

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria Bioimpedance Spectroscopy

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, <i>Bioimpedance Spectroscopy</i> , for medical necessity determinations. Refer to the Non-Medicare criteria below.

For Non-Medicare Members

Kaiser Permanente has elected to use the Bioimpedance Spectroscopy (A-0667) MCG* for medical necessity determinations. This service is not covered per MCG guidelines. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

*MCG Manuals are proprietary and cannot be published and/or distributed. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363.

If requesting this service, please send the following documentation to support medical necessity:

Last 6 months of clinical notes from requesting provider

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Lymphedema is a chronic progressive disorder of the lymphatic system characterized by interstitial accumulation of protein rich fluid. This occurs when lymphatic transport is reduced causing lymphatic stasis and subsequent protein accumulation within tissues. Accumulation of protein and fluid in the tissues triggers an inflammatory response and swelling that eventually leads to fibrosis. Primary lymphedema is rare and results from congenital anatomic abnormalities of the lymphatic system such as lymphatic hypoplasia or dysfunction of lymphatic valves. Secondary lymphedema on the other hand, is more common and may result from disease, trauma, surgery, or radiation therapy. In the United States, the most common cause of secondary lymphedema is malignancy and its related treatment, particularly in breast cancer patients treated with axillary surgery and/or

radiation therapy (Warren 2007).

The proportion of women who develop breast cancer-related lymphedema (BCRL) is estimated to range from 3-15% for women who had sentinel node biopsy and up to 49% among those who underwent axillary lymph node dissection. This big variation in reported incidence of lymphedema is due to lack of a standardized assessment and differences in diagnostic criteria. Lymphedema may cause limb swelling, heaviness, pain, pitting of the skin, tightness, inflammation, reduced mobility, and impaired limb function (Taylor 2006, Smoot 2011).

Accurate assessment of lymphedema may facilitate earlier diagnosis and monitoring of treatment response. Physical assessment of BCRL is performed by comparing the affected versus the unaffected arm, or by comparing postoperative with preoperative measurements. Physical measurements used include limb circumferential assessment with a tape measure, and limb volume measurement using water displacement or optoelectrical perometry (also known as infrared volumetry). Circumferential measurement is the most common clinical assessment measure used. Limb circumference is used to calculate volume by assuming either cylindrical or truncated cone geometry. It thus indirectly measures the limb volume and may be confounded by changes in muscle and fat mass. In addition, it may be hard to use for the hand due to its irregular shape. Water volumetry or displacement, in which the limb is lowered in a water tank, has been considered by many as the reference method for determining limb volume. It is a reliable method and provides a way of including volumetric measurements of the hand or foot in the total limb volume measurements. However, water displacement cannot distinguish changes due to fat or muscle from extracellular fluid accumulation. The Perometer is an opto-electrical device that has a square frame in which the extended extremity is placed. The frame emits infrared light and slides up and down scanning the patient's extremity and recording cross sectional information every 3 mm. Limb volume is then calculated based on the assumption that the cross-section is an ellipse or circle. Many investigators consider perometry the modern gold standard for the assessment of limb volume. It is however, bulky in size, not available in most clinics, and cannot be used for bed- ridden patients. In more challenging cases radiologic imaging studies as lymphoscintigraphy, magnetic resonance imaging, or computerized tomography may be necessary to diagnose lymphedema (Sander 2002, Warren 2007, Jain 2010, Czerniec 2010, Smoot 2011).

While circumference and volume measures are reliable measures for changes in limb volume, they are not specific to lymphedema. Bioimpedance analysis (BIA) or bioimpedance spectroscopy (BIS) has been proposed as an alternate method to differentiate the extracellular fluid compartment from the total limb volume. It attempts at measuring lymph volume directly and detecting early increase in the extracellular fluid at a subclinical stage of lymphedema before it is manifests as a change limb volume.

BIS is a noninvasive procedure that uses skin electrodes to pass a low-level alternating current through the limb and measures the opposition or impedance to the flow of this current. Current flows along the path of least resistance through the body and thus follows tissues with the highest water content. Tissues as fat and bone act as insulators, while electrolyte body fluids conduct electrical current and as the fluid increases, impedance to current flow decreases, i.e. changes in impedance are inversely proportional to the volume of the extracellular fluid in the extremity the level of impedance is not only a function of the type of tissue, but also the frequency of the current. At low frequencies, cell membranes are non-conductive and current passes only through the extracellular fluid, while at high frequencies, the current passes through cell membranes in addition to the extra-and intracellular fluids. BIS thus gives a measure of electrical impedance and not volume (Warren 2007, Jain 2010, Czerniec 2010).

Medical Technology Assessment Committee (MTAC)

Bioimpedance Lymph Analysis

06/20/2011: MTAC REVIEW

Evidence Conclusion: The 2010 report prepared for the AHRQ assessed the diagnosis

and treatment of secondary lymphedema in general, not specifically for cancer breast-related lymphedema. However, the reviewers indicated that most of the diagnostic studies involved patients with breast cancer. They noted that based on the evidence from the studied reviewed, there does not appear to be a gold standard for grading or measuring the severity of lymphedema. However, based on the extent of use and consistent evidence for reliability and validity, the reviewers of the AHRQ report recommend that measures of limb volume or circumference be considered the gold standard for diagnosing secondary lymphedema. They indicated that

© 2011, Kaiser Foundation Health Plan of Washington. All Rights Reserved. Back to Top there was very little evidence to allow making conclusions about the reliability of bioimpedance lymph analysis (BIA) which was listed among other tests. BIA was found to have good validity when compared with tape measured circumference or perometry, but lower correlation coefficients than those for the circumference-displacement comparisons. The AHRQ report also indicated that the diagnostic testing studies do not provide sufficient evidence to determine whether any of the test methods would influence the choice of lymphedema treatment or patient outcome. Two more recent studies published after the AHRQ report and critically appraised for this MTAC review do not provide any additional evidence on the accuracy, validity or reliability of BIA, or on its impact on patient management or outcome.

<u>Articles</u>: The search revealed a recent comprehensive review on the diagnosis and treatment of secondary lymphedema prepared for the Agency for Healthcare Research and Quality (AHRQ) Technology Assessment (TA) Program in May 2010. The literature search for this AHRQ report was made through January 2010. Two more recent studies that compared the accuracy and/or reliability of BIS to other physical measures used for the assessment of breast cancer-related lymphedema were critically appraised. <u>Czerniec SA</u>, <u>Ward LC</u>, <u>Refshauge KM</u>, et al Assessment of breast cancer-related arm lymphedema--comparison of physical measurement methods and self-report. <u>Cancer Invest.</u> 2010; 28:54-62. See <u>Evidence Table</u>. Smoot BJ, Wong JF, Dodd MJ. Comparison of diagnostic accuracy of clinical measures of breast cancer-related lymphedema: Area under the curve. *Arch Phys Med Rehabil.* 2011; 92:603-610. See <u>Evidence Table</u>.

The use of bioimpedance lymph analysis does not meet the Kaiser Permanente Medical Technology Assessment Criteria.

Applicable Codes

Considered Not Medically Necessary

CPT [®] or HCPC Codes	Description
0358T	Bioelectrical impedance analysis whole body composition assessment, with interpretation and report
93702	Bioimpedance spectroscopy (BIS), extracellular fluid analysis for lymphedema assessment(s)

*Note: Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

**To verify authorization requirements for a specific code by plan type, please use the <u>Pre-authorization Code</u> <u>Check.</u>

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MPC Medical Policy Committee

Review History	Description