospective studies are performed to suggest the preferred method of detection. Other methods, such as arm circumference, volumetric measurements, lymphangiography and lymphoscintigraphy were alternatives to BIS when it is not available or there are resource limitations.

- Thresholds to trigger early intervention in a surveillance program recommended by the expert panel were:
  (1) when an increase in L-Dex score is ≥6.5 in BIS compared to pre-surgical values
  (2) when a difference in volume measurements of ≥5 but <10% is seen compared to pre-surgery values and
  (3) when the patient has any arm symptoms such as swelling, heaviness, tightness and/or numbness (Wong, et al., 2024).

The American Society of Breast Surgeons (ASBrS) Lymphatic Surgery Working Group conducted a large review of the literature in order to develop guidelines on breast cancer- related lymphedema (BCRL) prevention and treatment. The article discusses tape measure, perometry, water displacement and bioimpedance spectroscopy as assessment tools for BCRL but does not make any recommendations (McEvoy, et al., 2022).

The ASBrS 2022 Consensus Guideline on Axillary Management for Patients With In-Situ and Invasive Breast Cancer addresses surgical techniques only, when discussing prevention of lymphedema.

The ASBrS 'Considerations for Clinicians in the Diagnosis, Prevention, and Treatment of Breast Cancer-Related Lymphedema: Recommendations from a Multidisciplinary Expert ASBrS Panel : Part 1: Definitions, Assessments, Education, and Future Directions' (McLaughlin, et al., 2017) states these recommendations:

- Recommendation 1: The panel agrees that clinicians should establish a surveillance plan because early diagnosis leads to early treatment and increases the likelihood for limited disease burden.
- Recommendation 2: The panel agrees that baseline and follow-up measurements of the ipsilateral and contralateral arms of all breast cancer patients are critical. All measurement techniques have advantages and disadvantages that should be considered when a comprehensive measurement strategy is developed that includes a combination of objective and subjective measures.

The 2022 American College of Cardiology (ACC) and the American Heart Association (AHA) Guideline for the Management of Heart Failure (Heidenreich, et al., 2022) does not address bioimpedance spectroscopy.

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD	National	No Determination found	
LCD		No Determination found	

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD = National Coverage Determination; LCD = Local Coverage Determination)

Coding Information

Notes:

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare & Medicaid Services (CMS) code updates may occur more frequently than policy updates.

2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
93702	Bioimpedance spectroscopy (BIS), extracellular fluid analysis for lymphedema assessment(s)

***Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.**

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Revision Details

Type of Revision	Summary of Changes	Date
Annual review	• No clinical policy statement changes.	7/15/2024

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