



Qualified Health Plans offered in North Carolina by CareSource North Carolina Co., d/b/a CareSource

<b>MEDICAL POLICY STATEMENT</b>	
<b>North Carolina Marketplace</b>	
<b>Policy Name &amp; Number</b>	<b>Date Effective</b>
Breast Cancer Index® (BCI) for Managing Breast Cancer Treatment- MP NC-MM-1515	06/01/2024
<b>Policy Type</b>	
<b>MEDICAL</b>	

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Medical Policy Statements prepared by CareSource and its affiliates do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medical Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination. According to the rules of Mental Health Parity Addiction Equity Act (MHPAEA), coverage for the diagnosis and treatment of a behavioral health disorder will not be subject to any limitations that are less favorable than the limitations that apply to medical conditions as covered under this policy.

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## A. Subject

### **Breast Cancer Index® (BCI) for Managing Breast Cancer Treatment**

## B. Background

According to the CDC each year in the United States, about 260,000 individuals are expected to be diagnosed with invasive breast cancer, of which approximately 90% are diagnosed with early-stage disease. Hormone-receptor positive (HR+) breast cancer is the most common subtype of breast cancer (~80% of cases) and has the most favorable prognosis overall. Standard-of-care treatment for HR+ disease includes primary adjuvant anti-estrogen therapy with tamoxifen, an aromatase inhibitor (AI), or a sequence of these.

Along with anti-estrogen therapy, there are two additional key treatment decisions which are priorities in the management of early-stage breast cancer. The first decision is whether the patient is of sufficient risk of recurrence to recommend systemic adjuvant chemotherapy. In addition, while HR+ early-stage breast cancer patients have a favorable prognosis overall, there is an ongoing risk of distant recurrence (DR) beyond year 5 (late recurrence), and 75% of deaths occur more than 5 years post-diagnosis. The second decision is whether to recommend extension of endocrine therapy beyond the initial primary adjuvant therapy. For each treatment decision, physicians and patients must weigh whether the potential benefit from the additional treatment regimen is likely to outweigh the risks of cardiovascular toxicity, bone fractures, and other side effects that impair quality of life and compliance.

The Breast Cancer Index (BCI) is a gene expression–based signature that consists of two functional biomarker panels, the HOXB13/IL17BR (H/I) ratio and the molecular grade index (MGI), that evaluate important estrogen signaling and proliferation pathways in breast cancer. It analyzes the activity of 11 genes that can influence how likely the cancer is to come back 5 to 10 years after diagnosis, as well as how likely a patient is to benefit from 5 additional years of hormonal therapy. The test provides both prognostic and predictive results.

The BCI Prognostic result estimates how likely the cancer is to come back 5 to 10 years after diagnosis (late recurrence). The result is given as a percentage. Example: a prognostic result of 2.2% means the patient has a 2.2% risk of the cancer coming back 5 to 10 years after diagnosis.

The BCI Predictive result is reported as "yes" or "no." A yes result means the patient is likely to benefit from 5 more years of hormonal therapy. A no result means the patient is not likely to benefit from 5 more years of hormonal therapy.

BCI is tested once per patient lifetime on formalin-fixed, paraffin-embedded (FFPE) tissue from the primary tumor specimen obtained prior to adjuvant treatment.

The MEDICAL Policy Statement detailed above has received due consideration as defined in the MEDICAL Policy Statement Policy and is approved.

### C. Definitions

- **Adjuvant Therapy for Early-stage Breast Cancer** – Tamoxifen is FDA approved for adjuvant hormone treatment of premenopausal and postmenopausal women (and men) with ER-positive early-stage breast cancer, and the aromatase inhibitors anastrozole, letrozole, and exemestane are approved for this use in postmenopausal women.
- **Gene Expression Testing** – A laboratory test that analyzes mRNA patterns to determine gene activity.
- **Predictive Molecular Markers** – Biomarkers which can be used to evaluate the likelihood of benefit from a specific clinical intervention, or the differential outcomes of more than one intervention.
- **Prognostic Molecular Markers** – Biological characteristics that are objectively measured and evaluated to predict the course of a disease or a response to a therapeutic intervention among patients with the same characteristic. Examples include the presence of a particular gene variant, patterns of gene expression or levels of a particular protein in body fluids.

### D. Policy

- I. CareSource considers Breast Cancer Index for breast cancer as a technique for managing the treatment of breast cancer in females or males with invasive breast cancer medically necessary in the following situations:
  - A. Member is newly diagnosed (within the last 6 months) and **ALL** of the following criteria are met:
    1. Lymph node negative or 1-3 positive ipsilateral axillary lymph nodes.
    2. No distant metastases.
    3. Estrogen receptor positive (ER+), or progesterone receptor positive (PR+), or both.
    4. HER2 (human epidermal growth factor receptor-2) receptor negative.
    5. Adjuvant chemotherapy is not precluded due to any other factor (eg, advanced age and/or significant co-morbidities).
  - B. Member is currently receiving adjuvant hormonal therapy (eg, Tamoxifen or an aromatase inhibitor) for a breast cancer and **ALL** of the following criteria are met:
    1. Hormone receptor-positive (estrogen receptor positive, progesterone receptor positive or both).
    2. HER2 receptor negative.
    3. The member and treating physician have had a discussion prior to testing
      - a. regarding the potential results of the test and
      - b. use of the results to guide a decision regarding extended adjuvant hormonal therapy.
- II. Gene expression profiling in breast cancer are unproven and not medically necessary for all other indications, including ductal carcinoma in situ (DCIS), due to insufficient evidence.

### E. Conditions of Coverage

N/A

The MEDICAL Policy Statement detailed above has received due consideration as defined in the MEDICAL Policy Statement Policy and is approved.

F. Related Policies/Rules  
 Medical Necessity Determinations

G. Review/Revision History

DATE		ACTION
<b>Date Issued</b>	06/21/2023	New Policy. Approved at committee.
<b>Date Revised</b>	03/13/2024	Updated reference. Approved at Committee.
<b>Date Effective</b>	06/01/2024	
<b>Date Archived</b>		

H. References

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3. Molecular Test Assessment: Breast Cancer Index (BioTheranostics Inc.) for Lymph Node-Negative Patients. Hayes; 2022. Accessed February 28, 2024. [www.hayesinc.com](http://www.hayesinc.com)
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