Molina Clinical Policy
Bioimpedance Analysis for Lymphedema Assessment: Policy No. 234

Last Approval: 10/12/2022
Next Review Due By: October 2023

OHIO MEDICAID: Molina Ohio Medicaid will not consider I/E references and will evaluate for medical necessity on an individual basis

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment and clinical recommendations for the Member. 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 (e.g., 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 MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

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 to measure 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 is held in one hand. The unit passes an imperceptible alternating electrical current through the electrodes and records the impedance at one or more frequencies. Data obtained are stored in the device, downloaded to a computer, and 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. (Hayes, 2021; Mehrara, 2021).

According to a Hayes Health Technology Assessment on *Bioelectrical Impedance Analysis for Assessment of Lymphedema,* studies of bioimpedance analysis (BIA) cite that clinical performance and accuracy of multiple frequency BIA (MFBIA) (e.g., 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. Only 7 of the reviewed studies investigated the capacity of MFBIA (BIS) to guide management of patients at risk for LE – these do not provide conclusive evidence of clinical utility. Additional studies are needed to determine the clinical role of BIS relative to established techniques (e.g., manual CM; automated perometry; self-monitoring; water displacement volumetry for LE diagnosis; prediction of LE development; guidance of LE therapy). (Hayes, 2021).

Several types of devices have been FDA-approved for bioimpedance measurements but, 2 classes of products are most often used for the assessment of lymphedema: body composition analyzers and extracellular fluid monitors. One device is the L-Dex U400 which is a bioelectrical impedance analyzer/monitor that utilizes impedance ratios to support the measurement of extra cellular fluid volume differences between the arms. This also aids in the clinical assessment of woman with unilateral lymphedema of the arm. (FDA, 2008).

COVERAGE POLICY

Bioimpedance devices (including the L-Dex U400) for the assessment, diagnosis, or management of Members with known or suspected lymphedema **is considered experimental, investigational, and unproven** due to insufficient evidence in peer reviewed medical literature that that have not established safety, efficacy, and effect on net health outcomes. (Hayes, 2021; AMR, 2018).

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

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. Published evidence consists of small randomized controlled trials (n < 300), systematic reviews, clinical comparison, prospective comparison studies, and case series.

Hayes et al. (2011) reported on the largest available study that compared bioimpedance with other techniques for assessment of lymphedema. The study enrolled 287 female breast cancer survivors – mean age 54 ± 10 years; treatments: mastectomy (26%), lymph node dissection (87%), radiation (70%), chemotherapy and/or hormone therapy (40%). Participants underwent bioimpedance, circumferential measurements, and self-assessment of lymphedema. Bioimpedance was measured with a SEAC SFB3 device. All three techniques were used at three-month intervals for one year, beginning six months after surgery. Results of these methods were not strongly correlated however, 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%. Of note, bioimpedance was assumed to be the most accurate method, with no attempt to evaluate whether false-positive or false-negative results were correctly assessed by the other measurement techniques.

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. Participants 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. Integration of other assessment methods (self-report, clinical observation, perometry) is important to ensure accurate detection of lymphedema.

A 12-month prospective feasibility study by Blaney et al. (2015) examined the efficacy of bioimpedance analysis (BIA) compared to circumferential measurements (CM) in detecting breast cancer-related lymphoedema (BCRL) in 126 participants (mean age 59 years). The majority of participants had Stage I (63.9 %), infiltrating ductal carcinoma (87.4 %) – 31.6 % were identified as having BCRL with 90.3 % detected by CM and 35.5 % by BIA (p = ≤0.0001). Researchers found no significant correlation between BIA and CM.

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 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 ± 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 (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). VD and bioimpedance demonstrated poor correlation with inconsistent overlap of measurements considered abnormal. Few patients with an abnormal L-Dex 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.

Dylke and Ward (2021) published a review of Bioelectrical Impedance Spectroscopy (BIS) over the last 30 years. It was recognized to possibly adapt BIS protocols in order to measure an increase in lymph volume. By the early 1990s, BIS was used for the early detection of breast cancer-related lymphedema. Over the last 20 years, BIS has become a widely accepted method for lymphedema assessment.

National and Specialty Organizations

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.

The **National Lymphedema Network (NLN)** (2011) published a position statement titled *Screening and Measurement for Early Detection of Breast Cancer-Related Lymphedema: The Imperative*. The statement outlines research conducted and states a need for additional research and education regarding lymphedema and breast cancer.

SUPPLEMENTAL INFORMATION

None.

CODING & BILLING INFORMATION

CPT Code

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

HCPCS Codes – N/A

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

10/12/2022 Policy reviewed, no changes to criteria.
10/13/2021 Policy reviewed, no changes to criteria, added to Overview and Summary of Medical Evidence sections, updated references.
9/16/2020 Policy reviewed, no changes to criteria, added Hayes information and updated references.
9/18/2019 Policy reviewed, no changes.
3/8/2018 Policy reviewed, no changes to criteria, updated Summary of Medical Evidence section and references.
12/16/2015, 9/15/2016, 6/22/2017 Policy reviewed, no changes.
2/2/2015 New policy.

REFERENCES

Government Agencies

1. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database (no National Coverage Determination identified). Available from CMS. Accessed August 17, 2022.
2. Food and Drug Administration (FDA). 510(k) summary: ImpediMed L-Dex U400 BIS extra cellular fluid analysis. Available from FDA. Published October 3, 2008. Accessed August 17, 2022.

Evidence Based Reviews and Publications

1. AMR Peer Review. Policy reviewed on February 1, 2018 by an Advanced Medical Reviews (AMR) practicing, board-certified physician in the areas of Family Medicine and Geriatric Medicine.
2. Hayes. Health technology assessment: Bioelectrical impedance analysis for assessment of lymphedema. Available from Hayes. Updated September 17, 2021. Accessed August 17, 2022. Registration and login required.
3. Mehrara B. Clinical features and diagnosis of peripheral lymphedema. Available from UpToDate. Updated June 11, 2021. Accessed August 17, 2022. Registration and login required.

Peer Reviewed Publications

1. Barrio AV, Eaton A, Frazier TG. A Prospective Validation Study of Bioimpedance with Volume Displacement in Early-Stage Breast Cancer Patients at Risk for Lymphedema. Ann Surg Oncol. 2015 Dec;22 Suppl 3:S370-5. doi: 10.1245/s10434-015-4683-0. Accessed Aug. 17, 2022.
2. Blaney JM, McCollum G, Lorimer J, Bradley J, Kennedy R, Rankin JP. Prospective surveillance of breast cancer-related lymphoedema in the first-year post-surgery: Feasibility and comparison of screening measures. Support Care Cancer. 2015 Jun;23(6):1549-59. doi: 10.1007/s00520-014-2504-9. Accessed August 17, 2022.
3. Dylke ES, Ward LC. Three decades of bioelectrical impedance spectroscopy in lymphedema assessment: An historical perspective. Lymphat Res Biol. 2021 Jun;19(3):206-214. doi: 10.1089/lrb.2020.0085. Accessed August 17, 2022.
4. Fu MR, Cleland CM, Guth AA, Kayal M, Haber J, Cartwright F, et al. L-dex ratio in detecting breast cancer-related lymphedema: reliability, sensitivity, and specificity. Lymphology. 2013 Jun;46(2):85-96. Available here. Accessed August 17, 2022.
5. Hayes SC, Speck RM, Reimet E, Stark A, Schmitz KH. Does the effect of weight lifting on lymphedema following breast cancer differ by diagnostic method: Results from a randomized controlled trial. Breast Cancer Res Treat. 2011 Nov;130(1):227-34. doi: 10.1007/s10549-011-1547-6. Accessed August 17, 2022.

National and Specialty Organizations

1. Agency for Healthcare Research and Quality (AHRQ). Technology assessment: Diagnosis and treatment of secondary lymphedema. Available from AHRQ. Published May 28, 2010. Accessed August 17, 2022.
2. National Lymphedema Network (NLN). Position statement: Screening and measurement for early detection of breast cancer-related lymphedema – the imperative. Available from NLN. Published April 2011. Accessed August 17, 2022.

Other Peer Reviewed and Professional Organization Publications (used in the development of this policy)

1. Bundred NJ, Stockton C, Keeley V, et al. Comparison of multi-frequency bioimpedance with perometry for the early detection and intervention of lymphoedema after axillary node clearance for breast cancer. Breast Cancer Res Treat. 2015 May;151(1):121-9. doi: 10.1007/s10549-015-3357-8. Accessed August 17, 2022.
2. Dylke ES, Schembri GP, Bailey DL, et al. Diagnosis of upper limb lymphedema: Development of an evidence-based approach. Acta Oncol. 2016 Dec;55(12):1477-1483. doi: 10.1080/0284186X.2016.1191668. Accessed August 17, 2022.
3. Hidding JT, Viehoff PB, Beurskens CH, et al. Measurement properties of instruments for measuring of lymphedema: Systematic review. Phys Ther. 2016 Dec;96(12):1965-1981. doi: 10.2522/ptj.20150412. Accessed August 17, 2022.
4. Lahtinen T, Seppälä J, Viren T, Johansson K. Experimental and analytical comparisons of tissue dielectric constant (TDC) and bioimpedance spectroscopy (BIS) in assessment of early arm lymphedema in breast cancer patients after axillary surgery and radiotherapy. Lymphat Res Biol. 2015 Sep;13(3):176-85. doi: 10.1089/lrb.2015.0019. Accessed August 17, 2022.
5. Shah C, Arthur DW, Wazer D, et al. The impact of early detection and intervention of breast cancer-related lymphedema: A systematic review. Cancer Med. 2016 Jun;5(6):1154-62. doi: 10.1002/cam4.691. Accessed August 17, 2022.

APPENDIX

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

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