MEDICAL POLICY – 2.01.82
Bioimpedance Devices for Detection and Management of Lymphedema

BCBSA Ref. Policy: 2.01.82
Effective Date: Sept. 1, 2017
Last Revised: Aug. 1, 2017
Replaces: N/A

RELATED MEDICAL POLICIES:
1.01.18 Pneumatic Compression Pumps for Treatment of Lymphedema and Venous Ulcers

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | CODING | RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

∞ Clicking this icon returns you to the hyperlinks menu above.

Introduction

Lymphedema is the buildup of fluid in the tissues. This buildup occurs because the normal circulation of the fluid (lymph) in the lymphatic system is interrupted or blocked. The buildup causes swelling (edema). When a person is born with an abnormality of the lymphatic system, it’s known as primary lymphedema. Secondary lymphedema occurs because of damage to the lymphatic system. This damage can be from surgery, radiation, or injury. A bioimpedance device sends a very low level of electric current through the body. How fast the electric current moves through the body is supposed to indicate body composition — including how much fluid is present. Using bioimpedance devices for lymphedema is investigational (unproven). More and larger studies are needed to determine whether this method is useful in identifying or treating lymphedema.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
Policy Coverage Criteria

<table>
<thead>
<tr>
<th>Device</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bioimpedance devices</td>
<td>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.</td>
</tr>
</tbody>
</table>

*Note:* To aid in the clinical assessment of lymphedema a bioimpedance spectroscopy (BIS) device measures the extracellular fluid volume impedance ratio (using a mild electrical current) between limbs.

Bioimpedance spectroscopy (BIS) device(s) includes but is not limited to the following:

- ImpediMed L-Dex™ U400 (see the Regulatory Status section and the FDA website)

## Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>CPT</td>
<td>Bioimpedance spectroscopy (BIS), extracellular fluid analysis for lymphedema assessment(s)</td>
</tr>
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</table>

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## Related Information
Definition of Terms

**Bioimpedance analysis:** A method involving passing an extremely low strength electrical current through the body and measuring the impedance to the flow of electrical current. It was first used over 30 years ago to measure the total water content of the body.

**Lymphedema:** A buildup of fluid (lymph) in the tissues because the normal circulation of the fluid in the lymphatic system is interrupted or blocked. The fluid buildup causes swelling (edema) in the arms and legs. The etiology (causes) of secondary lymphedema includes disease, trauma, or a medical treatment such as surgery or radiation.

Evidence Review

Description

Secondary lymphedema may develop following surgery for breast cancer. Bioimpedance, which uses resistance to electrical current in comparing the composition of fluid compartments, could potentially be used as a tool to diagnose lymphedema.

Background

Lymphedema is a chronic accumulation of fluid and fibrous tissue that results from the disruption of lymphatic drainage. Bioimpedance (with the use of bioimpedance spectroscopy analysis) uses resistance to electrical current to compare the composition of fluid compartments and has been evaluated as a technique for measuring lymphedema. Bioimpedance spectroscopy 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, because of the accumulation of excess interstitial fluid, tissue impedance decreases.

Secondary lymphedema of the upper extremity may develop following surgery for breast cancer and it has been reported in approximately 25% to 50% of women following mastectomy. Lymphedema can be a chronic, disfiguring condition. It results from lymphatic dysfunction or disruption and can be difficult to accurately diagnose and manage. At least 1 systematic review has found that early detection of secondary lymphedema in breast cancer improves outcomes. One challenge is identifying the clinically significant limb swelling through simple noninvasive
methods. Many techniques have been used for documenting lymphedema including measuring differences in limb volume (volume displacement) and limb circumference.

The detection of subclinical lymphedema (ie, the early detection of lymphedema before clinical symptoms become apparent) is another area of study. Detection of subclinical lymphedema (referred to as stage 0 lymphedema) is problematic. Subclinical disease may exist for months or years before overt edema is noted. This approach generally involves comparison of preoperative (ie, baseline) with postoperative measurements, because existing differences between upper extremities (like the effects of a dominant extremity) may obscure subtle differences resulting from the initial accumulation of fluid.

Bioimpedance has been proposed as a diagnostic test for this condition. In usual care, lymphedema is recognized either 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.

Summary of Evidence

For individuals who have known or suspected lymphedema who undergo 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 have 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 who are 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 included its retrospective design, lack of randomized or blinding, and lack of a systematic method for 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.

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in June 2017 did not identify any ongoing or unpublished trials that would likely influence this review.
Clinical Input Received from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may provide appropriate reviewers who collaborate with and make recommendations during this process, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

Clinical input on this policy was received from 2 academic medical centers and 2 specialty societies in 2011. Three of 4 reviewers agreed that bioimpedance devices are considered investigational for diagnosis, surveillance, and treatment of patients with lymphedema. The fourth reviewer, who was from an academic medical center, thought that use of the technology is a reasonable alternative, especially in situations in which minor lymphedema can have a large impact on a patient. One specialty society supported further research into effectiveness of this technology and recommended reimbursement in the context of relevant clinical trials.

Practice Guidelines and Position Statements

No relevant guidelines or statements were identified.

Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

Regulatory Status

Devices that have been cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process to aid in the assessment of lymphedema are summarized in Table 1.
Table 1. Food and Drug Administration–Cleared Bioimpedance Spectroscopy Devices for Lymphedema

<table>
<thead>
<tr>
<th>Year</th>
<th>Device</th>
<th>Manufacturer</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td>MoistureMeterD</td>
<td>Delfin Technologies (Stamford, CT)</td>
<td>To aid informing a clinical judgment of unilateral lymphedema in women</td>
</tr>
<tr>
<td>2007</td>
<td>ImpediMed L-Dex™ U400</td>
<td>ImpediMed (Carlsbad, CA)</td>
<td>To aid in the clinical assessment of unilateral lymphedema of the arms in women</td>
</tr>
</tbody>
</table>

FDA product code: OBH

References

# History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
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</thead>
<tbody>
<tr>
<td>05/10/11</td>
<td>Add to Medicine Section - New medical policy with literature review through March 2011, considered investigational.</td>
</tr>
<tr>
<td>01/06/12</td>
<td>Replace Policy – Policy updated with literature search, clinical input reviewed, policy statement unchanged.</td>
</tr>
<tr>
<td>09/13/12</td>
<td>Update Coding Section – ICD-10 codes are now effective 10/01/2014.</td>
</tr>
<tr>
<td>01/29/13</td>
<td>Replace policy. Policy updated with literature search. Policy statement unchanged. Rationale substantially rewritten. Reference 10 added; other references renumbered or removed. Update title to Related Policy 1.01.18.</td>
</tr>
<tr>
<td>01/21/14</td>
<td>Replace policy. Title changed to “Bioimpedance devices for detection and management of lymphedema”. A literature search through October 11, 2013 did not prompt the addition of new references. CPT code 38999 removed from Policy Guidelines (this code was not in listed within the coding section). Policy statement unchanged.</td>
</tr>
<tr>
<td>05/19/14</td>
<td>Update Related Policies. Remove 2.02.17 as it was archived.</td>
</tr>
<tr>
<td>01/13/15</td>
<td>Annual Review. Added Definition of Terms to Policy Guidelines. Policy updated with literature review through September 29, 2014. Reference 6 added; others renumbered. CPT 93702 added to coding section effective 01/01/2015. Policy statement unchanged.</td>
</tr>
<tr>
<td>01/08/16</td>
<td>Minor update. CPT code 0239T, deleted 12/31/14, removed from policy.</td>
</tr>
<tr>
<td>04/01/16</td>
<td>Annual Review, approved March 8, 2016. Policy updated with literature review through November 21, 2015; references 6-8 added. Policy statement unchanged.</td>
</tr>
</tbody>
</table>

**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2017 Premera All Rights Reserved.

**Scope:** Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member
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  • Information written in other languages

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Toll free 855-332-4535, Fax 425-918-5952. TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

You can also file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at:
https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:
U.S. Department of Health and Human Services
200 Independence Avenue SW, Room S09F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
Complaint forms are available at

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Français (French):

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Ang Paunawa na ito ay naglalaman ng mahalagang impormasyon. Ang paunawa na ito ay magmata ng mga impormasyon tungkol sa iyong aplikasyon o pagsakop sa pagbabayad ng Premera Blue Cross.

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