

# MEDICAL POLICY



MEDICAL POLICY DETAILS	
Medical Policy Title	BIOIMPEDANCE DEVICES for DETECTION and MANAGEMENT of LYMPHEDEMA
Policy Number	2.01.52
Category	Technology Assessment
Effective Date	08/17/17
Revised Date	05/17/18, 05/16/19
Product Disclaimer	<ul style="list-style-type: none"> <li>• If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</li> <li>• If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.</li> <li>• If a Medicare 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.</li> </ul>

## POLICY STATEMENT

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 regarding Experimental and Investigational Services*

## POLICY GUIDELINES

- I. 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 as an aid in the clinical assessment of unilateral lymphedema of the arms in women. It is not intended to diagnose or predict lymphedema.
- II. The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

## 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. It is more common than primary lymphedema.

Secondary lymphedema is most commonly caused by surgery (especially lymph node dissection, such as for breast cancer), radiation therapy (especially axillary or inguinal), trauma, lymphatic obstruction by tumor, and, in developing countries, 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. Breast cancer treatment is the most common cause of lymphedema in the United States.

Lymphedema is diagnosed based upon the patients' history and physical examination and is usually staged by observing a 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 and 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

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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 to treating lymphedema which has been suggested 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 there is an increase in extracellular fluid in the arm (lymphedema) present, the bioimpedance measurement will increase. Measurement of the extracellular fluid in the patient's upper limb through time allows for tracking fluid changes in the arm and assessing for early signs of lymphedema. Bioimpedance measurements are to be taken prior to surgery and then at regular follow-up intervals post-surgery. Patients are instructed to avoid caffeine and exercise 2 hours prior to the measurement being taken and to avoid alcohol at least 12 hours prior to the measurement being taken. Ideally the measurements should be taken at the same time of the day and month for each patient.

### **RATIONALE**

The National Comprehensive Cancer Network Guidelines in Oncology: Breast Cancer (2017) state that lymphedema is a common complication after treatment for breast cancer. Factors associated with increased risk of lymphedema include extent of axillary surgery, axillary radiation, infection and patient obesity. The panel recommends educating the 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). 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 randomized or 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.*

#### **CPT Codes**

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

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#### **HCPCS Codes**

<b>Code</b>	<b>Description</b>
No specific code(s)	

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**ICD10 Codes**

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

**REFERENCES**

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\*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.