

Subject: Bioimpedance for Lymphedema Assessment		Original Effective Date: 2/2/2015
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DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (i.e., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina Clinical Policy (MCP) document and provide the directive for all Medicare members.¹

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DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

There are multiple bioimpedance techniques, including single-frequency bioimpedance analysis (SFBIA), multiple-frequency bioimpedance analysis (MFBIA), bioimpedance spectroscopy (BIS), and whole body bioimpedance. These techniques use a non-invasive device that measures the extracellular fluid volume differences between the limbs to aid in the clinical assessment of lymphedema. The test relies on the electrical conductivity of body fluid to detect lymphedema and involves passing an extremely small electrical current through the body and measuring the opposition to the flow of this current (defined as impedance).

Bioimpedance decreases as tissue fluid increases. To measure bioimpedance a nurse or physician attaches electrodes to the wrists or ankles of the patient and connects the electrodes to wires that lead to a lightweight measurement unit that can be held in one hand. This unit passes an imperceptible alternating electrical current through the electrodes and records the impedance at one or more frequencies. The data obtained are stored in the device, downloaded to a computer, and then analyzed using software provided by the device manufacturer. Bioimpedance assessment of lymphedema is typically performed on an outpatient basis and prescribed by an oncologist or a specialist in physical medicine and rehabilitation.²²

There are several types of devices cleared by the FDA for bioimpedance measurements, but 2 classes of products are most often used for the assessment of lymphedema: body composition analyzers and extracellular fluid monitors. Examples of one such device are the L-Dex U400 (ImpediMed Ltd.).³

RECOMMENDATION

Bioimpedance for the assessment, diagnosis, or management of individuals with known or suspected lymphedema is considered investigational/experimental and unproven due to insufficient evidence in the peer reviewed medical literature that that have not established safety, efficacy and effect on net health outcomes.

SUMMARY OF MEDICAL EVIDENCE⁴⁻²⁰

There is insufficient published evidence to assess the role of bioimpedance in the clinical assessment of patients with lymphedema, the safety and/or impact on health outcomes or patient management. The published evidence is from a very limited number of studies with small patient populations and is insufficient to provide definitive proof that bioimpedance is accurate or clinically useful. The published evidence consists of small randomized controlled trials (n<300), systematic reviews, clinical comparison, prospective comparison studies, and case series. Below is a summary of the most relevant evidence based studies.

The largest available study that compared bioimpedance with other techniques for assessment of lymphedema was performed by Hayes et al. (2008). This study enrolled 287 female breast cancer survivors (mean age 54 ± 10 years; treatments: 26% mastectomy, 87% lymph node dissection, 70% radiation, 40% chemotherapy and/or hormone therapy) who underwent bioimpedance, circumferential measurements, and self-assessment of lymphedema. Bioimpedance was measured with a SEAC SFB3 device (ImpediMed Ltd.). All 3 techniques were used at 3-month intervals for 1 year, beginning 6 months after surgery. Since results of these methods were not strongly correlated, bioimpedance was chosen as the standard and indicated that 34% of women experienced clinically significant lymphedema. Compared with bioimpedance, circumferential measurements had 42% sensitivity and 88% specificity for detection of lymphedema. For self-assessment, the sensitivity was 61% and the specificity was 59%. A serious shortcoming of this study is that bioimpedance was assumed to be the most accurate method, apparently with no attempt to evaluate whether it gave false-positive or false-negative results that were correctly assessed by the other measurement techniques.¹¹

A clinical comparison study by Fu et al. (2013) examined the reliability, sensitivity and specificity of bioimpedance spectroscopy in the detection of lymphedema. Circumferential tape measurement was used to validate the presence of lymphedema in 250 women. Bioimpedance was used to measure lymph fluid changes. The 250 women in the study included healthy females, breast cancer survivors with lymphedema, and those who were at risk for developing lymphedema. Bioelectrical impedance analysis, as indicated by L-Dex ratio,

was highly reliable among healthy women (ICC=0.99; 95% CI = 0.99 - 0.99), survivors at-risk for lymphedema (ICC=0.99; 95% CI = 0.99 - 0.99), and all women (ICC=0.85; 95% CI = 0.81 - 0.87); reliability was acceptable for survivors with lymphedema (ICC=0.69; 95% CI = 0.54 to 0.80). The bioimpedance ratio correlated with limb volume by sequential circumferential tape measurement. The L-Dex ratio had a diagnostic cutoff of $>+7$ which missed 20% of true lymphedema cases. The researchers concluded that it is important for clinicians to integrate other assessment methods (such as self-report, clinical observation, or perometry) to ensure the accurate detection of lymphedema.¹⁰

A 12-month prospective feasibility study by Blaney et al (2014) examined the efficacy of bioimpedance analysis (BIA) compared to circumferential measurements (CM) in detecting breast cancer-related lymphoedema (BCRL) in One hundred twenty-six participants with mean age of 59 years. The majority having stage I (63.9 %), infiltrating ductal carcinoma (87.4 %). 31.6 % were identified as having BCRL, 90.3 % detected by CM and 35.5 % by BIA ($p \leq 0.0001$). Researchers found no significant correlation between BIA and CM.⁵

The Agency for Healthcare Research and Quality (AHRQ, 2010) published a technology assessment that identified eight studies that reported the sensitivity and specificity of tests to diagnose secondary lymphedema and two of those studies evaluated bioimpedance devices. The report indicated that limb volume and circumference remain the gold standard tests to assess the presence of secondary lymphedema. In addition, this technology assessment concluded that there is insufficient evidence to assess the reliability of other tests to measure lymphedema which are under study such as perometry, ultrasound, lymphoscintigraphy, and bioimpedance.²

Barrio et al. (2015) compared bioimpedance (L-Dex) and VD measurements in a prospective cohort of breast cancer patients at risk for lymphedema. Between 2010 and 2014, a total of 223 breast cancer patients were enrolled. Following exclusions ($n = 37$), 186 received baseline VD and L-Dex; follow-up measurements were performed at 3-6 months intervals for 3 years. At each visit, patients fitted into one of three categories: normal (normal VD and L-Dex); abnormal L-Dex (L-Dex > 10 or increase in 10 from baseline and normal VD); or lymphedema (relative arm volume difference of $>10\%$ by VD \pm abnormal L-Dex). Change in L-Dex was plotted against change in VD; correlation was assessed using the Pearson correlation. At a median follow-up of 18.2 months, 152 patients were normal, 25 had an abnormal L-Dex, and 9 developed lymphedema without a prior L-Dex abnormality. Of the 25 abnormal L-Dex patients, 4 progressed to lymphedema, for a total of 13 patients with lymphedema. Evaluating all time points, 186 patients had 829 follow-up measurements. Sensitivity and specificity of L-Dex compared with VD were 75 and 93 %, respectively. There was no correlation between change in VD and change in L-Dex at 3 months ($r = 0.31$) or 6 months ($r = 0.21$). In conclusion, VD and bioimpedance demonstrated poor correlation with inconsistent overlap of measurements considered abnormal. Of patients with an abnormal L-Dex, few progressed to lymphedema; most patients with lymphedema did not have a prior L-Dex abnormality. Further studies are needed to understand the clinical significance of bioimpedance.¹⁸

Hayes, Inc.²²

According to a recent Health Technology Assessment (2020): “The best available studies of bioimpedance analysis (BIA) have found that the clinical performance and accuracy of Multiple frequency BIA (MFBIA) (i.e.,

bioimpedance spectroscopy or BIS) is similar to or somewhat lower than the accuracy of other techniques for lymphedema (LE) diagnosis, prediction of LE development, and guidance of LE treatment. With regard to clinical utility, although 7 of the reviewed studies investigated the capacity of MFBIA (BIS) to guide management of patients at risk for LE, these studies do not provide conclusive evidence of clinical utility. Additional studies are needed to determine the clinical role of BIS relative to established techniques such as manual CM, automated perometry, self-monitoring, and water displacement volumetry for LE diagnosis, prediction of LE development, and guidance of LE therapy.”²²

CODING INFORMATION THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

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

HCPCS	Description
	N/A

ICD-10	Description: [For dates of service on or after 10/01/2015]
I89-I89.0	Lymphedema code range

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Government Agency

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Revision/Review History:

2/2/15: New Policy

12/16/15, 9/15/16 & 6/22/17: Policy reviewed, no changes.

3/8/18: This policy was reviewed and this device remains controversial and experimental. The following sections were updated: summary of medical evidence and references.

9/18/19: Policy reviewed, no changes.

9/16/20: Policy reviewed, no changes. Added TOC and Hayes information. Updated references.