Effective November 1, 2023, refer to CMS Manual 100-02, Chapter 16-General Exclusions from Coverage for services included in this policy.

BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Bioimpedance Devices for Detection of Lymphedema

Policy #: 438
Latest Review Date: January 2023
Category: Medicine
ARCHIVED EFFECTIVE 11/1/2023

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Effective for dates of service March 24, 2020 and after:

Blue Advantage will treat **devices using bioimpedance** (bioelectrical impedance spectroscopy) as a **non-covered benefit** and as **investigational** for use in the diagnosis, surveillance or treatment of patients with lymphedema, including use in subclinical secondary lymphedema.

Effective for dates of service March 1, 2017 through March 23, 2020, refer to LCD L36954.

Effective for dates of service prior to March 17, 2017:

Blue Advantage will treat **devices using bioimpedance (bioelectrical impedance spectroscopy)** as a **non-covered** benefit and as **investigational** for use in the diagnosis, surveillance, or treatment of patients with lymphedema, including use in subclinical secondary lymphedema.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

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

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=29,612 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 (i.e., axillary-lymph-node dissection, greater number of lymph nodes dissected, mastectomy) and being overweight or obese.

Diagnosis and Staging
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 (magnetic resonance imaging), computed tomography, ultrasound, or lymphoscintigraphy, may be used to differentiate lymphedema from others 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.

KEY POINTS:
The review has been updated regularly with MEDLINE searches, most recently through October 17, 2022.

Summary of Evidence:
For individuals who have known or suspected lymphedema who receive bioimpedance spectroscopy, the evidence includes a systematic review, one RCT, one prospective comparative observational study, and multiple uncontrolled observational studies. The 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.

Practice Guidelines and Position Statements
National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines on Survivorship (v.1.2022), and Breast Cancer (v.4.2022), recommend education, monitoring, and referral for lymphedema management as needed. Neither guideline mentions bioimpedance.

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

KEY WORDS:

Bioelectrical impedance testing, Bioimpedance spectroscopy, Lymphedema, bioimpedance testing, Bioimpedance analysis, BIS, Impedance plethysmography, Impedimed, LDex, Plethysmography, MoistureMeterD, SOZO, WHCRA, Women's Health and Cancer Rights Act

APPROVED BY GOVERNING BODIES:

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

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, Limited (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

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT Codes:

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

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POLICY HISTORY:

Adopted for Blue Advantage, July 2010
Available for comment July 23-September 6, 2010
Medical Policy Group, December 2010
Medical Policy Group, April 2011
Medical Policy Group, September 2012
Medical Policy Group, November 2012
Medical Policy Group, November 2013
Medical Policy Group, November 2014
Medical Policy Group, January 2016
Medical Policy Group, February 2017
Medical Policy Group, April 2020: Reinstated policy effective March 24, 2020.
Medical Policy Group, January 2021
Medical Policy Group, January 2022

Medical Policy Group, January 2023
Medical Policy Group, November 2023: Archived effective 11/1/2023.

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.