# **Medical Coverage Policy** | Bioimpedance Devices for Detection and Management of Lymphedema



**EFFECTIVE DATE:** 1 | 1 | 2015

**POLICY LAST UPDATED:** 06 | 19 | 2018

#### **OVERVIEW**

Secondary lymphedema may develop following surgery for breast cancer. Bioelectrical impedance is being studied as a diagnostic test for lymphedema, particularly for subclinical disease. Bioimpedance, which uses resistance to electrical current in comparing the composition of fluid compartments, could potentially be used as a tool to diagnose lymphedema.

#### **MEDICAL CRITERIA**

Not applicable

# **PRIOR AUTHORIZATION**

Not applicable

## **POLICY STATEMENT**

# BlueCHiP for Medicare

Devices using bioimpedance (bioelectrical impedance spectroscopy) are not covered for use in the diagnosis, surveillance, or treatment of patients with lymphedema, including use in subclinical secondary lymphedema as the evidence is insufficient to determine the effects of the technology on health outcomes.

#### **Commercial Products**

Devices using bioimpedance (bioelectrical impedance spectroscopy) are considered not medically necessary for use in the diagnosis, surveillance, or treatment of patients with lymphedema, including use in subclinical secondary lymphedema as he evidence is insufficient to determine the effects of the technology on health outcomes.

## **COVERAGE**

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for applicable not medically necessary benefits/coverage.

## **BACKGROUND**

Bioimpedance with the use of bioimpedance spectroscopy analysis, which uses resistance to electrical current to compare the composition of fluid compartments, has been evaluated as a technique for measuring lymphedema, a chronic accumulation of fluid and fibrous tissue that results from the disruption of lymphatic drainage. 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.

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 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.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 (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

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 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.

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 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.

#### **CODING**

The following code is not medically necessary for BlueCHiP for Medicare and Commercial Products: 93702 Bioimpedance spectroscopy (BIS), extracellular fluid analysis for lymphedema assessment(s)

# **RELATED POLICIES**

None

#### **PUBLISHED**

Provider Update, August 2018 Provider Update, December 2017 Provider Update, August 2016 Provider Update, October 2015

# **REFERENCES**

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