Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

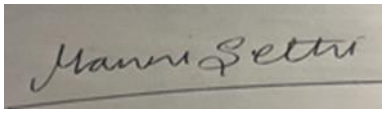
Plan: AmeriHealth Caritas Pennsylvania & Keystone First	Submission Date: 5/1/2025
Policy Number: CCP.1308	Effective Date: 6/1/2017 Revision Date: 4/2025
Policy Name: Bioimpedance devices for detecting lymphedema	

Type of Submission:

☐ New Policy	☒ Prior Authorization Policy
☒ Revised Policy*	☐ Base Policy
☐ Annual Review- no revisions	☒ Experimental/Investigational Policy
	☐ Statewide PDL
	☐ Other:

*All revisions to the policy must be highlighted using track changes throughout the document.

Please provide any clarifying information for the policy below:

Name of Authorized Individual (Please type or print): Manni Sethi, MD, MBA, CHCQM	Signature of Authorized Individual: 

Keystone First
Family of Health Plans

Bioimpedance devices for detecting lymphedema

Clinical Policy ID: CCP.1308

Recent review date: 4/2025

Next review date: 8/2026

Policy contains: Bioimpedance devices; breast cancer; lymphedema.

Keystone First has developed clinical policies to assist with making coverage determinations. Keystone First's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by Keystone First, on a case by case basis, when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First's clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First will update its clinical policies as necessary. Keystone First's clinical policies are not guarantees of payment.

Coverage policy

Bioimpedance devices for detecting lymphedema are investigational/not clinically proven and, therefore, not medically necessary.

Any requests for services that do not meet criteria set in this policy may be evaluated on a case-by-case basis through a program exception process as described in 55 Pa. Code §1150.63 and as required under Section V.A.1.3. of the HealthChoices Agreement.

Limitations

No limitations were identified during the writing of this policy.

Alternative covered services

Various radiographic, imaging, and other methods of detecting lymphedema.

Background

Lymphedema is a swelling in the interstitial space due to accumulation of protein-rich fluid resulting from congenital or acquired damage to the lymphatic system. There are three stages of the disease, from 0 (the least severe) to 3 (the most severe) (International Society of Lymphology, 2020). Stage 0 (subclinical edema) is increasingly recognized as a lymphedema stage where swelling is not evident although lymphatic transport is impaired.

Primary lymphedema refers to congenital cases of the disease that manifest before age two; lymphedema praecox, which occurs at puberty; and lymphedema tarda, which occurs after age 35. The more common secondary lymphedema refers to cases acquired from disruption to the lymphatic system, from disease, trauma, surgery, or radiation (Chaput, 2020). In the United States, malignancies and related treatments (radiation, surgery) are the most common causes of secondary lymphedema. Lymphedema is common particularly among patients following breast cancer treatment and can have debilitating effects on quality of life and function. Early detection/diagnosis is crucial for optimal management, as early-stage lymphedema is more responsive to treatment (National Comprehensive Cancer Network, 2023).

Several methods are available for detecting lymphedema and distinguishing it from other edematous etiologies. Diagnosis occurs clinically through history and physical examination, and in some cases, using computed tomography, magnetic resonance imaging, and lymphoscintigraphy (Sleigh, 2023). The difference in circumference between affected and unaffected arms determines severity, with larger differences being more severe. Typically, one to two assessments of circumference occur before, during, and after the patient's treatment. However, detection of subclinical lymphedema is difficult with current diagnostic methods.

Several methods exist for evaluating limb volume. Options include water displacement, tape measurement, and infrared perometry. Bioelectrical impedance spectroscopy (abbreviated "bioimpedance") has been proposed as a method for detecting subclinical lymphedema. The portability of these options makes them potentially viable for at-home use (Ridner, 2014).

Bioimpedance uses resistance to electrical current to calculate the total water content in the body (Ridner, 2014). Patients lie supine when the test is administered. An example of a bioimpedance analyzer available for commercial use in the United States is the SOZO® bioimpedance plethysmograph (ImpediMed Limited, Carlsbad, California). SOZO is approved for adults who will have or who have had lymph nodes from the axillary or pelvic regions either removed, damaged, or irradiated (U.S. Food and Drug Administration, 2018). The device uses proprietary L-Dex® technology over a wide spectrum of frequencies from 3 kHz to 1000 kHz to provide a detailed fluid and tissue analysis as an aid to the clinical assessment of lymphedema. The L-Dex® U400 device was discontinued in 2018 (ImpediMed Limited, 2024).

Findings

To date, no professional society guidelines have been issued on use of bioimpedance after cancer treatment. The National Comprehensive Care Network supports the use of screening for lymphedema for cancer survivors by "symptom assessment, clinical exam, and, if available, bioimpedance spectroscopy," as early detection optimizes management of lymphedema. However, the Network did not mention any references supporting its stance (National Comprehensive Cancer Network, 2023).

In November 2016, consensus recommendations for techniques, protocols, and detection summarized data supporting use of the procedure for recently treated breast cancer patients (Shah, 2016). Authors identify higher-risk patients as those who underwent mastectomy, auxiliary lymph node dissection, sentinel node biopsy (over six nodes sampled), regional nodal irradiation, or taxane based chemotherapy. A report of the American College of Radiology on upper extremity swelling did not mention bioimpedance (Dill, 2019).

A systematic review of 22 studies found bioimpedance analysis for prospective surveillance detected chronic breast cancer-related lymphedema. L-Dex scores differed significantly between lymphedema patients and healthy participants, and bioimpedance scores correlated with volume of lymphedema (Forte, 2020, 2021).

A systematic review of 50 studies (n = 67,000) reported incidence of breast cancer related lymphedema was 3.1% for patients monitored with bioimpedance spectroscopy. This rate is much lower than the 12.9% with

background monitoring and 17.0% with circumference monitoring. The study suggests monitoring with bioimpedance permits early detection of lymphedema, but this requires validation (Shah, 2021).

A systematic literature review identified four guidelines on lymphedema diagnosis and treatment. Only two of the four guidelines included bioimpedance, and these were published in 2006 and 2008 (O'Donnell, 2020).

A systematic review of 16 studies assessed the ability of bioimpedance to detect lymphedema after gynecological surgery. Sensitivity and specificity of detection were 73% and 84%, respectively, and lower limb lymphedema was detectable at an early stage before it became clinically detectable. Authors state more studies comparing bioimpedance with the general population are needed (Asklof, 2018).

An American Physical Therapy Association guideline recommended bioimpedance to detect subclinical and early-stage lymphedema in patients at risk (Stage 0 and 1) for breast cancer–related lymphedema, as well as moderate to late-stage cases. Both recommendations were designated Strength B (Levenhagen, 2017).

A comprehensive literature review concluded that bioimpedance spectroscopy is an accurate diagnostic tool for pre-existent lymphedema but has not been validated for early detection (Seward, 2016). A systematic review found that bioimpedance was highly accurate in measuring lymphedema in the lower extremities (interrater correlation coefficient .89), but not in higher extremities, in which coefficients for water volumetry, tape measurement, and perometry ranged from .98 to .99 (Hidding, 2016).

Several analyses have compared bioimpedance with perometry arm measurement, with mixed results. A study to predict development of lymphedema in 964 breast cancer patients who underwent axillary node clearance found arm volume measurement remains the gold standard (Bundred, 2015).

In 2018, we added one medical technology briefing from the National Institute for Health and Care Excellence (2017) finding that the L-Dex U400 was not as effective as current tests for diagnosing lymphedema.

In 2019, we added no new relevant literature to the policy.

In 2020, we added no new relevant literature to the policy.

In 2021, we updated the references and added interim results from a new randomized controlled trial (Ridner, 2019).

In 2022, we updated the references by adding several systematic reviews.

In 2023, we added a review of 12 studies (n = 2,907) of breast cancer-related lymphedema that concluded early intervention reduces chronic lymphedema rates. The "strongest data" was observed from bioimpedance spectroscopy with a compression garment, 12 hours daily for four weeks, superior to tape measurement plus early intervention (Whitworth, 2022). We also removed five references and citations published prior to 2013.

We also added a review (n = 963) of post-mastectomy patients followed for a median of 32.9 months that bioimpedance spectroscopy (compared to tape measurement) triggered an intervention at a lower rate, with a higher median months to trigger, and lower post-intervention progression (*P* = .016) (Ridner, 2022).

In 2024, we added a reference that summarized articles on the effectiveness of bioimpedance for lymphedema after breast cancer surgery. The article cited guidelines that address bioimpedance, including those from the National Comprehensive Cancer Network, American Physical Therapy Association, and Australian Lymphology Association (Shah, 2023).

The article also included guidelines on bioimpedance use for surveillance. These uses include any surgical lymph node evaluation, regional node irradiation, and/or taxane-based chemotherapy. Authors concluded that L-Dex 0400 and SOZO devices were equally effective. The article made recommendations for frequency of use, at baseline and at various post-operative stages (Shah, 2023).

We also added a study (n = 753) that found significantly fewer women monitored for lymphedema using early surveillance (versus traditional referrals) with bioimpedance were diagnosed with clinical lymphedema ($P < .001$). Authors support adoption of early monitoring using bioimpedance (Koelmeyer, 2019).

In 2025, policy references updated. No new relevant literature found and no policy changes were warranted.

References

On March 17, 2025, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “bioimpedance,” “lymphedema/diagnosis (MeSH),” and “lymphedema.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

Asklof M, Kiothede P, Wodlin NB, Nilsson L. Bioelectrical impedance analysis: A new method to evaluate lymphoedema, fluid status, and tissue damage. *Eur J Obstet Gynecol Reprod Biol*. 2018;228:111-119. Doi: 10.1016/j.ejogrb.2018.06.024.

Bundred NJ, Stockton C, Keeley V, et al. Comparison of multi-frequency bioimpedance with perometry for the early detection and intervention of lymphedema after axillary node clearance for breast cancer. *Breast Cancer Res Treat*. 2015;151(1):121-129. Doi: 10.1007/s10549-015-3357-8.

Chaput G, Ibrahim M, Towers A. Cancer-related lymphedema: Clinical pearls for providers. *Curr Oncol*. 2020;27(6):336-340. Doi: 10.3747/co.27.7225.

Dill KE, Bennett SJ, Hanley M, et al. Expert Panel on Vascular Imaging. ACR appropriateness criteria® upper extremity swelling. Reston (VA): American College of Radiology. https://acsearch.acr.org/docs/69417/Narrative/. Published 2014. Revised 2019.

Forte AJ, Huayllani MT, Boczar D, et al. Bioimpedance spectroscopy for assessment of breast cancer related lymphedema: A systematic review. *Plast Surg Nurs*. 2020;40(2):86-90. Doi: 10.1097/PSN.0000000000000306.

Forte AJ, Huayllani MT, Boczar D, et al. Use of bioimpedance spectroscopy for prospective surveillance and early diagnosis of breast cancer-related lymphedema. *Breast Dis*. 2021;40(2):85-93. Doi: 10.3233/BD-201008.

Hidding JT, Viehoff PB, Beurskens CH, van Laarhoven HW, Nijhuis-van der Sanden MW, van der Wees PJ. Measurement properties of instruments for measuring of lymphedema: Systematic review. *Phys Ther.* 2016;96(12):1965-1981. Doi: 10.2522/ptj.20150412.

Impedimed Limited. L-dex® u400. https://www.impedimed.com/products/l-dex-u400/. Published 2024.

International Society of Lymphology. The diagnosis and treatment of peripheral lymphedema. 2020 Consensus Document of the International Society of Lymphology. *Lymphology* 2020;53:3-19. https://isl.arizona.edu/sites/default/files/2021-09/Consensus%20Document-SM.pdf

Koelmeyer LA, Borotkanics RJ, Alcorso J, et al. Early surveillance is associated with less incidence and severity of breast cancer-related lymphedema compared with a traditional referral model of care. *Cancer*. 2019;125(6):854-862. Doi: 10.1002/cncr.31873.

Levenhagen K, Davies C, Perdomo M, Ryans K, Gilchrist L. Diagnosis of upper quadrant lymphedema secondary to cancer: Clinical practice guideline from the Oncology Section of the American Physical Therapy Association. *Phys Ther*. 2017;97(7):729-745. Doi: 10.1093/ptj/pzx050.

National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology. Supportive Care: Survivorship. Version 2.2024. www.nccn.org. Last updated December 9, 2024.

National Institute for Health and Care Excellence. L-Dex U400 for lymphoedema after breast cancer treatment. Medtech innovation briefing [MIB111]. https://www.nice.org.uk/advice/mib111. Published July 4, 2017.

O'Donnell TF, Allison GM, Iafrati MD. A systematic review of guidelines for lymphedema and the need for contemporary intrasocietal guidelines for the management of lymphedema. *J Vasc Surg Venous Lymphat Disord*. 2020;8(4):676-684. Doi: 10.1016/j.jvsv.2020.03.006.

Ridner SH, Bonner CM, Doersam JK, Rhoten BA, Schultze B, Dietrich MS. Bioelectrical impedance self-measurement protocol development and daily variation between healthy volunteers and breast cancer survivors with lymphedema. *Lymphat Res Biol.* 2014;12(1):2-9. Doi: 10.1089/lrb.2013.0020.

Ridner SH, Dietrich MS, Cowher MS, et al. A randomized trial evaluating bioimpedance spectroscopy versus tape measurement for the prevention of lymphedema following treatment for breast cancer: Interim analysis. *Ann Surg Oncol.* 2019;26(10):3250-3259. Doi: 10.1245/s10434-019-07344-5.

Ridner SH, Dietrich MS, Boyages J, et al. A comparison of bioimpedance spectroscopy or tape measure triggered compression intervention in chronic breast cancer lymphedema prevention. *Lymphat Res Biol*. 2022;20(6):618-628. Doi: 10.1089/lrb.2021.0084.

Seward C, Skolny M, Brunelle C, Asdourian M, Salama L, Taghian AG. A comprehensive review of bioimpedance spectroscopy as a diagnostic tool for the detection and measurement of breast cancer-related lymphedema. *J Surg Oncol.* 2016;114(5):537-542. Doi: 10.1002/jso.24365.

Shah C, Vicine FA, Arthur D. Bioimpedance spectroscopy for breast cancer related lymphedema assessment: Clinical practice guidelines. *Breast J.* 2016;22(5):645-650. Doi: 10.1111/tbj.12647.

Shah C, Zambelli-Weiner A, Delgado N, Sier A, Bauserman R, Nelms. The impact of monitoring techniques on progression to chronic breast cancer-related lymphedema: A meta-analysis comparing bioimpedance spectroscopy versus circumferential measurement. *Breast Cancer Res Treat*. 2021;185(3):709-740. Doi: 10.1007/s10549-020-05988-6.

Shah C, Whitworth P, Valente S, et al. Bioimpedance spectroscopy for breast cancer-related lymphedema assessment: Clinical practice guidelines. *Breast Cancer Res Treat*. 2023;198(1):1-9. Doi: 10.1007/s10549-022-06850-7.

Sleigh BC, Manna B. Lymphedema. In: *Statpearls* [internet]. Treasure Island (FL): Statpearls publishing. https://www.ncbi.nlm.nih.gov/books/NBK537239/. Last updated April 19, 2023.

U.S. Food and Drug Administration. 510(k) approval letter (k1801260). Sozo impedence plethysmograph. https://www.accessdata.fda.gov/cdrh_docs/pdf18/K180126.pdf. Published April 16, 2018.

Whitworth P, Vicini F, Valente SA, et al. Reducing rates of chronic breast cancer-related lymphedema with screening and early interventions: An update of recent data. *Cancer Surviv*. 2022. Doi: 10.1007/s11764-022-01242-8.

Policy updates

5/2017: initial review date and clinical policy effective date: 6/2017

6/2018: Policy references updated.

2/2019: Policy references updated.

1/2020: Policy references updated.

3/2021: Policy references updated.

3/2022: Policy references updated.

3/2023: Policy references updated.

4/2024: Policy references updated.

4/2025: Policy references updated.