Prior Authorization Review Panel
MCO Policy Submission

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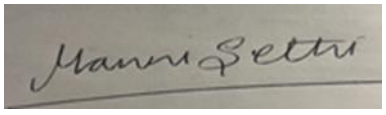
Plan: AmeriHealth Caritas Pennsylvania Community HealthChoices & Keystone First Community HealthChoices	Submission Date: 5/1/2026
Policy Number: ccp.1308	Effective Date: 6/1/2017 Revision Date: 4/1/2026
Policy Name: Bioimpedance spectroscopy extracellular fluid analysis	

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
Community HealthChoices

Bioimpedance spectroscopy extracellular fluid analysis

Clinical Policy ID: CCP.1308

Recent review date: 4/2026

Next review date: 8/2027

Policy contains: Bioimpedance extracellular fluid analysis;; breast cancer; lymphedema.

Keystone First Community HealthChoices has developed clinical policies to assist with making coverage determinations. Keystone First Community HealthChoices' 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 Community HealthChoices, 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 Community HealthChoices' 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 Community HealthChoices' clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First Community HealthChoices will update its clinical policies as necessary. Keystone First Community HealthChoices' clinical policies are not guarantees of payment.

Coverage policy

Bioimpedance spectroscopy is clinically proven and, therefore, may be medically necessary for the detection and surveillance of breast cancer-related lymphedema (Shah, 2023; see also Davies, 2020; Levenhagen, 2017; National Comprehensive Cancer Network, 2026a; National Comprehensive Cancer Network, 2026b; Wong, 2024) when ALL of the following criteria are met:

- The member has a breast cancer diagnosis and has undergone treatment with at least one of the following: axillary lymph node surgery; regional lymph node radiation therapy; taxane-based chemotherapy.
- Additional risk factors include but are not limited to a body mass index of 30 kg/m² or higher, 15 or more axillary lymph nodes removed, and post-operative complications; AND

Limitations
All other uses of bioimpedance are not medically necessary.

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. The International Society of Lymphology describes

stages of the disease ranging from 0 (the least severe, subclinical) to 3 (the most severe) (International Society of Lymphology, 2020). Stage 0 is characterized by impaired lymphatic transport in the absence of visible swelling. Stages 0 and 1 are responsive to conservative treatment, whereas Stages 2 and 3, marked by irreversible tissue changes including fibrosis, are substantially less responsive to intervention (National Comprehensive Cancer Network, 2026a). 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 are the most common causes of secondary lymphedema, and breast cancer treatment accounts for a substantial proportion of cases. Incidence varies by treatment modality: sentinel lymph node biopsy alone carries a risk below 10%, axillary lymph node dissection increases the risk to approximately 20%, and the combination of axillary dissection with regional nodal irradiation and systemic therapy is associated with incidence rates as high as 50% (Shah, 2023). Cumulative incidence at 10 years of follow-up after breast cancer treatment reaches 41% (National Comprehensive Cancer Network, 2026a). Risk factors identified across multiple professional organizations include axillary lymph node surgery, regional lymph node radiation therapy, taxane-based chemotherapy, body mass index of 30 kg/m² or higher, greater number of lymph nodes removed, and postoperative complications (National Comprehensive Cancer Network, 2026a; National Comprehensive Cancer Network, 2026b; Shah, 2016; Wong, 2024). An international expert panel ranked axillary lymph node dissection, postoperative radiotherapy, and the number of lymph nodes dissected as the highest-importance risk factors, with 90.6%, 84.4%, and 60.9% of panelists, respectively, selecting each among the top five determinants (Wong, 2024). Approximately 75% of cases develop within 3 years of treatment, although lymphedema can occur at any point in survivorship (National Comprehensive Cancer Network, 2026a).

Early detection and diagnosis are critical for optimal management, as early-stage lymphedema is more responsive to treatment than established disease (National Comprehensive Cancer Network, 2026a). However, detection of subclinical lymphedema is difficult with conventional diagnostic methods. Without a preoperative baseline measurement, misdiagnosis occurs in up to 50% of cases (National Comprehensive Cancer Network, 2026a). Diagnosis occurs clinically through history and physical examination, and in some cases through computed tomography, magnetic resonance imaging, and lymphoscintigraphy (Sleigh, 2023). 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 by measuring extracellular fluid accumulation before visible swelling develops. The portability of these options makes them potentially viable for both clinical and at-home use (Ridner, 2014).

Bioimpedance uses resistance to electrical current to calculate the total water content in the body (Ridner, 2014). The individual lies 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 cleared by the U.S. Food and Drug Administration 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

The published evidence on bioimpedance spectroscopy for detection and surveillance of breast cancer-related lymphedema includes clinical practice guidelines from multiple professional organizations, systematic reviews and meta-analyses of diagnostic accuracy and surveillance outcomes, and primary research studies. The evidence is concentrated in upper-extremity presentations following breast cancer treatment.

Clinical practice guidelines

A 2020 systematic review identified four clinical practice guidelines addressing lymphedema diagnosis and treatment, of which two included bioimpedance (O'Donnell, 2020). The guideline landscape has since expanded, with current guidance from the National Comprehensive Cancer Network, the American Physical Therapy Association, the Academy of Oncologic Physical Therapy, and the Multinational Association of Supportive Care in Cancer incorporating bioimpedance spectroscopy as a recommended or endorsed tool for early detection of breast cancer-related lymphedema within prospective surveillance programs (Davies, 2020; Levenhagen, 2017; National Comprehensive Cancer Network, 2026a; National Comprehensive Cancer Network, 2026b; Shah, 2023; Wong, 2024).

The National Comprehensive Cancer Network Survivorship guideline recommends that survivors at risk for lymphedema be regularly screened using validated volumetric tools or tools that measure extracellular fluid, explicitly including bioimpedance spectroscopy, and recommends pretreatment baseline measurements for individuals with treatment-related risk factors (National Comprehensive Cancer Network, 2026a). The National Comprehensive Cancer Network Breast Cancer guideline recommends considering pretreatment measurement of both arms as a baseline for individuals with lymphedema risk factors and cross-references the Survivorship guideline for assessment guidance (National Comprehensive Cancer Network, 2026b).

The American Physical Therapy Association diagnostic guideline recommends bioimpedance analysis to detect subclinical and early-stage lymphedema in individuals at risk for breast cancer-related lymphedema, including Stage 0 and Stage 1, with a Grade B recommendation based on Level II diagnostic accuracy evidence (Levenhagen, 2017). A companion interventions guideline from the Academy of Oncologic Physical Therapy establishes that subclinical and early-stage lymphedema detected through bioimpedance surveillance is managed with compression garment therapy (Davies, 2020). An international expert panel of 55 multidisciplinary clinicians convened by the Multinational Association of Supportive Care in Cancer reached consensus through a Delphi process that a prospective surveillance program is recommended to reduce the risk of chronic lymphedema after breast cancer surgery and that bioimpedance spectroscopy is a commonly used method for early detection within such programs (Wong, 2024). A separate clinical practice guideline concluded that bioimpedance spectroscopy represents a standard diagnostic approach for breast cancer-related lymphedema and supports routine use beginning at pretreatment, with the option to initiate surveillance post-treatment when no baseline is available (Shah, 2023). The American College of Radiology appropriateness criteria for upper-extremity swelling did not address bioimpedance (Dill, 2019).

These guidelines identify consistent risk factors for breast cancer-related lymphedema. Axillary lymph node surgery, regional lymph node radiation therapy, and taxane-based chemotherapy are recognized as primary treatment-related risk factors, with additional risk conferred by elevated body mass index, greater number of lymph nodes removed, and postoperative complications (National Comprehensive Cancer Network, 2026a; National Comprehensive Cancer Network, 2026b; Shah, 2023; Wong, 2024). An international Delphi panel ranked axillary lymph node dissection, postoperative radiotherapy, and the number of lymph nodes dissected

among the top five risk factors, with 90.6%, 84.4%, and 60.9% of panelists, respectively, selecting each (Wong, 2024). Consensus recommendations published in 2016 identified similar higher-risk populations, including those who underwent mastectomy, axillary lymph node dissection, sentinel node biopsy with more than six nodes sampled, regional nodal irradiation, or taxane-based chemotherapy (Shah, 2016).

Guidelines specify L-Dex score thresholds for clinical decision-making. When a preoperative baseline is available, treatment is recommended when the L-Dex score increases 6.5 or more from the pre-surgical value, with more intensive treatment indicated when the difference exceeds 10 (Shah, 2023; Wong, 2024). Without a preoperative baseline, an L-Dex score above 7.1 is recommended as the diagnostic cutoff (Levenhagen, 2017). Surveillance can begin post-treatment if no baseline is available and the L-Dex score is within the normal range (Shah, 2023). The interventions guideline recommends a monitoring schedule beginning with a preoperative assessment, repeated every 3 months for the first year postoperatively, then biannually for up to 5 years (Davies, 2020).

Systematic reviews and meta-analyses

Diagnostic accuracy

Initial systematic reviews established bioimpedance spectroscopy as an accurate diagnostic tool for established lymphedema while identifying limitations for early detection. A comprehensive literature review concluded that bioimpedance spectroscopy demonstrated accuracy for pre-existent lymphedema but had not been validated for early detection (Seward, 2016). A systematic review of measurement reliability found that bioimpedance achieved high accuracy in the lower extremities (interrater correlation coefficient 0.89) but that water volumetry, tape measurement, and perometry produced higher correlation coefficients (0.98 to 0.99) for upper-extremity measurement (Hidding, 2016). Subsequent analyses established a quantitative evidence base across multiple diagnostic performance metrics.

The American Physical Therapy Association clinical practice guideline synthesized published diagnostic accuracy data and reported sensitivity ranging from 0.66 to 1.00 and specificity from 0.84 to 0.98, with the highest accuracy in a research model with an area under the curve of 0.88 (Levenhagen, 2017). The same analysis reported interrater reliability of 0.95, intrarater reliability of 0.99, and a coefficient of variance of 0.2% to 0.27% (Levenhagen, 2017). A systematic review of 22 studies found that L-Dex scores differed significantly between individuals with lymphedema and healthy participants and that bioimpedance scores correlated with lymphedema volume (Forte, 2020, 2021). A 2026 systematic review evaluating 14 measurement instruments across 44 studies found that multi-frequency bioimpedance analysis yielded a Youden index at or above 0.90, the highest diagnostic value achieved by any individual instrument among alternatives that included perometry, magnetic resonance imaging, tape measurement, water volumetry, and clinical assessment (Buitenhuis, 2026). Bioimpedance spectroscopy detects extracellular fluid accumulation indicative of subclinical lymphedema before visible swelling develops, enabling identification of Stage 0 and Stage 1 disease when conservative intervention is most effective (Levenhagen, 2017; National Comprehensive Cancer Network, 2026a).

Prospective surveillance outcomes

The PREVENT randomized controlled trial enrolled 879 participants and compared bioimpedance spectroscopy-guided surveillance with tape measurement over a median follow-up of 33 months. Bioimpedance spectroscopy-guided surveillance with early compression garment intervention was associated with an 11.3% absolute reduction and a 59% relative reduction in chronic breast cancer-related lymphedema compared with tape

measurement, with fewer false-positive triggers in the bioimpedance group (Shah, 2023). The investigators classified this as Level I evidence and noted that comparable randomized evidence does not exist for other breast cancer-related lymphedema diagnostic techniques (Shah, 2023). Based on these data, the intervention threshold was refined from an L-Dex change of 10 (3 standard deviations above baseline) to 6.5 (2 standard deviations) to improve sensitivity for subclinical disease (Shah, 2023).

A meta-analysis of 50 studies encompassing approximately 67,000 individuals reported that the incidence of breast cancer-related lymphedema was 3.1% among individuals monitored with bioimpedance spectroscopy, compared with 12.9% with background monitoring and 17.0% with circumference monitoring (Shah, 2021). Real-world institutional data from multiple prospective cohorts demonstrate rates of clinical lymphedema of 4% to 14% with bioimpedance spectroscopy surveillance compared with 36% to 39% without prospective surveillance, alongside reductions in the proportion of individuals presenting with advanced-stage disease (Shah, 2023). Management of early-stage lymphedema costs an estimated $636 per individual per year, compared with $3,125 for late-stage disease, and bioimpedance spectroscopy-guided surveillance reduced costs by $356 to $770 per individual (Shah, 2023).

Other evidence

A study of 964 participants with breast cancer who underwent axillary node clearance found that arm volume measurement remained the reference standard for predicting lymphedema development (Bundred, 2015). A systematic review of 16 studies assessing bioimpedance for detection of lymphedema after gynecological surgery reported sensitivity of 73% and specificity of 84%, with lower-limb lymphedema detectable before clinical presentation, although the authors concluded that further comparative studies are needed (Asklof, 2018).

Knowledge gaps and limitations

The available evidence for bioimpedance spectroscopy is concentrated in upper-extremity breast cancer-related lymphedema; data for lower-extremity and other cancer-related lymphedema presentations are more limited (Asklof, 2018; Levenhagen, 2017). Bioimpedance analysis may not reliably detect late-stage tissue changes, including fibrosis and adipose infiltration, that occur in more advanced lymphedema (Levenhagen, 2017). The 2026 systematic review of measurement instruments found that while multi-frequency bioimpedance analysis demonstrated the highest diagnostic value among the instruments evaluated, the overall quality of the supporting evidence was characterized as insufficient, and no single instrument has been established as a definitive reference standard across edema types and anatomical locations (Buitenhuis, 2026). Expert consensus acknowledges that additional prospective studies are needed before a single preferred detection method can be designated (Wong, 2024).

In 2026 we revised the coverage determination for bioimpedance spectroscopy from investigational/not medically necessary to clinically proven and medically necessary for the detection and surveillance of breast cancer-related lymphedema, updated clinical practice guideline citations to reflect 2026 National Comprehensive Cancer Network Survivorship and Breast Cancer guideline versions, and added the Wong 2024 international Delphi consensus recommendations from the Multinational Association of Supportive Care in Cancer and Buitenhuis 2026 diagnostic accuracy evidence.

References

On March 18, 2026, 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.

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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.

4/2026: Policy references updated. Coverage shifted to medically necessary.

Related codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy CCP.1308 This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

Code	Code description
CPT 93702	Bioimpedance spectroscopy, extracellular fluid analysis