CareSource

MEDICAL POLICY STATEMENT
Georgia Medicaid

Policy Name & Number	Date Effective
Breast Cancer Index® (BCI) for Managing Breast Cancer Treatment GA-MCD-MM-1512	11/01/2023
Policy Type	
MEDICAL	

Medical Policy Statement prepared by CareSource and its affiliates are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

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.

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; and
2. No distant metastases; and
3. Estrogen receptor positive (ER+), or progesterone receptor positive (PR+), or both; and
4. HER2 (human epidermal growth factor receptor-2) receptor negative; and
5. Adjuvant chemotherapy is not precluded due to any other factor (e.g., advanced age and/or significant co-morbidities).

B. Member is currently receiving adjuvant hormonal therapy (e.g., 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); and
2. HER2 receptor negative; and
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

F. Related Policies/Rules
Medical Necessity Determinations

G. Review/Revision History

	DATE	ACTION
Date Issued	06/21/2023	New Policy. Approved at committee.
Date Revised		
Date Effective	11/01/2023	
Date Archived		

H. References

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4. Local Coverage Determination L37913. MolDX: Breast Cancer Index® (BCI) Gene Expression Test (2023). Retrieved May 16, 2023 from www.cms.gov.
5. National Cancer Institute (NCI) Fact Sheet. Hormone Therapy for Breast Cancer. Retrieved May 16, 2023 from www.cancer.gov.
6. Noodhoek I, et al. Breast Cancer Index Predicts Extended Endocrine Benefit to Individualize Selection of Patients with HR+ Early-stage Breast Cancer for 10 Years of Endocrine Therapy. Clin Cancer Res. 2021 Jan 1;27(1):311-319. doi: 10.1158/1078-0432.CCR-20-2737. Epub 2020 Oct 27. PMID: 33109739. Retrieved May 16, 2023 from www. pubmed.ncbi.nlm.nih.gov.
7. Optum EncoderPro for Payer Professionals. CPT code 81518. Retrieved May 16, 2023 from www.encoderprofp.com.
8. Sanft T, et al. Prospective assessment of the decision-making impact of the Breast Cancer Index in recommending extended adjuvant endocrine therapy for patients with early-stage ER-positive breast cancer. Breast Cancer Res Treat. 2015 Dec;154(3):533-41. doi: 10.1007/s10549-015-3631-9. Epub 2015 Nov 14. PMID: 26578401. Retrieved May 16, 2023 from www. pubmed.ncbi.nlm.nih.gov.

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