MEDICAL POLICY

POLICY TITLE	BIOIMPEDANCE DEVICES FOR DETECTION AND MANAGEMENT OF LYMPHEDEMA
POLICY NUMBER	MP-2.190

Original Issue Date (Created):	**12/1/2015**
Most Recent Review Date (Revised):	**6/5/2018**
Effective Date:	**8/1/2018**

I. 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. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Cross-reference:

MP-6.013 Pneumatic Compression Devices for the Treatment of Lymphedema and Venous Insufficiency

MP-6.044 End-Diastolic Pneumatic Compression Boot as a Treatment of Peripheral Vascular Disease or Lymphedema

II. PRODUCT VARIATIONS

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This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

FEP PPO - Refer to FEP Medical Policy Manual MP-2.01.82, Bioimpedance Devices for Detection and Management of Lymphedema. The FEP Medical Policy Manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

III. DESCRIPTION/BACKGROUND

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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 1 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 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 informing 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.

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IV. RATIONALE

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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. 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 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.

V. DEFINITIONS

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NA

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

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Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their

benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational:

CPT Codes®								
93702								

IX. REFERENCES

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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*
9. *Blue Cross Blue Shield Association Medical Policy Reference Manual. 2.01.82, Bioimpedance Devices for Detection and Management of Lymphedema. January 2018.*

X. POLICY HISTORY

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MP 2.190	**CAC 7/21/15** New policy. New investigational policy statement added indicating 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. Coding added.
	CAC 7/26/2016 Consensus Review. No changes to the policy statements. References and rational updated. Coding reviewed.
	Administrative Update 11/23/16 Variations reformatted
	CAC 9/26/17 Consensus review. Policy statement unchanged. Description/Background, Rationale and Reference sections updated. Coding reviewed.
	6/5/18 Consensus. No change to policy statements. References updated. Rationale condensed to include summary only.

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