Bioimpedance Devices for Detection and Management of Lymphedema

Policy # 00780
Original Effective Date: 06/01/2022
Current Effective Date: 06/01/2022

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Surgical Treatments for Breast Cancer-Related Lymphedema is addressed separately in medical policy 00635.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers devices using bioimpedance (bioelectrical impedance spectroscopy) for use in the diagnosis, surveillance, or treatment of patients with lymphedema, including use in subclinical secondary lymphedema. to be **investigational.***

Background/Overview

Lymphedema

Lymphedema is an accumulation of fluid due to disruption of lymphatic drainage. Lymphedema can be caused by congenital or inherited abnormalities in the lymphatic system (primary lymphedema) but is most often caused by acquired damage to the lymphatic system (secondary lymphedema). Breast cancer treatment is one of the most common causes of secondary lymphedema. Both the surgical removal of lymph nodes and radiotherapy are associated with development lymphedema in patients with breast cancer. In a systematic review of 72 studies (N=29612 women), DiSipio et al (2013) reported that approximately 1 in 5 women who survive breast cancer will develop arm lymphedema. Risk factors for development of lymphedema that had a strong level of evidence were extensive surgery (ie, axillary-lymph-node dissection, greater number of lymph nodes dissected, mastectomy) and being overweight or obese.

Diagnosis and Staging

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A diagnosis of secondary lymphedema is based on history (e.g., cancer treatment, trauma) and physical examination (localized, progressive edema and asymmetric limb measurements) when other causes of edema can be excluded. Imaging, such as MRI, computed tomography, ultrasound, or lymphoscintigraphy, may be used to differentiate lymphedema from other causes of edema in diagnostically challenging cases.

Table 1 lists International Society of Lymphology guidance for staging lymphedema based on "softness" or "firmness" of the limb and the changes with an elevation of the limb.

Table 1. Recommendations for Staging Lymphedema

Stage	Description
Stage 0 (subclinical)	Swelling is not evident and most patients are asymptomatic despite impaired lymphatic transport
Stage I (mild)	Accumulation of fluid that subsides (usually within 24 hours) with limb elevation; soft edema that may pit, without evidence of dermal fibrosis
Stage II (moderate)	Does not resolve with limb elevation alone; limb may no longer pit on examination
Stage III (severe)	Lymphostatic elephantiasis; pitting can be absent; skin has trophic changes

Management and Treatment

Lymphedema is treated using elevation, compression, and exercise. Conservative therapy may consist of several features depending on the severity of the lymphedema. Patients are educated on the importance of self-care including hygiene practices to prevent infection, maintaining ideal body weight through diet and exercise, and limb elevation. Compression therapy consists of repeatedly applying padding and bandages or compression garments. Manual lymphatic drainage is a light pressure massage performed by trained physical therapists or by patients designed to move fluid from obstructed areas into functioning lymph vessels and lymph nodes. Complete decongestive therapy is a multiphase treatment program involving all of the previously mentioned conservative treatment components at different intensities. Pneumatic compression pumps may also be considered as an adjunct to conservative therapy or as an alternative to self-manual lymphatic drainage in patients who have difficulty performing self-manual lymphatic drainage. In patients with more

advanced lymphedema after fat deposition and tissue fibrosis has occurred, palliative surgery using reductive techniques such as liposuction may be performed.

Bioimpedance Spectroscopy
Bioimpedance spectroscopy is based on the theory that the level of opposition to the 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.

Bioimpedance has been proposed as a diagnostic test for this condition. In usual care, lymphedema is recognized clinically or via limb measurements. However, management via bioelectrical impedance spectroscopy has been proposed as a way to implement early treatment of subclinical lymphedema to potentially reduce its severity.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
Devices that have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process to aid in the assessment of lymphedema are summarized in Table 2.

Table 2. FDA Cleared Bioimpedance Spectroscopy Devices for Lymphedema

Year	Device	Manufacturer	510(k) Number	Indication
2018	SOZO	ImpediMed (Carlsbad, CA)	K180126	For adults at risk of lymphedema. Supports the measurement of extracellular fluid volume differences between the limbs and is presented to the clinician on an L-Dex scale as an aid to their clinical assessment of lymphedema.

				The device is only indicated 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)	K143310	Supports local assessment of tissue water differences between affected and contralateral non-affected arm tissues to aid in forming a clinical judgment of unilateral lymphedema in women. The device is not intended to make diagnosis or predict arm lymphedema.
2007	ImpediMed L-Dex™‡ U400	ImpediMed (Carlsbad, CA)	K050415	Supports the measurement of extracellular fluid volume differences between the arms to aid in the clinical assessment of unilateral lymphedema of the arm in women. This device is not intended to diagnose or predict

				lymphedema of an extremity.

FDA product code: OBH.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Secondary lymphedema may develop following treatment for breast cancer. Bioimpedance, which uses resistance to electrical current to compare the composition of fluid compartments, could be used as a tool to diagnose lymphedema.

For individuals who have known or suspected lymphedema who receive bioimpedance spectroscopy, the evidence includes a systematic review, 1 RCT, 1 prospective comparative observational study, and multiple uncontrolled observational studies. Relevant outcomes are test validity, symptoms, and quality of life. Diagnostic accuracy studies have found a poor correlation between bioimpedance analysis and the reference standard (volume displacement or circumferential measurement). Interim results from an ongoing RCT comparing bioimpedance with standard tape measure following treatment for breast cancer have been published. Overall, 109 of 508 (21.5%) patients received early treatment due to reaching a pre-determined threshold to trigger an intervention. A total of 12 triggering patients progressed to clinical lymphedema (2 in the bioimpedance group [4.9%] and 10 in the tape measure group [14.7%]; P=0.130). The RCT was limited by its open-label design and lack of reporting of important health outcomes. The single prospective comparative study found a significantly lower rate of clinical lymphedema in patients managed with bioimpedance devices but had several limitations, including nonrandomized design, lack of blinding, lack of complete data on a substantial proportion of enrolled patients, and lack of a systematic method for diagnosing lymphedema in the control group. Retrospective studies suggested that postoperative bioimpedance monitoring is feasible but provide limited information about its efficacy. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

Clinical Input From Physician Specialty Societies and Academic Medical Centers
While the various physician specialty societies and academic medical centers may collaborate and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 2 specialty societies and 2 academic medical centers while this policy was under review in 2011. Three of 4 reviewers agreed that bioimpedance devices are considered investigational for diagnosis, surveillance, and treatment of patients with lymphedema. The fourth reviewer, from an academic medical center, considered the use of the technology a reasonable alternative, especially in situations in which minor lymphedema can have a large impact on a patient. One specialty society supported further research into the effectiveness of this technology and recommended reimbursement in the context of relevant clinical trials.

Practice Guidelines and Position Statements
National Comprehensive Cancer Network Clinical Practice Guidelines on Survivorship (v.2.2020) and Breast Cancer (v.6.2020) recommend education, monitoring, and referral for lymphedema management as needed. Neither guideline mentions bioimpedance.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 3.

Table 3. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date

Ongoing			
NCT03978754	Assessment of Breast Cancer-Related Arm Lymphedema—Comparison of Traditional Measurement Methods and Indocyanine Green (ICG) Lymphography	300	Jan 2022 (recruiting as of Jun 2019)
NCT02743858	A Prospective Surveillance Program for Assessment and Treatment of Breast Cancer-Related Lymphedema After Axillary Lymph Node Dissection	850	Apr 2021 (recruiting as of Feb 2020)
NCT01544335	Evaluation of the Validity of BIS as a Tool for Quantification of Lymphedema Through Comparison With Perometry and Self-Report	27 0	Dec 2020
Unpublished			

BIS: bioimpedance spectroscopy; NCT: national clinical trial.

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Policy History

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03/03/2022 Medical Policy Committee review
03/09/2022 Medical Policy Implementation Committee approval. New policy.
Next Scheduled Review Date: 03/2023

Coding

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	93702
HCPCS	No codes
ICD-10 Diagnosis	I97.2, Z90.10-Z90.13

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or

diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

1. Consultation with technology evaluation center(s);
2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

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NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.