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Medical Policy Manual Durable Medical Equipment, Policy No. 82

Bioimpedance Devices for Detection and Management of Lymphedema

Effective: October 1, 2026

Next Review: June 2027
Last Review: August 2026

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Secondary lymphedema may develop following surgery for breast cancer. Bioelectrical impedance (bioimpedance) is being studied as a diagnostic test for lymphedema, particularly for early detection of “subclinical” disease.

MEDICAL POLICY CRITERIA

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: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

None

BACKGROUND

Secondary lymphedema of the upper extremity may develop following surgical treatment for breast cancer; it has been reported in approximately 25% to 50% of women following mastectomy. This can be a chronic, disfiguring condition. It results from lymphatic dysfunction or disruption and can be difficult to accurately diagnose and manage. One challenge is identifying the presence of clinically significant limb swelling through simple noninvasive methods. Many techniques have been used for documenting lymphedema including measuring differences in limb volume (volume displacement) and limb circumference. A number of newer techniques are being evaluated, including bioimpedance with use of bioimpedance spectroscopy (BIS) analysis, which uses resistance to electrical current in comparing the composition of fluid compartments. BIS is based on the theory that the amount of opposition to 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.

The detection of subclinical lymphedema, that is, the early detection of lymphedema before clinical symptoms become apparent is another area of study. Detection of subclinical lymphedema (referred to as Stage 0 lymphedema) is problematic. Subclinical disease may exist for months or years before overt edema is noted. This approach generally involves comparison of preoperative with postoperative measurements, since existing differences between upper extremities (like the effects of a dominant extremity) may obscure early, subtle differences resulting from the initial accumulation of fluid. Bioimpedance has been proposed as one diagnostic test for this condition. Those who support the approach to diagnose subclinical disease believe that early treatment of subclinical lymphedema should result in less severe chronic disease.

REGULATORY STATUS

Devices that have been cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process to aid in the assessment of lymphedema are summarized in Table 1.

Table 1. Food and Drug Administration-Cleared Bioelectrical Impedance Spectroscopy Lymphedema Devices

Year	Device	Manufacturer	Indication
2018	SOZO	ImpediMed (Carlsbad, CA)	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)	To aid informing a clinical judgment of unilateral lymphedema in women
2007	ImpediMed L-Dex™ U400	ImpediMed, Limited (Carlsbad, CA)	To aid informing a clinical judgment of unilateral lymphedema in women

EVIDENCE SUMMARY

Assessment of a diagnostic technology typically focuses on the following three parameters: 1) technical performance; 2) diagnostic performance (i.e., sensitivity, specificity, and positive and negative predictive value) in appropriate populations of patients; and 3) demonstration that the diagnostic information can be used to improve patient outcomes (clinical utility). While in some

cases, tests can be adequately evaluated using technical and diagnostic performance, when a test identifies a new or different group of patients with a disease, randomized controlled trials (RCTs) are needed to demonstrate impact of the test on the net health outcome.

Most studies reported on secondary lymphedema of the upper extremity following surgery for breast cancer. The generally accepted approach to the diagnosis of lymphedema uses measurement of volume displacement and/or limb circumference. Most studies related to diagnosis involve these approaches. In contrast, the literature regarding bioelectrical impedance analysis is limited.

TECHNICAL PERFORMANCE

Technical performance of a device is typically assessed with two types of studies, those that compare test measurements with a gold standard and those that compare results taken with the same device on different occasions (test-retest). While there is no absolute gold standard for diagnosis of lymphedema, the de facto gold standards are limb volume and/or limb circumference. These measurements have been judged to be both valid and reliable.

Dylke (2017) reported generally relatively high sensitivity (76%) and high specificity (93%) of bioimpedance spectroscopy for the detection of lymphedema, compared with lymphoscintigraphy, in a group of women (n=68 with prior lymphedema due to breast cancer; n=13 controls; and n=6 with breast cancer but no lymphedema).[1]

A 2010 publication by Czerniec reported on measurement of lymphedema in a small group of patients, 33 with lymphedema and 18 without.[2] The aim of this study was to determine the relationship between physical methods of measuring lymphedema and self-reported swelling. Measurement techniques included self-report, bioimpedance spectroscopy, perometry, and the truncated cone method. The authors noted that the physical measurement tools were highly reliable with high concordance (0.89 to 0.99, respectively). In this study, self-report correlated moderately with physical measurements (0.65 to 0.71, respectively) and was moderately reliable. The authors concluded that lymphedema assessment methods are concordant and reliable but not interchangeable.

In a 2007 study, Warren evaluated 15 patients with upper- or lower-extremity secondary lymphedema documented by lymphoscintigraphy, along with seven healthy controls using BIS analysis.[3] In addition, both the affected and the unaffected limbs in lymphedema patients were evaluated so patients also served as their own controls. According to BIS in the lymphedema patients, the average ratio of current flow of the affected limb to the unaffected limb (impedance ratio) was 0.9 (range, 0.67-1.01). In the control group, the average impedance ratio was 0.99 (range, 0.95-1.02). Lower impedance ratio values correlated with higher levels of accumulated fluid.

DIAGNOSTIC PERFORMANCE

Diagnostic performance is evaluated by the ability of a test to accurately diagnose a clinical condition in comparison with the gold standard. The sensitivity of a test is the ability to detect a disease when the condition is present (true positive), while specificity indicates the ability to detect whether disease exists in patients who are suspected of disease but who do not have the condition (true negative). Evaluation of diagnostic performance, therefore, requires independent assessment by the two methods in a population of patients who are suspected of disease but who do not all have the disease.

Systematic Review and Technology Assessment

A systematic review published by Shaw (2016) evaluated bioimpedance spectroscopy for lymphedema.[4] The systematic review included many of the same studies summarized within the evidence review section of this policy. The systematic review authors concluded that bioimpedance has increased sensitivity and the ability to detect subclinical phase of disease. However, many of the included studies have methodological limitations and the systematic review authors did not quality appraise the included studies for potential risk of bias limiting the conclusions that can be drawn.

An AHRQ technology assessment on the diagnosis and treatment of secondary lymphedema, was published in May, 2010.[5] The assessment identified eight studies that reported the sensitivity and specificity of tests to diagnose secondary lymphedema. The investigators noted that there is no true “gold standard” to grade the severity of lymphedema; currently, limb volume and circumference are used as a de facto “gold standard.” Overall, study investigators concluded that due to the heterogeneity among studies, the body of evidence does not permit conclusions regarding the optimal diagnostic test for detection of secondary lymphedema.

The two studies that evaluated bioimpedance devices are briefly described below:

- In a study from Australia, Cornish followed 102 patients after treatment for breast cancer.[6] Twenty patients developed lymphedema in the 24 months follow-up period, and in these 20 cases, multi-frequency bioelectrical impedance analysis (MFBIA) predicted the onset of the condition up to 10 months before the condition was diagnosed clinically. Estimates of the sensitivity and specificity were both approximately 100%. At the time of detection by MFBIA, only one of the patients had a positive test result from the total limb volume determined from the circumferential measures.

- In another study from Australia, Hayes noted that the point prevalence of lymphedema varies according to the approach to diagnosis.[7] In this study, lymphedema status was assessed at 3-month intervals between six and 18 months post-surgery in a sample of Australian women with unilateral, invasive breast cancer, using three methods: bioimpedance spectroscopy (BIS), difference between sum of arm circumferences (SOAC), and self-report. Depending on the method, point prevalence ranged between 8 to 28%, with one in five to two in five women experiencing lymphedema at some point in time. According to the technology assessment, the sensitivity and specificity of bioimpedance compared to SOAC was 42% and 88%, respectively and the sensitivity and specificity of bioimpedance compared to self-report was 61% and 59%, respectively.

The technology assessment concluded that in contrast to information about the techniques of circumferential measurement and volume displacement, “there is too little evidence to draw conclusions about the reliability of…bioimpedance.” The report also noted that the studies do not allow conclusions about the potential impact of timing of the initial intervention.

Subsequent to the AHRQ review, several additional studies have been published on the diagnostic performance of bioimpedance devices for detecting lymphedema. These studies tended to have relatively small sample sizes and varied in their assessment protocols, outcome measures and reference standards. Representative studies are described next.

Nonrandomized Studies

A 2015 study by Barrio 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 (VD, the reference standard). Patients then had regular follow-up volumetric measurements every 3 to 6 months for three years. At the last follow-up (median, 18.2 months), 152 patients (82%) were normal, 21 (11%) had an abnormal L-Dex and no lymphedema by VD, four (2%) had an abnormal L-Dex and lymphedema by VD, and nine (5%) had lymphedema without prior L-Dex abnormality. In an analysis including only patients with at least six 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. In addition, the correlation between changes in VD and changes in L-Dex results were in the low-to-moderate range at three months (r=0.31) and six 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%).

Another 2015 prospective study by Blaney included 126 women newly diagnosed with stages I-III unilateral breast cancer.[9] A total of 115 women underwent baseline assessment with a bioimpedance device (L-Dex) and circumferential measurement (CM). CM was used as the reference standard, although the authors noted the test is an imperfect criterion standard. Postsurgical follow-up assessments were planned every three months for a year. The number of women completing these assessments was 109 (95%) at three months, 89 (77%) at 6 months, 79 (69%) at nine months, and 71 (62%) at 12 months. During the 12- month study, 31 participants were identified as having lymphedema by at least one of the assessment methods. Twenty-eight of 31 (90%) were identified by CM and 11 (35%) by bioimpedance analysis. There was no statistically significant correlation between bioimpedance analysis and CM.

Bundred (2015)[10] conducted a study to compare multifrequency bioimpedance and perometer arm measurements to predict the development of lymphedema in breast cancer patients undergoing axillary node clearance (ANC) to identify the most appropriate early treatment intervention. The primary outcome measure was the incidence of lymphedema (≥10% arm volume increase) compared with arm measurements by perometer at two and five years after node clearance. A total of 612 patients had follow-up data. Study results indicate a moderate correlation between perometer and bioimpedance at three months (r = 0.40) and 6 months (r = 0.60), with a sensitivity of 73 % and specificity of 84 %. Study authors reported that the modest correlation observed between methods at six months suggests that perometer arm volume measurements remain gold standard, although longer term follow-up is required to further investigate the use of bioimpedance to detect lymphedema.

In 2013, Berlit reported on 60 women who were evaluated for secondary lymphedema following breast cancer surgery using whole-body bioimpedance analysis. The study was conducted in Germany and used a device available in that country. Fourteen women were lost to follow-up and seven of the remaining 42 women (14%) developed upper limb lymphedema. Compared with circumferential limb measurements and patient baseline impedance values prior to surgery, bioimpedance analysis had a sensitivity of 85.7% and specificity of 97.4% for detection of arm lymphedema. The negative predictive value was 97.4%, indicating that a negative test rules out lymphedema with a high degree of certainty. However, the positive predictive value was relatively low at 54.6%, indicating that a positive test does not rule in lymphedema with certainty.

In 2011 Smoot reported on diagnostic test characteristics including sensitivity, specificity, and area under the receiver-operating-characteristic (ROC) curve for a number of tests used in the diagnosis of breast cancer-related lymphedema.[11] For this study, a total of 141 women were classified as having (n=70) or not having (n=71) breast cancer-related lymphedema (BCRL) based on past diagnosis by a health care provider. Areas under the curve for a number of bioimpedance measures and volume measures were in the 0.79 to 0.88 range, with overlap in confidence intervals. Given questions about the standard used for diagnosis and apparent lack of patients with subclinical lymphedema, this study provided little new information.

Similarly, a 2012 retrospective review of bioimpedance analysis in 64 women who underwent surgery for breast cancer failed to include a reference standard test for comparison. In addition, the authors did not report on diagnostic performance (i.e., sensitivity and specificity).[12] Additional similar studies were identified.[13-15] However, no diagnostic accuracy data was reported. Because of these study design limitations, conclusions on the diagnostic performance cannot be reached.

CLINICAL UTILITY

Clinical utility is evaluated by the ability of a test to guide patient management in order to improve health outcomes. Randomized trials comparing the health outcomes of patients managed with versus without the use of bioimpedance are needed to demonstrate the impact of the test on net health outcome. A related question is whether early detection and treatment of subclinical lymphedema using a bioimpedance device or another detection method improves health outcomes. The literature on treatment shows variability among studies regarding response to therapy for secondary lymphedema. Some studies found that mild disease was more responsive to treatment; other studies did not. Similarly, when the duration of symptoms were reported, there was no clear relationship between duration of the edema and response to treatment.

Shah (2023) published a review of literature and proposed guidelines for the use of bioelectrical impedance spectroscopy following breast cancer treatment.[16] The proposed guidelines recommend the use of bioimpedance for breast cancer-related lymphedema, however the guidelines are based on limited evidence of clinical utility which includes only one RCT and non-randomized studies. Additional high-quality evidence is necessary to guide decision making and establish clinical utility for this technology.

One RCT compared bioimpedance to volume measurements calculated from arm circumference using a tape measure.[17] The study is ongoing but preliminary results on the first 508 patients have been published. 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 >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 >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. 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 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.

Laidley (2016) reported on a retrospective cohort study which reported the feasibility and outcomes for postoperative bioimpedance monitoring in women following axillary lymph node surgery for breast cancer.[18] A total of 326 patients who had undergone some form of axillary staging and preoperative and at least two postoperative bioimpedance measurements met the study's eligibility criteria, out of a review of 1113 patients treated at two surgical practices. The cumulative incidence of subclinical breast cancer-related lymphedema was 12.3%.

An observational study by Soran compared clinical lymphedema rates in patients managed with and without bioimpedance analysis was published in 2014.[15] This study involved prospective detection of subclinical lymphedema in 186 women with breast cancer who were managed with L-Dex or tape measurement of limb circumference. Measurements were obtained at baseline and at three- to six-month intervals for five 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 demographic and clinical characteristics of the preoperative and control groups and of the preoperative and postoperative groups; they did not identify any statistically significant differences. In the preoperative group, 28 of 72 women (36%) were diagnosed with subclinical lymphedema and referred for treatment; two women progressed to clinical lymphedema. In the control group, 16 women (36%) developed clinical lymphedema during follow-up. A limitation of the study is that there was no alternative method for detecting subclinical women in the control group so that they could receive treatment early. Moreover, the women were not randomized to a treatment group and complete information (pre- and postoperative measures of lymphedema) was available for only a subset of the total population.

A study by Stout Gergich is frequently cited as support for early detection and treatment of subclinical lymphedema.[19] In this study, lymphedema was identified in 43 of 196 women who participated in a prospective breast cancer morbidity trial. Limb volume was measured preoperatively and at 3-month intervals after surgery using perimetry (another evolving technique). If an increase of greater than 3% in upper limb volume developed compared with the preoperative volume, then a diagnosis of lymphedema was made and a compression garment intervention was prescribed for four weeks. Statistical analysis was a repeated-measures analysis of variance by time and limb ($p<0.001$) comparing the lymphedema cohort with an age-matched control group. In this study, the time to onset of lymphedema averaged 6.9 months postoperatively. The mean (+/-standard deviation [SD]) affected limb volume increase was 83 mL (+/-119 mL) at lymphedema onset compared with baseline. Of note, clinical lymphedema is generally felt to be apparent when 200 mL of fluid accumulates. After

the intervention, a statistically significant mean 48 mL (+/-103 mL) volume decrease was realized. The mean duration of the intervention was 4.4 weeks. Volume reduction was maintained at an average follow-up of 4.8 months after the intervention. The authors concluded that a short trial of compression garments effectively treated subclinical lymphedema. This study does not answer the key question, that is, whether net health outcome was improved by early intervention. In addition, the role of novel diagnostic testing compared to the use of the de facto gold standard tests (limb volume or circumference) also needs to be evaluated.

In a study from Europe involving 55 women who had breast cancer and axillary node dissection, Boccardo evaluated a preventive protocol for lymphedema.[20] The preventive group had volumetric (arm volume) measurements performed preoperatively and at 1, 3, 5, 12, and 24 months postoperatively. The protocol for this group included principles to minimize lymphedema risk, lymphoscintigraphy preoperatively and at 6 months postoperatively, and early management of the condition once identified. Clinically significant lymphedema was an increase of at least 200 mL from the preoperative difference between the two arms. Assessments at two years were completed for 89% of the 55 women who were randomly assigned to either preventive group or control. Of the 49 who were measured at two years, 10 (21%) were identified with secondary lymphedema with an incidence of 8% in the preventive group and 33% in controls. The authors noted that these prophylactic strategies appear to reduce the development of secondary lymphedema and alter its progression. This was a relatively small study, and the various interventions used may have each played a role in the outcome for this study.

PRACTICE GUIDELINE SUMMARY

There are currently no clinical practice guidelines that recommend the use of bioimpedance devices for early detection or treatment of lymphedema.

SUMMARY

There is not enough research to show that bioimpedance improves health outcomes for people with known or suspected lymphedema. No clinical guidelines based on research recommend bioimpedance for people with known or suspected lymphedema. Therefore, use of bioimpedance is considered investigational in the diagnosis or management of patients with known or suspected lymphedema.

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CODES

Codes	Number	Description
CPT	93702	Bioimpedance spectroscopy (BIS), extracellular fluid analysis for lymphedema assessment(s)
HCPCS	None	

Date of Origin: *April 2011*