BlueCross BlueShield of North Carolina

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Corporate Medical Policy

Bioimpedance Devices for Detection of Lymphedema

File Name: bioimpedance_devices_for_detection_of_lymphedema
Origination: 7/2010
Last Review: 11/2024

Description of Procedure or Service

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.

Bioimpedance spectroscopy (BIS) 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.

Regulatory Status

The ImpediMed L-Dex™ U400 was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process in 2007. According to the FDA letter, the device is "to aid in the clinical assessment of unilateral lymphedema of the arms in women. The device is not intended to diagnose or predict lymphedema of an extremity." In 2011, the approval was amended to include use in the arm and leg in women, and the leg in men. The MoistureMeterD (Delfin Technologies, Stamford, CT) was cleared for marketing in 2015 "to aid in forming a clinical judgement of unilateral lymphedema in women". The SOZO® (ImpediMed) received FDA clearance in 2018 as "A bioimpedance spectroscopy device for use on adult human patients, utilizing impedance ratios that are displayed as an L-Dex ratio that supports the measurement of extracellular 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 use of the device to obtain an L-Dex score 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".

Related Policies

Pneumatic Compression Pumps for Treatment of Lymphedema and Venous Ulcers
Surgical Treatments for Lymphedema

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

Bioimpedance devices for detection of lymphedema are considered investigational. BCBSNC does not provide coverage for investigational services or procedures.

Bioimpedance Devices for Detection of Lymphedema

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When bioimpedance devices for detection of lymphedema are covered

Not applicable.

When bioimpedance devices for detection of lymphedema are not covered

Devices using bioimpedance (bioelectrical impedance spectroscopy) are considered **investigational** for use in the diagnosis, surveillance, or treatment of individuals with lymphedema, including use in subclinical secondary lymphedema.

Policy Guidelines

For individuals who have known or suspected lymphedema who receive bioimpedance spectroscopy, the evidence includes a systematic reviews, one randomized controlled trial (RCT), one prospective comparative observational study, and multiple uncontrolled observational studies. Relevant outcomes are test validity, symptoms, and quality of life. Diagnostic accuracy studies 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 interventionat 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 inpatients 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.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: *93702*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

FDA 510(k) summary: ImpediMed L-Dex U400 BIS Extra Cellular Fluid Analysis. Available online at: www.accessdata.fda.gov/cdrh_docs/pdf8/K080825.pdf Last accessed March 2010.

Cornish BH, Chapman M, Hirst C et al. Early diagnosis of lymphedema using multiple frequency bioimpedance. Lymphology 2001; 34(1):2-11.

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Warren AG, Janz BA, Slavin SA et al. The use of bioimpedance analysis to evaluate lymphedema. Ann Plast Surg 2007; 58(5):541-3.

Stout Gergich NL, Pfalzer LA, McGarvey C et al. Preoperative assessment enables the early diagnosis and successful treatment of lymphedema. Cancer 2008; 112(12):2809-19.

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Medical Director review 7/22/2010

Oremus M, Walker K, Dayes I et al. Diagnosis and treatment of secondary lymphedema. Technology Assessment Report Project ID:LYMT0908; May 28, 2010. (Based on research conducted by the McMaster University Evidence-based Practice Center under contract to the Agency for Healthcare Research and Quality (AHRQ).) Available online at: http://www.cmms.hhs.gov/determinationprocess/downloads/id66aTA.pdf. Last accessed April

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Specialty Matched Consultant Advisory Panel 11/2012

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Specialty Matched Consultant Advisory Panel 11/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.82, 1/11/2018

Specialty Matched Consultant Advisory Panel 11/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.82, 1/17/2019

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Specialty Matched Consultant Advisory Panel 11/2021

Specialty Matched Consultant Advisory Panel 11/2022

Specialty Matched Consultant Advisory Panel 11/2023

Medical Director Review 11/2023

Specialty Matched Consultant Advisory Panel 11/2024

Medical Director Review 11/2024

Policy Implementation/Update Information

8/17/10	New policy issued. 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. (adn)
12/21/10	Specialty Matched Consultant Advisory Panel review 11/29/10. Policy accepted as written. (adn)
1/4/2011	CPT code 0239T added to the Billing/Coding section. (adn)
12/20/11	Rationale in the Policy Guidelines section updated. References updated. No change in policy statement: 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. Specialty Matched Consultant Advisory Panel review 11/30/11. (adn)
1/15/13	Specialty Matched Consultant Advisory Panel review 12/4/12. References updated. No change in policy statement. (sk)
1/14/14	Specialty Matched Consultant Advisory Panel review 11/20/13. No change in policy statement. (sk)
2/11/14	Reference added. No change to Policy Statement. (sk)
12/30/14	Specialty Matched Consultant Advisory Panel review 11/24/14. Code 93702 added to Billing/Coding section for effective date 1/1/2015. Code 0239T deleted. No change in policy statement. (sk)
2/10/15	Reference added. (sk)
12/30/15	Specialty Matched Consultant Advisory Panel review 11/18/2015. (sk)
4/1/16	Reference added. Policy Guidelines updated. (sk)
12/30/16	Specialty Matched Consultant Advisory Panel review 11/30/2016. (sk)
7/28/17	Reference added. (sk)
12/15/17	Specialty Matched Consultant Advisory Panel review 11/29/2017. (sk)
3/9/18	Reference added. (sk)
12/14/18	Specialty Matched Consultant Advisory Panel review 11/28/2018. (sk)
2/12/19	Reference added. (sk)
12/10/19	Specialty Matched Consultant Advisory Panel review 11/20/2019. (sk)
8/25/20	Reference added. Description section updated. Related policy added. Policy Guidelines updated. (sk)

12/8/20 Regulatory status updated. Specialty Matched Consultant Advisory Panel review 11/18/2020. (sk)

3/9/21 Reference added. (sk)

11/30/21 Specialty Matched Consultant Advisory Panel review 11/17/2021. (sk)

5/2/23 Specialty Matched Consultant Advisory Panel review 11/16/2022. (sk)

12/5/23 Reference added. Specialty Matched Consultant Advisory Panel review 11/2023. Medical Director Review 11/2023. (rp)

12/31/24 Reference added. Policy Guidelines updated with results of PREVENT RTC. Specialty Matched Consultant Advisory Panel review 11/2024. Medical Director review 11/2024. (rp)