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):	**2/18/2021**
Effective Date:	**7/1/2021**

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

II. PRODUCT VARIATIONS TOP

This policy is only applicable to certain programs and products administered by Capital BlueCross please see additional information below, and subject to benefit variations as discussed in Section VI below.

***Note** -* The Federal Employee Program (FEP) Service Benefit Plan does not have a medical policy related to these services.

III. DESCRIPTION/BACKGROUND TOP

Lymphedema
Lymphedema is an accumulation of fluid due to disruption of lymphatic drainage. Lymphedema can be caused by congenital or inherited abnormalities in the lymphatic system (primary

lymphedema) but is most often caused by acquired damage to the lymphatic system (secondary lymphedema). Breast cancer treatment is one of the most common causes of secondary lymphedema. Both the surgical removal of lymph nodes and radiotherapy are associated with development lymphedema in patients with breast cancer. In a systematic review of 72 studies (N=29612 women), it was reported that approximately 1 in 5 women who survive breast cancer will develop arm lymphedema. Risk factors for development of lymphedema that had a strong level of evidence were extensive surgery (i.e., axillary-lymph-node dissection, greater number of lymph nodes dissected, mastectomy) and being overweight or obese.

Diagnosis

A diagnosis of secondary lymphedema is based on history (e.g., cancer treatment, trauma) and physical examination (localized, progressive edema and asymmetric limb measurements) when other causes of edema can be excluded. Imaging, such as MRI, computed tomography, ultrasound, or lymphoscintigraphy, may be used to differentiate lymphedema from other causes of edema in diagnostically challenging cases.

Management and Treatment

Lymphedema is treated using elevation, compression, and exercise. Conservative therapy may consist of several features depending on the severity of the lymphedema. Patients are educated on the importance of self-care including hygiene practices to prevent infection, maintaining ideal body weight through diet and exercise, and limb elevation. Compression therapy consists of repeatedly applying padding and bandages or compression garments. Manual lymphatic drainage is a light pressure massage performed by trained physical therapists or by patients designed to move fluid from obstructed areas into functioning lymph vessels and lymph nodes. Complete decongestive therapy is a multiphase treatment program involving all of the previously mentioned conservative treatment components at different intensities. Pneumatic compression pumps may also be considered as an adjunct to conservative therapy or as an alternative to self-manual lymphatic drainage in patients who have difficulty performing self-manual lymphatic drainage. In patients with more advanced lymphedema after fat deposition and tissue fibrosis has occurred, palliative surgery using reductive techniques such as liposuction may be performed.

Bioimpedance Spectroscopy

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 (FDA) through the 510(k) process to aid in the assessment of lymphedema are summarized in Table 1.

Table 1. FDA Cleared Bioimpedance Spectroscopy Devices for Lymphedema

Year	Device	Manufacturer	Indication
2018	SOZO	ImpediMed (Carlsbad, CA)	For adults at risk of lymphedema. Supports the measurement of extracellular fluid volume differences between the limbs and is presented to the clinician on an L-Dex scale as an aid to their clinical assessment of lymphedema. The device is only indicated for patients who will have or who have had lymph nodes, from the axillary and/or pelvic regions, either removed, damaged or irradiated.
2015	MoistureMeterD	Delfin Technologies (Stamford, CT)	Supports local assessment of tissue water differences between affected and contralateral non-affected arm tissues to aid in forming a clinical judgment of unilateral lymphedema in women. The device is not intended to make diagnosis or predict arm lymphedema.
2007	ImpediMed L-Dex™ U400	ImpediMed (Carlsbad, CA)	Supports the measurement of extracellular fluid volume differences between the arms to aid in the clinical assessment of unilateral lymphedema of the arm in women. This device is not intended to diagnose or predict lymphedema of an extremity.

FDA product code: OBH.

IV. RATIONALE

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Summary of Evidence

For individuals who have known or suspected lymphedema who receive bioimpedance spectroscopy, the evidence includes a systematic review, one RCT, one prospective comparative

observational study, and multiple uncontrolled observational studies. The relevant outcomes are test validity, symptoms, and quality of life. Diagnostic accuracy studies have found a poor correlation between bioimpedance analysis and the reference standard (volume displacement or circumferential measurement). Interim results from an ongoing RCT comparing bioimpedance with standard tape measure following treatment for breast cancer have been published. Overall, 109 of 508 (21.5%) patients received early treatment due to reaching a pre-determined threshold to trigger an intervention. A total of 12 triggering patients progressed to clinical lymphedema (2 in the bioimpedance group [4.9%] and 10 in the tape measure group [14.7%]; P=0.130). The RCT was limited by its open-label design and lack of reporting of important health outcomes. The single prospective comparative study found a significantly lower rate of clinical lymphedema in patients managed with bioimpedance devices but had several limitations, including nonrandomized design, lack of blinding, lack of complete data on a substantial proportion of enrolled patients, and lack of a systematic method for diagnosing lymphedema in the control group. Retrospective studies suggested that postoperative bioimpedance monitoring is feasible but provide 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 health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member’s health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital BlueCross. Members and providers should consult the member’s health benefit plan for 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. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital BlueCross' Provider Services or Member Services. 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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22. *Blue Cross Blue Shield Association Medical Policy Reference Manual. 2.01.82, Bioimpedance Devices for Detection and Management of Lymphedema. February 2021.*

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 review. No change to policy statements. References updated. Rationale condensed to include summary only.
	4/15/19 Consensus review. No change to policy statements.
	4/16/2020 Consensus review. No change to policy statement. References added. Description/Background and Rationale sections updated. FEP policy removed. Coding reviewed.
	2/18/2021 Consensus review. Policy statement unchanged. References updated.

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