

Corporate Medical Policy

Bioimpedance Devices for Detection of Lymphedema

File Name: bioimpedance_devices_for_detection_of_lymphedema
Origination: 7/2010
Last CAP Review: 11/2011
Next CAP Review: 11/2012
Last Review: 11/2011

Description of Procedure or Service

Secondary lymphedema may develop following surgery for breast cancer. Bioelectrical impedance 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 by 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

One of the devices is the ImpediMed L-Dex™ U400 cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process in 2007 and in 2008. According to the FDA letter, the device is “to aid in the clinical assessment of unilateral lymphedema of the arm in women. The device is not intended to diagnose or predict lymphedema of an extremity.”

******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 design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

Bioimpedance Devices for Detection of Lymphedema

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

There is minimal information about the technical and diagnostic performance of bioimpedance testing in the diagnosis and surveillance of secondary lymphedema, especially for subclinical disease. In addition, there are no data from comparative clinical trials that demonstrate the impact of bioimpedance on clinical outcomes (clinical utility). The approach to subclinical lymphedema (diagnosis and treatment) appears to be under active investigation. The impact on net health outcome is not known. Thus, based on the current scientific evidence, bioimpedance testing in the diagnosis or management of patients with known or suspected lymphedema is considered investigational.

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: 0239T

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.

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.

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.82, 3/11/2010

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:

Bioimpedance Devices for Detection of Lymphedema

<http://www.cmms.hhs.gov/determinationprocess/downloads/id66aTA.pdf>. Last accessed April
BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.82, 4/14/2011

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)

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.