BlueCross BlueShield Federal Employee Program.

FEP 2.01.82 Bioimpedance Devices for Detection and Management of Lymphedema

Effective Date: April 15, 2018

Related Policies:
1.01.18 Pneumatic Compression Pumps for Treatment of Lymphedema and Venous Ulcers

Bioimpedance Devices for Detection and Management of Lymphedema

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.

FDA 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

POLICY STATEMENT

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.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.

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RATIONALE

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.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

No relevant guidelines or statements were identified.

U.S. Preventive Services Task Force Recommendations

Not applicable.

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.

REFERENCES

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POLICY HISTORY

Date	Action	Description
June 2012	New Policy	
March 2013	Update Policy	Policy updated with literature search. Policy statement unchanged. Rationale rewritten. Reference 10 added; other references renumbered or removed.
March 2014	Update Policy	Policy updated with literature review, Policy statement unchanged. Policy title changed to: “Bioimpedance devices for detection and management of lymphedema.”
March 2015	Update Policy	Policy updated with literature review. Policy statement unchanged. Reference 6 added.
June 2016	Update Policy	Policy updated with literature review through November 21, 2015; references 6-8 added. Policy statement unchanged.
March 2018	Update Policy	Policy updated with literature review through November 15, 2017; references 3, 9, 11 added. Policy statement unchanged except “not medically necessary” wording changed to “investigational” due to FDA 510k approval of devices.

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