Clinical Policy Title: Bioimpedance devices for detecting lymphedema

Clinical Policy Number: 05.01.06

Effective Date: June 1, 2017
Initial Review Date: April 19, 2017
Most Recent Review Date: April 10, 2018
Next Review Date: April 2019

Related policies:
None.

ABOUT THIS POLICY: Select Health of South Carolina has developed clinical policies to assist with making coverage determinations. Select Health of South Carolina’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by Select Health of South Carolina when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Select Health of South Carolina’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Select Health of South Carolina’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Select Health of South Carolina will update its clinical policies as necessary. Select Health of South Carolina’s clinical policies are not guarantees of payment.

Coverage policy

Use of bioimpedance devices for detecting lymphedema has not been clinically proven, and therefore, is not medically necessary (Barrio, 2015; Blaney, 2015; Bundred, 2015; Choi, 2014; Hayes, 2015).

Limitations:
None.

Alternative covered services:

Various radiographic, imaging, and other methods of detecting lymphedema.

Background

Lymphedema is a swelling in the interstitial space due to accumulation of protein rich fluid that results from congenital or acquired damage to the lymphatic system. There are four stages of the disease, with 0 being the least severe and 3 being the most severe (International Society of Lymphology [ISL], 2009).
Primary lymphedema refers to congenital cases of the disease that manifest before age two; lymphedema praecox, which occurs at puberty; and lymphedema tarda, which occurs after age 35. The more common secondary lymphedema refers to cases acquired from disruption to the lymphatic system, from disease, trauma, surgery, or radiation (Oremus, 2010). Primary lymphedema is a result of improper lymphatic development not linked to injury, trauma, illness, or disease (Morgan, 2008). Globally, filarial larvae from a mosquito bite that develop into worms that damage the lymphatic system is the most common etiology of secondary lymphedema. In the U.S., malignancies and related treatments (radiation, surgery) are the most common causes of secondary lymphedema.

Lymphedema is common in post-treatment cancer patients, especially breast cancer. A trial of 936 women with breast cancer who underwent sentinel lymph node biopsy found 5 percent had upper extremity secondary lymphedema. In those who also underwent axillary lymph node dissection, the incidence climbed to 16 percent (McLaughlin, 2008). The rate of upper extremity lymphedema after mastectomy was estimated to be 24 to 49 percent (Warren, 2007). Incidence of upper extremity lymphedema in breast cancer patients five years after diagnosis has been estimated at 40 percent (Armer, 2010; Norman, 2009). Of 664 auxiliary node dissection patients with and without radiation therapy, 30 and 19 percent developed lymphedema (Miller, 2014). Five to 49 percent of women treated for cervical, endometrial, and vulvar malignancies are diagnosed with lymphedema (Rockson, 2008).

Lymphedema is usually diagnosed through history and physical examination; in some cases, computed tomography, magnetic resonance imaging, and lymphoscintigraphy are used (Simonian, 2008). Severity of cases is classified by the difference in circumference between affected and unaffected arms, with larger numbers being more severe. Typically, one to two assessments of circumference are made before, during, and after the patient’s treatment.

Treatments for lymphedema include non-surgical interventions, including compression techniques, decongestive therapy, manual lymphatic drainage, exercise, laser treatment, ultrasound, and aquatherapy. Physicians, massage therapists, and nurses can administer treatments. Surgery may also be performed when needed (Oremus, 2010). Surveillance programs can include circumferential arm measures, perometry, bioimpedance, exercise programs, prophylactic/early intervention compression garments, and referral for complete decongestive therapy (Ostby, 2014).

Bioimpedance, an abbreviation for bioelectrical impedance spectroscopy, is a means of diagnosing lymphedema up to a frequency level of 30 kHz. Above that level, the technique is not reliable (Gaw, 2011). The test uses resistance to electrical current in comparing composition of fluid compartments to help diagnose lymphedema. Treatments are administered in a clinical setting, but have been demonstrated to produce accurate results when the patient self-administers at home (Ridner, 2014). Patients lie supine when the test is administered.
Select Health of South Carolina searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on February 28, 2018. Search terms were: “bioimpedance” and “lymphedema” and “breast cancer.”

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews.**
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

To date, no professional society guidelines have been issued on use of bioimpedance after cancer treatment. In November 2016, recommendations for techniques, protocols, and detection were issued by three radiation oncologists from Ohio, Michigan, and Virginia, who summarize data supporting use of the procedure for recently-treated breast cancer patients. Authors identify higher-risk patients as those who underwent mastectomy, auxiliary lymph node dissection, sentinel node biopsy (over six nodes sampled), regional nodal irradiation, or taxene based chemotherapy (Shah, 2016). A report of the American College of Radiology on upper extremity swelling did not mention bioimpedance (Dill, 2014).

A 2015 Hayes review of 25 studies on bioimpedance spectroscopy included only two randomized controlled trials (RCTs); authors rated evidence as very low quality (Hayes, 2015). The panel declared that insufficient evidence on lymphedema detection or assessment from bioimpedance exists. Moreover, very limited evidence exists on clinical utility or the impact of bioimpedance on patient management or outcomes. The technology was compared with bioelectrical impedance analysis, dual-energy X-ray absorptiometry, circumferential measurement, perometry, and self-reporting.

A comprehensive literature review concluded that bioimpedance spectroscopy is an accurate diagnostic tool for pre-existent lymphedema, but has not been validated for early detection (Seward, 2016). A systematic review found that bioimpedance was highly accurate in measuring lymphedema in the lower extremities (Interrater Correlation Coefficient .89), at but not in higher extremities, in which coefficients for water volumetry, tape measurement, and perometry were .98 to .99 (Hidding, 2016).
Several analyses have compared bioimpedance with perometry arm measurement, with mixed results. In a report to the Agency for Health Research and Quality, correlation coefficients for bioimpedance were between 0.61 and 0.99, lower than methods like perometer and tape measure of the arm (ISL, 2009). A study to predict development of lymphedema in 964 breast cancer patients who underwent axillary node clearance found arm volume measurement remains the gold standard (Bundred, 2015).

Other studies found bioimpedance to be an accurate means of identifying women with lymphedema, compared to arm measurement (Smoot, 2011). One found it to produce inter-limb ratios similar to perometry for women without lymphedema, but higher ratios for women with the disorder (Czerniec 2011). Bioimpedance was similar to perometry in its ability to predict water volumes in arms of women with and without lymphedema (Ward, 2009).

Various studies determined that bioimpedance was less effective in identifying or predicting lymphedema, compared to other methods:

**Arm Circumference Measurement.** A study of 73 patients found that compared to upper and lower arm circumference, extracellular fluid was correlated, but bioimpedance was only correlated with arm circumference below the elbow (Kim, 2011).

**Ultrasound.** Reports determined bioimpedance failed to accurately predict compressibility from ultrasound (Choi, 2014), and identified lymphedema in 31.6 percent of cases, much less than the 90.3 percent figure with circumferential measurement (Blaney, 2015). An analysis found that compressibility in the arms of breast-cancer related lymphedema determined by ultrasound was not as accurate when bioimpedance or circumferential measurement was used (Choi, 2014).

**Tonometry.** Although bioimpedance of changes in post-operative breast fluid levels and tonometry of changes in tissue resistance to compression were both found to be reliable, ranges of covariance for tonometry (1.29 to 3.25 percent) were higher than bioimpedance (0.20 to 0.86) (Moseley, 2008).

**Tissue Dielectric Constant.** In 100 women surgically treated for breast cancer tested for lymphedema, bioimpedance spectroscopy had lower sensitivity (42.1 vs. 65.8 percent), and similar specificity (93.5 vs. 83.9 percent) compared to tissue dielectric constant. Affected to contralateral arm ratios for upper arm (1.12 vs. 1.56) and forearm (1.12 vs. 1.28) were lower for bioimpedance (Lahtinen, 2015).

**Volume Displacement.** After (median) follow up of 18.2 months of 186 breast cancer patients, the sensitivity and specificity of bioimpedance compared with volume displacement were 75 and 93 percent, considered a poor correlation. Volume displacement was considered by the authors as the gold standard for measuring breast cancer-related lymphedema (Barrio, 2015).
An analysis of cost savings for a managed care company estimated that $315,711, or 3 cents per member per month, was realized by using bioimpedance on 627 women with breast cancer. Most savings resulted from fewer infections or hospitalizations (Bilir, 2012).

Policy updates:

In 2018, we did not identify any new relevant literature.

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tbody>
<tr>
<td>Hayes (2015)</td>
<td>Key points:</td>
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</table>
| Review of studies on bioimpedance spectroscopy | • 25 studies, only two were RCTs (very low quality evidence)  
• Comparison of bioimpedance with dual energy X-ray absorptiometry, circumference measurement, perometry, and self-reporting  
• Insufficient evidence exists on clinical utility or impact on patient management or outcomes |
| Lahtinen (2015)  | Key points:                       |
| Compares bioimpedance with tissue dielectric constant for early diagnosis of lymphedema | • 100 women treated for breast cancer with surgery, axillary dissection, and radiotherapy  
• Affected and contralateral arms measured with tissue dielectric constant and bioimpedance spectroscopy  
• Sensitivity significantly higher for TDC (65.8% vs. 42.1%)  
• Specificity not significantly lower for TDC (83.9% vs. 93.5%)  
• TDC ratios for upper arm and forearm (1.56 and 1.28) both significantly greater than for bioimpedance (1.12) |
| Bundred (2015)   | Key points:                       |
| Bioimpedance vs. perometer arm measurement to predict lymphedema development | • Study of 964 women who underwent axillary node clearance to enable early intervention  
• 612 women had a minimum six months of follow-up data, using perometer arm measurement and bioimpedance electrical analysis, to detect lymphedema  
• Modest correlation (r=0.60) between two methods after six months  
• Authors conclude arm measurement remains gold standard for detecting lymphedema |
| Bilir (2012)     | Key points:                       |
| Economic outcomes of bioimpedance spectroscopy to detect lymphedema | • 627 breast cancer patients enrolled in managed care plan, treated with bioimpedance spectroscopy  
• Cost savings was $315,711, or 3 cents per enrolled member per month |

References

Professional society guidelines/other:


Peer-reviewed references:

Armer JM, Stewart BR. Post-breast cancer lymphedema: incidence increases from 12 to 30 to 60 months. Lymphology. 2010;43(3):118-127.


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cancer-related arm lymphedema using perometry and bioimpedance spectroscopy. Support Care

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Hidding JT, Viehoff PB, Beurskens CH, van Laarhoven HW, Nijhuis-van der Sanden MW, van der Wees PJ.

International Society of Lymphology (ISL). The diagnosis and treatment of peripheral lymphedema. 2009

Kim L, Jeon JY, Sung IY, Jeong SY, Do JH, Kim HJ. Prediction of treatment outcome with bioimpedance

Lahtinen T, Seppala 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

years after sentinel lymph node biopsy or axillary dissection: objective measurements. J Clin Oncol.

Miller CL, Specht MC, Skolny MN, et al. Risk of lymphedema after mastectomy: potential benefit of

Moseley A, Piller N. Reliability of bioimpedance spectroscopy and tonometry after breast conserving

Norman SA, Localio AR, Potshnik SL, et al. Lymphedema in breast cancer survivors: incidence, degree,

Ostby PL, Armer JM, Dale Ps, Van Loo MJ, Wilbanks CL, Stewart BR. Surveillance recommendations in


**CMS National Coverage Determinations (NCDs):**

No NCDs identified as of the writing of this policy.

**Local Coverage Determinations (LCDs):**


**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

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<th>Comments</th>
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