MEDICAL POLICY

POLICY TITLE	**BIOIMPEDANCE DEVICES FOR DETECTION AND MANAGEMENT OF LYMPHEDEMA**
POLICY NUMBER	**MP 2.190**

CLINICAL BENEFIT	☐ MINIMIZE SAFETY RISK OR CONCERN. ☐ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☒ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	**1/1/2025**

I. POLICY

Devices using bioimpedance (bioelectrical impedance spectroscopy) may be considered **medically necessary** for individuals at risk of developing lymphedema (e.g., undergoing breast cancer treatment, lymph node biopsy, regional lymphadenectomy, and/or radiation therapy for other non-breast malignancies).

Devices using bioimpedance (bioelectrical impedance spectroscopy) are considered **investigational** for all other uses. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

POLICY GUIDELINES

National Comprehensive Cancer Network Guidelines for Survivorship (Version 1.2023)
"Early detection/diagnosis and early referral are key for optimal lymphedema management because stages 0 and 1 are reversible, whereas stages 2 and 3 are less responsive to treatment. Therefore, survivors at risk for lymphedema should be regularly screened for lymphedema by symptom assessment, clinical exam, and, if available, bioimpedance spectroscopy. Patients should be educated about early symptoms and signs of lymphedema including fullness, tightness, heaviness, and pain."

"If possible, pretreatment limb measurement of both sides should be performed as a baseline for survivors with treatment-related or individual risk factors, preferably by a trained lymphedema specialist."

The NCCN outline the stages of lymphedema as follows:

- Stage 0 (latent/subclinical): Lymphatic dysfunction without swelling; subtle symptoms, such as a feeling of heaviness or fatigue in the limb, may be present.

- Stage 1 (spontaneously reversible): Accumulation of fluid and protein causing swelling; pitting edema may be evident; increased girth, heaviness, and/or stiffness of affected area. For the limbs, swelling is relieved with elevation.
- Stage 2 (irreversible): Spongy tissue consistency, with pitting edema that becomes less evident as swelling increases; tissue fibrosis causing hardness and increase in size. For the limbs, swelling is not relieved with elevation.
- Stage 3 (lymphostatic elephantiasis): Severe dry, scaly, thickened skin; increased swelling and girth of affected area; can be debilitating. In the limbs, fluid leakage and blisters are common. Fungal infection and papilloma may occur. Pitting can be absent due to progressive deposition of fat and fibrosis, which is the hallmark of later stage lymphedema.

National Comprehensive Cancer Network Guidelines for Breast Cancer (Version 5.2023)
"Lymphedema is a potential side effect after the treatment of axillary lymph node surgery resulting from damage to the lymphatic system. Early detection/diagnosis of lymphedema is key for optimal management. Consider pretreatment measurement of both arms as a baseline for patients with risk factors for lymphedema."

National Lymphedema Network
Screening and Measurement for Early Detection of Breast Cancer Related Lymphedema:
"Circumferential tape measurements are acceptable when made with a flexible, non-elastic Gulick II (or similar) tape measure. (6) At minimum, six measurements are recommended: circumference at the mid-hand, wrist, elbow, upper arm just below the axilla, and at 10cm distal to and proximal to the lateral epicondyle on both arms. Bioelectrical spectroscopy (BIS) or infrared perometry are suggested as alternative or adjunct methods to circumferential measurement. Specific protocols describing standard positions and measurements for these procedures should be in place"

American Physical Therapy Association
"Bioimpedance analysis should be used to detect lymphatic transport impairments and diagnose subclinical and early-stage lymphedema in patients at risk for breast cancer–related lymphedema (Stage 0 and 1)."
Evidence Quality: Level II reliability, validity, and diagnostic accuracy; Recommendation Strength: Grade B"

Cross-reference:

MP 6.013 Pneumatic Compression Devices for the Treatment of Lymphedema and Venous Insufficiency

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II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital Blue Cross please see additional information below, and subject to benefit variations as discussed in Section VI below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

III. DESCRIPTION/BACKGROUND

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Lymphedema

Lymphedema is an accumulation of fluid due to disruption of lymphatic drainage. Lymphedema can be caused by congenital or inherited abnormalities in the lymphatic system (primary lymphedema) but is most often caused by acquired damage to the lymphatic system (secondary lymphedema), often as a result cancer treatment. Survivors who had surgery, radiation, or chemoradiation to the axillary, supraclavicular, cervical, or pelvic inguinal lymph node system are at risk for the development of lymphedema. Sentinel node biopsy also increases the risk of lymphedema, although it poses less risk than complete dissection. A BMI ≥30 kg/m2, localized infection, increased number of nodes removed, and higher initial extent of disease raise the risk of lymphedema development.

Diagnosis

A diagnosis of secondary lymphedema is based on history (e.g., cancer treatment, trauma) and physical examination (localized, progressive edema, and asymmetric limb measurements) when other causes of edema can be excluded. Imaging, such as MRI, computed tomography, ultrasound, or lymphoscintigraphy, may be used to differentiate lymphedema from other causes of edema in diagnostically challenging cases.

Management and Treatment

Lymphedema is treated using elevation, compression, and exercise. Conservative therapy may consist of several features depending on the severity of the lymphedema. Patients are educated on the importance of self-care including hygiene practices to prevent infection, maintaining ideal body weight through diet and exercise, and limb elevation. Compression therapy consists of repeatedly applying padding and bandages or compression garments. Manual lymphatic drainage is a light pressure massage performed by trained physical therapists or by patients designed to move fluid from obstructed areas into functioning lymph vessels and lymph nodes. Complete decongestive therapy is a multiphase treatment program involving all of the previously mentioned conservative treatment components at different intensities. Pneumatic compression pumps may also be considered as an adjunct to conservative therapy or as an alternative to self-manual lymphatic drainage in patients who have difficulty performing self-manual lymphatic drainage. In patients with more advanced lymphedema after fat deposition and tissue fibrosis has occurred, palliative surgery using reductive techniques such as liposuction may be performed.

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Bioimpedance Spectroscopy
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.

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.

Regulatory Status
Devices that have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process to aid in the assessment of lymphedema are summarized in **Table 1**. These include the SOZO (K180126), Moisture-MeterD (K143310), and ImpediMed L-Dex™ U400 (K050415).

Table 1. FDA Cleared Bioimpedance Spectroscopy Devices for Lymphedema

Device and Manufacturer	Indication
SOZO ImpediMed (Carlsbad, CA) 2018	For adults at risk of lymphedema. Supports the measurement of extracellular fluid volume differences between the limbs and is presented to the clinician on an L-Dex scale as an aid to their clinical assessment of lymphedema. The device is only indicated for patients who will have or who have had lymph nodes, from the axillary and/or pelvic regions, either removed, damaged, or irradiated.
Moisture-MeterD Delfin Technologies (Stamford, CT)2015	Supports local assessment of tissue water differences between affected and contralateral non-affected arm tissues to aid in forming a clinical judgment of unilateral lymphedema in women. The device is not intended to make diagnosis or predict arm lymphedema.
ImpediMed L-Dex™ U400 ImpediMed (Carlsbad, CA) 2007	Supports the measurement of extracellular fluid volume differences between the arms to aid in the clinical assessment of unilateral lymphedema of the arm in women. This device is not intended to diagnose or predict lymphedema of an extremity.

FDA product code: OBH.

IV. RATIONALE

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Summary of Evidence

For individuals who have known or suspected lymphedema who receive bioimpedance spectroscopy, the evidence includes a systematic review, one RCT, prospective comparative observational studies, and multiple uncontrolled observational studies. The relevant outcomes are test validity, symptoms, and quality of life. Results from the PREVENT trial compared bioimpedance with standard tape measure following treatment for breast cancer. At a median follow up of 32.9 months, BIS patients triggered intervention at a lower rate than tape measured patients (20.1% vs 27.5%) and fewer patients progressed in this group (7.9% vs 19.2%). The RCT was limited by its open label design and lack of reporting on important health outcomes. The single prospective comparative study found a significantly lower rate of clinical lymphedema in patients managed with bioimpedance devices but had several limitations, including nonrandomized design, lack of blinding, lack of complete data on a substantial proportion of enrolled patients, and lack of a systematic method for diagnosing lymphedema in the control group. Retrospective studies suggested that postoperative bioimpedance monitoring is feasible but provide limited information about its efficacy. As more studies emerge, there may be stronger evidence to suggest the benefits of this technology. With the recently published results of the PREVENT trial and current societal guidance, there is sufficient evidence to determine the positive effects of the technology on health outcomes.

V. DEFINITIONS

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NA

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits, and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

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Capital Blue Cross' medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's

plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Medically Necessary

Procedure Codes								
93702								

IX. REFERENCES

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X. POLICY HISTORY

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MP 2.190	**04/16/2020 Consensus Review.** No change to policy statement. References added. Description/Background and Rationale sections updated. FEP policy removed. Coding reviewed.
	02/18/2021 Consensus Review. Policy statement unchanged. References updated.
	02/03/2022 Consensus Review. Policy statement unchanged. References updated.
	02/07/2023 Consensus Review. Policy statement unchanged. NCCN statement added. Added policy guidelines. Literature review and updated references.
	02/16/2024 Major Review. Bioimpedance spectroscopy now MN for at risk individuals. Update to policy guidelines, background, rationale, and references.
	11/19/2024 Administrative Update. Removed NCCN statement.

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BlueShield Association. Communications issued by Capital Blue Cross in its capacity as administrator of programs and provider relations for all companies.