MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**Bioimpedance Devices for Detection and Management of Lymphedema**
Policy Number	**2.01.52**
Category	**Technology Assessment**
Original Effective Date	**08/17/17**
Committee Approval Date	**05/17/18, 05/16/19, 5/21/20, 5/20/21, 05/19/22, 05/18/23**
Current Effective Date	**05/18/23**
Archived Date	**N/A**
Archive Review Date	**N/A**
Product Disclaimer	• *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.*

POLICY STATEMENT

I. Based on our criteria and assessment of the peer-reviewed literature, devices using bioimpedance (bioelectrical impedance spectroscopy), are considered **investigational** for use in the diagnosis, surveillance, or treatment of patients with lymphedema, including use in subclinical secondary lymphedema.

Refer to Corporate Medical Policy #1.01.17 Pneumatic Compression Devices/lymphedema Pumps

Refer to Corporate Medical Policy #11.01.03 Experimental and Investigational Services

POLICY GUIDELINES

I. The ImpediMed Sozo received 510(k) clearance from the U.S. Food and Drug Administration (FDA) in 2017. SOZO readings, using bioimpedance spectroscopy (BIS) and L-Dex technology are a non-invasive and sensitive method to aid in the clinical assessment and early detection of lymphedema of the limb.

DESCRIPTION

Lymphedema is the abnormal accumulation of lymph fluid in the subcutaneous tissues of an affected body part due to an obstruction of the lymphatic flow. Primary lymphedema is present at birth, while secondary lymphedema is a disorder of lymphatic flow that is caused by some other disease or condition. Secondary lymphedema is more common than primary lymphedema. Secondary lymphedema is most commonly caused by surgery, especially lymph node dissection for breast cancer, radiation therapy (axillary, supraclavicular, cervical, or inguinal lymph node system), trauma, lymphatic obstruction by a tumor, or lymphatic filariasis. Secondary lymphedema may also result from compression of the lymphatic and venous channels, resulting from leakage of fluid into interstitial tissues in patients with chronic venous insufficiency. In the United States, breast cancer treatment is the most common cause of lymphedema.

Lymphedema is diagnosed based upon a patient's history and physical examination, which is staged by observing the patient's physical condition. One challenge, especially in women with breast cancer after surgery, is identifying the presence of clinically significant limb swelling through simple noninvasive methods. Volume displacement is considered the "gold standard" for lymphedema diagnosis. Measurements obtained by volume displacement have been shown to be reproducible, with an error rate of less than 1%. Arm volume measurements with water displacement are performed by comparing the volume of water displaced between the affected and unaffected limb, then reported as an interlimb volume difference. Another widely accepted measure of lymphedema is limb circumference compared with that of the unaffected limb or compared with that of the same limb before the interventions or events that led to lymphedema. Patient education regarding the signs and symptoms of developing lymphedema, as well as early identification and treatment of lymphedema, is believed to yield better patient outcomes.

One approach suggested for the management of lymphedema is treatment of subclinical (Stage 0) disease. Subclinical lymphedema occurs when there are early changes within the tissues without obvious noticeable swelling or symptoms. Subclinical lymphedema may exist for months or years before overt edema is noted and detection of lymphedema at this stage is difficult. Bioimpedance has been proposed as a diagnostic test for detection of subclinical lymphedema.

Bioimpedance involves applying a very mild electrical current to the body. To detect lymphedema in the upper extremity, the current is applied to the arm. As the current travels through the arm there is resistance. The level of impedance or resistance of a patient's arm to the current can be measured and converted into clinically useful measurements. If an increase in extracellular fluid in the arm (lymphedema) is present, the bioimpedance measurement will increase. Measurement of the extracellular fluid in the patient's upper limb over time allows for tracking fluid changes in the arm and assessing for early signs of lymphedema. Bioimpedance measurements are taken prior to surgery and then at regular follow-up intervals post-surgery. Patients are instructed to avoid caffeine, exercise two hours prior to the measurement being taken, and to avoid alcohol for at least 12 hours prior to the measurement being taken.

RATIONALE

The National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology: Breast Cancer (V4.2023) states that lymphedema is a potential side effect after the treatment of axillary lymph node surgery resulting from damage to the lymphatic system. Factors associated with increased risk of lymphedema include extent of axillary surgery, axillary radiation, infection, and patient obesity. Early detection/diagnosis of lymphedema is key for optimal management because stages 0 and 1 are reversible, while stages 2 and 3 are less responsive to treatment. Consider pretreatment measurement of both arms as a baseline for patients with risk factors for lymphedema. The panel recommends educating patients on lymphedema, monitoring for lymphedema, and referring for lymphedema management as needed.

The evidence for bioimpedance devices in individuals who have known**,** or suspected lymphedema includes several prospective studies on diagnostic accuracy and a controlled observational study evaluating clinical utility. Relevant outcomes are test accuracy and validity, symptoms, and quality of life. Recent diagnostic accuracy studies found a poor correlation between bioimpedance analysis and the reference standard (volume displacement or circumferential measurement). Randomized controlled trials exist which evaluate the clinical utility of bioimpedance devices in the management of patients with lymphedema or at high risk of developing lymphedema. The single prospective comparative study found a significantly lower rate of clinical lymphedema in patients managed with bioimpedance devices. Limitations of this study include the blinding, and lack of a systematic method of detecting early or subclinical lymphedema in the control group. The evidence is insufficient to determine the effects of the technology on health outcomes.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

CPT Codes

Code	Description
93702 **(E/I)**	Bioimpedance spectroscopy (BIS), extracellular fluid analysis for lymphedema assessment(s)

HCPCS Codes

Code	Description
No specific code(s)	

ICD10 Codes

Code	Description
I89.0 - I89.9	Other noninfective disorders of lymphatic vessels and lymph nodes (code range)
I97.2	Postmastectomy lymphedema syndrome

REFERENCES

Borman P, et al. The comparative frequency of breast cancer-related lymphedema determined by bioimpedance spectroscopy and circumferential measurements. Eur J Breast Health 2022 Jan;18(2):148-154

Kilgore LJ, et al. Reducing breast cancer-related lymphedema (BCRL) through prospective surveillance monitoring using bioimpedance spectroscopy (BIS) and patient directed self-interventions. Ann Surg Oncol 2018;25(10):2948-2952.

Koelmeyer LA, et al. Early surveillance is associated with less incidence and severity of breast cancer-related lymphedema compared with a traditional referral model of care. Cancer 2019;125(6):854-862.

Lim SM, et al. Utilization of bioelectrical impedance analysis for detection of lymphedema in breast cancer survivors: a prospective cross sectional study. BMC Cancer 2019 Jul;19(1):669.

*National Comprehensive Cancer Network (NCCN). Clinical practice guidelines in oncology. Breast Cancer. V.4.2023. March 23, 2023 [https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf] accessed 03/30/23.

*Oremus M, Walker K, Dayes I, et al. Technology Assessment: Diagnosis and treatment of secondary lymphedema. 2010; [https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/id66aTA.pdf]. Accessed 3/30/23.

Ridner SH, et al. A Comparison of bioimpedance spectroscopy or tape measure triggered compression intervention in chronic breast cancer lymphedema prevention. Lymphatic Research and Biology 2022 Jan 28;Online ahead of print.

Ridner SH, et al. A randomized trial evaluating bioimpedance spectroscopy versus tape measurement for the prevention of lymphedema following treatment for breast cancer: interim analysis. Ann Surg Oncol 2019 Oct:26(10):3250-3259.

*Seward C, et al. A comprehensive review of bioimpedance spectroscopy as a diagnostic tool for the detection and measurement of breast cancer-related lymphedema. J Surg Oncol 2016 Oct;114(5):537-42.

*Shah C, et al. The impact of early detection and intervention of breast cancer-related lymphedema: a systematic review. Cancer Med 2016 Jun;5(6):1154-62.

*Shah C, et al. The impact of monitoring techniques on progression to chronic breast cancer-related lymphedema: a meta-analysis comparing bioimpedance spectroscopy versus circumferential measurements. Breast Cancer Research and Treatment 2021 Feb;185(3):709-740.

Sutherland A, et al. Is bioimpedance spectroscopy a useful tool for objectively assessing lymphovensous bypass surgical outcomes in breast cancer related lymphedema? Breast Cancer Research and Treatment 2021 Feb;186(1):1-6

*Key Article

KEY WORDS

Bioimpedance, bioelectrical impedance spectroscopy

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based on our review, bioimpedance devices for the detection and management of lymphedema is not addressed in National or Regional Medicare coverage determinations or policies.