

Protocol

Bioimpedance Devices for Detection and Management of Lymphedema

(20182)

| | | | |
|-------------------------|----|--|--------------------------------|
| Medical Benefit | | Effective Date: 07/01/18 | Next Review Date: 03/21 |
| Preauthorization | No | Review Dates: 03/18, 03/19, 03/20 | |

This protocol considers this test or procedure investigational. If the physician feels this service is medically necessary, preauthorization is recommended.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

| Populations | Interventions | Comparators | Outcomes |
|---|--|--|---|
| Individuals: <ul style="list-style-type: none">• With known or suspected lymphedema | Interventions of interest are: <ul style="list-style-type: none">• Bioimpedance spectroscopy | Comparators of interest are: <ul style="list-style-type: none">• Volume displacement• Circumferential measurement | Relevant outcomes include: <ul style="list-style-type: none">• Test validity• Symptoms• Quality of life |

DESCRIPTION

Secondary lymphedema may develop following surgery 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.

SUMMARY OF EVIDENCE

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. The relevant outcomes are test 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 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 randomization 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.

POLICY

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.

BACKGROUND

LYMPHEDEMA

Lymphedema is a chronic accumulation of fluid and fibrous tissue that results from the disruption of lymphatic drainage. Secondary lymphedema of the upper extremity may develop following surgery for breast cancer; it has been reported in approximately 25% to 50% of women following mastectomy. Lymphedema can be a disfiguring condition. It results from lymphatic dysfunction or disruption and can be difficult to diagnose and manage accurately. At least one systematic review has found that early detection of secondary lymphedema in breast cancer improves outcomes.¹ 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 (i.e., 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. The subclinical disease may exist for months or years before overt edema is noted. This approach generally involves comparison of preoperative (i.e., 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.

Diagnosis

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, 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

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

| Year | Device | Manufacturer | Indication |
|------|-----------------------|------------------------------------|--|
| 2015 | MoistureMeterD | Delfin Technologies (Stamford, CT) | To aid in forming a clinical judgment of unilateral lymphedema in women |
| 2007 | ImpediMed L-Dex™ U400 | ImpediMed (Carlsbad, CA) | To aid clinical assessment of unilateral lymphedema of the arms in women |

FDA product code: OBH.

RELATED PROTOCOL

Pneumatic Compression Pumps for Treatment of Lymphedema and Venous Ulcers

Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary Services Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

1. Shah C, Arthur DW, Wazer D, et al. The impact of early detection and intervention of breast cancer-related lymphedema: a systematic review. *Cancer Med.* Jun 2016;5(6):1154-1162. PMID 26993371
2. Oremus M, Walker K, Dayes I, et al. *Technology Assessment: Diagnosis and treatment of secondary lymphedema.* Rockville, MD: Agency for Healthcare Research and Quality; 2010.
3. Cornish BH, Chapman M, Hirst C, et al. Early diagnosis of lymphedema using multiple frequency bioimpedance. *Lymphology.* Mar 2001;34(1):2-11. PMID 11307661
4. 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.* Mar 2008;41(1):18-28. PMID 18581955
5. Barrio AV, Eaton A, Frazier TG. A prospective validation study of bioimpedance with volume displacement in early-stage breast cancer patients at risk for lymphedema. *Ann Surg Oncol.* Dec 2015;22 Suppl 3:370-375. PMID 26085222
6. Blaney JM, McCollum G, Lorimer J, et al. Prospective surveillance of breast cancer-related lymphoedema in the first-year post-surgery: feasibility and comparison of screening measures. *Support Care Cancer.* Jun 2015;23(6):1549-1559. PMID 25398360
7. Soran A, Ozmen T, McGuire KP, et al. The importance of detection of subclinical lymphedema for the prevention of breast cancer-related clinical lymphedema after axillary lymph node dissection; a prospective observational study. *Lymphat Res Biol.* Dec 2014;12(4):289-294. PMID 25495384
8. Laidley A, Anglin B. The impact of L-Dex((R)) Measurements in assessing breast cancer-related lymphedema as part of routine clinical practice. *Front Oncol.* Sep 2016;6:192. PMID 27656420