

Corporate Medical Policy

Bioimpedance Devices for Detection of Lymphedema

File Name: bioimpedance_devices_for_detection_of_lymphedema
Origination: 7/2010
Last CAP Review: 11/2018
Next CAP Review: 11/2019
Last Review: 11/2018

Description of Procedure or Service

Secondary lymphedema may develop following surgery for breast cancer. Bioimpedance is being studied as a diagnostic test for lymphedema, particularly for subclinical disease.

Many techniques have been used for documenting lymphedema including measuring differences in limb volume (volume displacement) and limb circumference. Bioimpedance spectroscopy (BIS) analysis uses resistance to electrical current in comparing the composition of fluid compartments. BIS is based on the theory that the amount of opposition to 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.

The detection of subclinical lymphedema is another area of study. Early detection of lymphedema before clinical symptoms become apparent (referred to as Stage 0 lymphedema) is problematic. This approach generally involves comparison of preoperative with postoperative measurements, since existing differences between upper extremities may obscure early, subtle differences resulting from the initial accumulation of fluid. Bioimpedance has been proposed as one diagnostic test for this condition. Those who support diagnosis of subclinical disease believe that early treatment of subclinical lymphedema should result in less severe chronic disease.

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.” The MoistureMeterD (Delfin Technologies, Stamford, CT) was cleared for marketing in 2015 “to aid in forming a clinical judgement of unilateral lymphedema in women”.

Related Policies

Pneumatic Compression Pumps for Treatment of Lymphedema and Venous Ulcers

*****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.

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

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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 patients 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 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). There are no randomized controlled trials evaluating 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 retrospective design, lack of randomization or blinding, and lack of a systematic method of detecting early or subclinical lymphedema in the control group. An additional retrospective analysis suggested that postoperative bioimpedance monitoring is feasible, but provides limited information about its efficacy. The evidence is insufficient to determine the effects of the technology on health outcomes.

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.

Hayes S, Janda M, Cornish B et al. Lymphedema secondary to breast cancer: how choice of measure influences diagnosis, prevalence, and identifiable risk factors. *Lymphology* 2008; 41(1):18-28.

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

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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 11/2016

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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

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)

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- 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)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.