Bioimpedance for the Detection of Lymphedema

Policy Number:	**M20121204038**
Effective Date:	**1/1/2013**
Sponsoring Department:	**Health Care Services**
Impacted Department(s):	**Health Care Services**

Type of Policy: ☒ Internal ☒ External

Data Classification: ☐Confidential ☐Restricted ☒Public

Applies to (Line of Business):

☐ Corporate (All)
☒ State Products, if yes which plan(s): ☒MediSource; ☒ MediSource Connect; ☒Child Health Plus ☒Essential Plan
☒ Medicare, if yes, which plan(s): ☒MAPD; ☐PDP; ☒ISNP; ☒CSNP
☒ Commercial, if yes, which type: ☒Large Group; ☒Small Group; ☒Individual
☒ Self-Funded Services *(Refer to specific Summary Plan Descriptions (SPDs) to determine any pre-authorization or pre-certification requirements and coverage limitations. In the event of any conflict between this policy and the SPD of a Self-Funded Plan, the SPD shall supersede the policy.)*

Excluded Products within the Selected Lines of Business (LOB)

N/A

Applicable to Vendors? Yes ☐ No☒

Purpose and Applicability:

To state Independent Health's coverage policy regarding bioimpedance for detection of lymphedema.

Policy:

Commercial, Self-Funded and Medicare Advantage:
There is a lack of comparative clinical trials that demonstrate the impact of bioimpedance on clinical outcomes for detection of lymphedema. The efficacy of this procedure cannot be established by review of the available published peer review literature. Therefore, Independent Health considers bioimpedance for the detection of lymphedema experimental/investigational.

MediSource, MediSource Connect, Child Health Plus and Essential Plan:
MediSource, MediSource Connect, Child Health Plus and Essential Plan do not cover bioimpedance for the detection of lymphedema.

Background:
Bioimpedance spectroscopy is a measure of resistance met by a current passed through the skin via electrodes. The difference appreciated between the readings pre- and post-surgery is proposed to determine the presence or lack of lymphedema. Bioimpedance is proposed as a means to detect early onset LE prior to physical changes, although standardized procedures and metrics have yet to be established.

The US Food and Drug Administration (FDA) has approved devices for bioimpedance for detection of lymphedema.

Early identification of those women at risk for lymphedema and secondary prevention measures may potentially keep lymphedema from progressing to a higher clinical stage; lymphedema is often difficult to treat if it progresses. Clinical measurements are obtained initially to establish a baseline before breast cancer treatments and afterward at intervals to track changes during treatment. Alternatively, changes in arm circumference or volume relative to the contralateral normal limb can be performed. There is currently no consensus on how frequently these measurements should be performed, or on the frequency of follow-up of women at risk for developing lymphedema.

Evidence for bioimpedance for lymphedema is of overall very low quality. Very few studies evaluated clinical utility or the impact of bioimpedance on patient management or outcomes. Unresolved questions remain regarding whether bioimpedance is superior to current assessment techniques for lymphedema. The National Comprehensive Cancer Network and the National Cancer Institute do not mention bioimpedance in their guidelines.

An evaluation of the peer-reviewed scientific literature, including but not limited to subscription materials, has provided Independent Health the basis for its medical necessity coverage outlined above.

Pre-Authorization Required? Yes ☒ No☐

Pre-authorization is required for this service.

Definitions

Bioimpedance measures the impedance or opposition to the flow of an electric current through the body fluids contained mainly in the lean and fat tissue.

Lymphedema is a condition characterized by edema and protein in the tissues caused by fluid that is not drained in the lymphatic system. In oncology, the most common etiology for the development of lymphedema is the impaired or disrupted flow of lymph fluid through the draining lymphatic vessels and lymph nodes, usually because of surgery and/or radiation therapy. If the uninjured lymphatic vessels are unable to accommodate the increased lymphatic load, an accumulation of lymph fluid develops in the dependent tissues. Without intervention, lymphedema can lead to progressive swelling, fibrosis of the soft tissues, neurologic changes (e.g., pain and/or paresthesia), and infection.

References

Related Policies, Processes and Other Documents

N/A

Non-Regulatory references

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. 2015 Dec;22 Suppl 3:S370-5.

Hayes, Inc., Health Technology Assessment Bioelectrical Impedance (Bioimpedance) Analysis for Assessment of Lymphedema, Lansdale, PA: August 2020.

National Cancer Institute (NCI) [web site]. Lymphedema (PDQ®)–Health Professional Version. Updated March 22, 2023 Available at: https://www.cancer.gov/about-cancer/treatment/side-effects/lymphedema/lymphedema-hp-pdq Accessed May 25, 2022.

National Comprehensive Cancer Network (NCCN) [web site]. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines ®) Breast Cancer Version 4.2023 — March 23, 2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf Accessed August 23, 2023.

Mehrara, B. Breast cancer-associated lymphedema In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed August 23, 2023.

Oremus M, Walker K, Dayes I, et al. Diagnosis and treatment of secondary lymphedema. Technology Assessment, Agency for Healthcare Research and Quality (AHRQ) May 28, 2010. Available at: http://www.cms.gov/determinationprocess/downloads/id66aTA.pdf
Accessed August 23, 2023.

Regulatory References

Food and Drug Administration (FDA) [website]. Center for Devices and Radiological Health (CDRH). Premarket Notification 510(k) Summary ImpediMed Extra Cellular Fluid Analysis, Model L-DEX U400. Available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K080825
Accessed August 23, 2023.

This policy contains medical necessity criteria that apply for this service. Please note that payment for covered services is subject to eligibility criteria, contract exclusions and the limitations noted in the member's contract at the time the services are rendered.

Version Control

Signature / Approval on File? Yes ☒ No☐

Revision Date	Owner	Notes
1/1/2024	Health Care Services	Revised
11/1/2023	Health Care Services	Reviewed
11/1/2022	Health Care Services	Revised
8/1/2022	Health Care Services	Reviewed
9/1/2021	Health Care Services	Revised
10/1/2020	Health Care Services	Revised
4/1/2020	Medical Management	Revised
5/1/2019	Medical Management	Revised
5/1/2018	Medical Management	Revised
5/1/2017	Medical Management	Revised
6/1/2016	Medical Management	Revised
6/1/2015	Medical Management	Revised
4/1/2014	Medical Management	Revised