

Bioimpedance Devices for Detection and Management of Lymphedema

Medicare Advantage Medical Policy # MA-158

Original Effective Date: 01/01/2026

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Applies to all products administered or underwritten by the Health Plan, unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Health Plan may consider bioimpedance spectroscopy to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for bioimpedance spectroscopy will be considered for the diagnosis and/or surveillance of subclinical lymphedema when the following criteria are met:

- The individual is asymptomatic adult with history of surgery (e.g., axillary lymph node dissection or sentinel lymph node biopsy with > 6 nodes removed), radiotherapy (i.e., regional lymph node irradiation), or trauma impacting the lymphatic system, and testing would guide decisions regarding early intervention (eg, physical therapy, complete decongestive therapy); **AND**
- Measurements will be performed at the following intervals:
 1. A baseline measurement before lymphatic system intervention
 2. Every 3 months for the first year after intervention
 3. Every 6 months on years 2 and 3 after intervention
 4. Every 12 months for years 4 and beyond after intervention.

When 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 Health Plan considers bioimpedance spectroscopy in other situations to be **investigational.***

Policy Guidelines

Medically necessary positions are based on clinical input.

For individuals who are asymptomatic but are at elevated risk for lymphedema due to prior radiation, surgery, or trauma impacting the lymphatic system, clinical input supports that use of bioimpedance

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spectroscopy is consistent with generally accepted medical practice and that its clinical use is expected to provide a clinically meaningful improvement in net health outcome. Bioimpedance spectroscopy in this high-risk, asymptomatic, surveillance context can prompt early intervention and limit progression to chronic lymphedema with fibrosis.

For individuals with clinically diagnosed and/or symptomatic lymphedema, bioimpedance spectroscopy provides limited incremental utility for the optimization of decongestive therapy - may confirm maximal expected benefit from conservative therapies and thus inform decisions concerning treatment escalation.

An optimal surveillance frequency in individuals at high-risk for the development of secondary lymphedema has not been established. Lymphedema experts generally recommend assessments every 6 months until year 3 as reasonable and what is used by most centers on the basis of the PREVENT randomized controlled trial (RCT).

Background/Overview

Lymphedema

Lymphedema is an accumulation of fluid due to disruption of lymphatic drainage. It is characterized by nonpitting swelling of an extremity or trunk, and is associated with wound healing impairment, recurrent skin infections, and decreased quality of life. 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 (surgical removal of lymph nodes and radiotherapy) is one of the most common causes of secondary lymphedema. In a systematic review of 72 studies (N=29,612 women), DiSipio et al (2013) reported that nearly 20% of breast cancer survivors will develop arm lymphedema. The risk factors with robust evidence for the development of lymphedema included extensive surgical procedures (such as axillary lymph node dissection, a higher number of lymph nodes removed, and mastectomy) as well as 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, 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 (2023) based on "softness" or "firmness" of the limb and the changes with an elevation of the limb.

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Table 1. Recommendations for Staging Lymphedema

Stage	Description
Stage 0 (latent or subclinical)	Swelling is not yet evident despite impaired lymph transport, subtle alterations in tissue fluid/composition, and changes in subjective symptoms. It can be transitory and may exist months or years before overt edema occurs (Stages 1-III).
Stage I (mild)	Early accumulation of fluid relatively high in protein content (e.g., in comparison with "venous" edema) which subsides with limb elevation. Pitting may occur. An increase in various types of proliferating cells may also be seen.
Stage II (moderate)	Involves the permanent accumulation of pathologic solids such as fat and proteins and limb elevation alone rarely reduces tissue swelling, and pitting is manifest. Later in this stage, the limb may not pit as excess subcutaneous fat and fibrosis develop.
Stage III (severe)	Encompasses lymphostatic elephantiasis where pitting can be absent and trophic skin changes such as acanthosis, alterations in skin character and thickness, further deposition of fat and fibrosis, and warty overgrowths have developed. It should be noted that a limb may exhibit more than one stage, which may reflect alterations in different lymphatic territories.

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. Individuals 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 affected individuals 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 individuals who have difficulty performing self-manual lymphatic drainage. In individuals 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.

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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)

A selection of devices that have been cleared for marketing by the U.S. FDA through the 510(k) process to aid in the assessment of lymphedema are summarized in Table 2. Among the FDA-approved bioimpedance devices are SOZO (ImpediMed), MoistureMeterD (Delfin Technologies), and the L-Dex U400 (ImpediMed). The L-Dex U400 was discontinued by its manufacturer in November 2018.

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.

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

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practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Description

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.

Summary of Evidence

For individuals who have known or suspected lymphedema who receive bioimpedance spectroscopy, the evidence includes systematic reviews, 1 randomized controlled trial (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). Results from the PREVENT RCT comparing bioimpedance with standard tape measure following treatment for breast cancer have been published. At a median follow-up of 32.9 months, BIS patients triggered intervention at a lower rate than tape measured patients (20.1% vs 27.5%) and fewer patients progressed in this group (7.9% vs 19.2%). 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 BIS 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

The purpose of the remaining sections in Supplemental Information is to provide reference material regarding existing practice guidelines and position statements, U.S. Preventive Services Task Force Recommendations and Medicare National Coverage Decisions and registered, ongoing clinical trials. Inclusion in the Supplemental Information does not imply endorsement and information may not necessarily be used in formulating the evidence review conclusions.

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.

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2025 Input

In response to requests, clinical input was received from 3 respondents identified by the National Commission on Lymphatic Diseases (NCLD) or an academic medical center. In addition to this request, a plastic surgeon specializing in lymphedema research and reconstruction was interviewed.

For individuals with known or suspected (ie, clinically diagnosed or symptomatic) lymphedema, clinical input supports that use of bioimpedance spectroscopy is consistent with generally accepted medical practice. Feedback on whether this use results in a clinically meaningful improvement in net health outcome was mixed, with the primary benefit limited to situations where confirmation of maximal benefit from conservative measures such as decongestive therapy can help inform decisions around escalation of therapy. For individuals who are asymptomatic but are at elevated risk for lymphedema due to prior radiation, surgery, or trauma impacting the lymphatic system, clinical input supports that use of bioimpedance spectroscopy is consistent with generally accepted medical practice and that its clinical use is expected to provide a clinically meaningful improvement in net health outcome. Bioimpedance spectroscopy in this high-risk, surveillance context can prompt early intervention and limit progression to chronic, irreversible lymphedema with fibrosis.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in ‘Supplemental Information’ if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

National Comprehensive Cancer Network

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines on Survivorship (v.2.2025) recommends that survivors at risk for lymphedema should be regularly screened for lymphedema by symptom assessment, clinical exam, and, if available, bioimpedance spectroscopy. NCCN notes that survivors who had surgery, radiation, or chemoradiation to the axillary, supraclavicular, cervical, or pelvic inguinal lymph node system are at risk. While sentinel node biopsy also increases risk of lymphedema, it poses less risk than complete dissection. Other factors increasing risk of lymphedema development include BMI ≥ 30 kg/m², localized infection, increased number of nodes removed, and higher initial extent of disease.

NCCN Clinical Practice Guidelines on Breast Cancer (v.4.2025) recommend education, monitoring, and referral for lymphedema management as needed. For further information they refer the reader to the Survivorship Guidelines.

U.S. Preventive Services Task Force Recommendations

Not applicable.

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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 ongoing and 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
<i>Ongoing</i>			
NCT01521741	Prospective Screening for Breast Cancer-related Lymphedema: Analysis of Objective Measurements, Symptoms, Functionality, and Quality of Life Questionnaires to Evaluate Lymphedema in Patients Following Treatment for Breast Cancer.	10000	Dec 2026
NCT03292198 ^a	Treatment Indications for Breast Cancer-related Subclinical Lymphedema Identified Through a Bioimpedance Surveillance Model	267	Dec 2025
NCT03978754	Assessment of Breast Cancer-Related Arm Lymphedema—Comparison of Traditional Measurement Methods and Indocyanine Green (ICG) Lymphography	1600	Jan 2022 (status unknown)
NCT02743858	A Prospective Surveillance Program for Assessment and Treatment of Breast Cancer-Related Lymphedema After Axillary Lymph Node Dissection	1250	Apr 2025 (recruiting as of Oct 2024)

^a Denotes industry-sponsored or cosponsored trial; BIS: bioimpedance spectroscopy; NCT: national clinical trial.

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 25. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology: Breast Cancer. Version 4.2025. Updated April 17, 2025. https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf.

Policy History

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10/21/2025 Utilization Management Committee review/approval. New policy.

Next Scheduled Review Date: 10/2026

Coding

The five character codes included in the Health Plan Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2024 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character

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identifying codes and modifiers for reporting medical services and procedures performed by physician.

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CPT is a registered trademark of the American Medical Association.

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	All related diagnoses

*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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****Medically Necessary (or “Medical Necessity”)** - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient’s health insurance contract contains language that differs from the Health Plan’s 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 Health Plan recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

NOTICE: All codes listed on the Medical Policy require prior authorization. This ensures appropriate utilization and alignment with current clinical guidelines.

Medicare Advantage Members

Established coverage criteria for Medicare Advantage members can be found in Medicare coverage guidelines in statutes, regulations, National Coverage Determinations (NCD)s, and Local Coverage Determinations (LCD)s. To determine if a National or Local Coverage Determination addresses coverage for a specific service, refer to the Medicare Coverage Database at the following link: <https://www.cms.gov/medicare-coverage-database/search.aspx>. You may wish to review the Guide

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to the MCD Search here: <https://www.cms.gov/medicare-coverage-database/help/mcd-benehelp.aspx>.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, internal coverage criteria may be developed. This policy is to serve as the summary of evidence, a list of resources and an explanation of the rationale that supports the adoption of this internal coverage criteria.

InterQual®

InterQual® is utilized as a source of medical evidence to support medical necessity and level of care decisions. InterQual® criteria are intended to be used in connection with the independent professional medical judgment of a qualified health care provider. InterQual® criteria are clinically based on best practice, clinical data, and medical literature. The criteria are updated continually and released annually. InterQual® criteria are a first-level screening tool to assist in determining if the proposed services are clinically indicated and provided in the appropriate level or whether further evaluation is required. The utilization review staff does the first-level screening. If the criteria are met, the case is approved; if the criteria are not met, the case is referred to the medical director.