Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines:

# Breast Cancer Gene Expression Tests

*Effective: January 1, 2025*

| | |
|---|---|
| **Prior Authorization Required**<br>If REQUIRED, submit supporting clinical documentation pertinent to service request to the FAX numbers below. | Yes ☒ No ☐ |
| **Notification Required**<br>IF REQUIRED, concurrent review may apply | Yes ☐ No ☒ |

**Applies to:**

**Commercial Products**

☐ Harvard Pilgrim Health Care Commercial products; 800-232-0816

☒ Tufts Health Plan Commercial products; 617-972-9409

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

**Public Plans Products**

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); 888-415-9055

☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; 888-415-9055

☐ Tufts Health RITogether – A Rhode Island Medicaid Plan; 857-304-6404

☐ Tufts Health One Care – A dual-eligible product; 857-304-6304

**Senior Products**

☐ Harvard Pilgrim Health Care Stride Medicare Advantage; 866-874-0857

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); 617-673-0965

☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); 617-673-0965

☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); 617-673-0965

**Note:** While you may not be the provider responsible for obtaining prior authorization or notifying Point32Health, as a condition of payment you will need to ensure that any necessary prior authorization has been obtained and/or Point32Health has received proper notification. If notification is required, providers may additionally be required to provide updated clinical information to qualify for continued service.

## Overview

Breast cancer gene expression (BCE) tests, including Breast Cancer Index (BCI), Prosigna and EndoPredict, are used to help evaluate the likely course of disease and the risk of recurrence in a post-menopausal individual diagnosed with early-stage disease. BCE tests are used to guide treatment decisions regarding adjuvant treatment (endocrine therapy and/or chemotherapy).

Breast Cancer Index is also used to guide treatment decisions for extended adjuvant endocrine therapy beyond five years.

## Clinical Guideline Coverage Criteria

The Plan considers breast cancer gene expression testing (Breast Cancer Index, Prosigna **OR** EndoPredict) as medically necessary for post-menopausal individuals diagnosed with early-stage, invasive breast cancer when the following criteria are met:

1. BCE test will be utilized to guide treatment decision regarding adjuvant treatment **and**;
    a. Axillary-node status is negative or node-positive with 1-3 involved ipsilateral axillary lymph nodes; and
    b. Breast tumor is hormone receptor positive (HR+) [estrogen receptor-positive (ER+) and/or progesterone receptor-positive (PR+)]; **and**
        i. Breast tumor is human epidermal growth factor receptor 2 (HER2) -negative; **and**

c. There is no evidence of distant metastatic breast cancer; **and**
d. Adjuvant chemotherapy is not precluded due to any other factor (e.g., advanced age, significant co-morbidities);

**OR**

2. The Plan considers Breast Cancer Index as medically necessary when utilized to guide treatment decision regarding extended endocrine therapy with tamoxifen, an aromatase inhibitor (AI) or a sequence of tamoxifen followed by an AI; **and**
   a. Ancillary node status is negative or node-positive with 1-3 positive nodes breast; **and**
   b. Member has been treated with 5 years of primary endocrine therapy and is without evidence of recurrence

## Limitations

The Plan will not cover:

1. More than one type of BCE test (e.g., Oncotype Dx Breast, MammaPrint, BCI) to determine necessity of adjuvant treatment on same tumor

## Codes

The following code(s) require prior authorization:

**Table 1: CPT/HCPCS Codes**

| Code | Description |
|---|---|
| 81518 | Oncology (breast), mRNA, gene expression profiling by real-time RT-PCR of 11 genes (7 content and 4 housekeeping), utilizing formalin fixed paraffin-embedded tissue, algorithms reported as percentage risk for metastatic recurrence and likelihood of benefit from extended endocrine therapy |
| 81520 | Oncology (breast), mRNA gene expression profiling by hybrid capture of 58 genes (50 content and 8 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a recurrence risk score |
| 81522 | Oncology (breast), mRNA, gene expression profiling by RT-PCR of 12 genes (8 content and 4 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as recurrence risk score |

**References:**


1. Bartlett JMS, Sgroi DC, Treuner K, et al. Breast Cancer Index and prediction of benefit from extended endocrine therapy in breast cancer patients treated in the Adjuvant Tamoxifen-To Offer More? (aTTom) trial. *Ann Oncol*. 2019;30(11):1776-1783. doi:10.1093/annonc/mdz289.
2. Raab R, Ismaila N, Andre F, Stearns V, Kalinsky K. Biomarkers for Adjuvant Endocrine and Chemotherapy in Early-Stage Breast Cancer: ASCO Guideline Update Q and A [published online ahead of print, 2022 Jun 21]. *JCO Oncol Pract*. 2022;OP2200230. doi:10.1200/OP.22.00230
3. National Comprehensive Cancer Network, NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines); Breast Cancer, Version 4.2023. Accessed June 28, 2023. breast.pdf (nccn.org)
4. Foukakis T, MD, PhD; Bergh J, MD, PhD, FRCP, Hurvitz S, MD, FACP. Deciding when to use adjuvant chemotherapy for hormone receptor-positive, HER2-negative breast cancer. Accessed by subscription only July 13, 2022. Deciding when to use adjuvant chemotherapy for hormone receptor-positive, HER2-negative breast cancer - UpToDate
5. National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Breast Cancer V.4.2022. Accessed November 1, 2022. breast.pdf (nccn.org)
6. O'Shaughnessy J, Encarnacion CA, O'Neal B, et. al. The Breast Cancer Index Registry Study: Initial analysis of the first 1,000 patients. Journal of Clinical Oncology 2022 40:16_suppl, e12513-e12513.
7. Liefers GL, Noordhoek I, Putter H, et. al. Journal. Predictive performance of breast cancer index (BCI) and clinical treatment score post-5 years (CTS5) in the IDEAL study. Journal of Clinical Oncology 2022 40:16_suppl, 545-545.
8. Andre F, Ismaila N, Allison KH, et al. Biomarkers for Adjuvant Endocrine and Chemotherapy in Early-Stage Breast Cancer: ASCO Guideline Update [published correction appears in J Clin Oncol. 2022 Aug 1;40(22):2514]. *J Clin Oncol*. 2022;40(16):1816-1837.

## Approval And Revision History

July 20, 2022: Reviewed by the Medical Policy Approval Committee (MPAC) for effective date of September 1, 2022.

Subsequent endorsement date(s) and changes made:

- June 15, 2022: AIM Specialty Health® implementation for management of genetics reviewed by MPAC. Effective October 1, 2022, Medical Necessity Guideline no longer applicable to Tufts Health Together, Tufts Health Direct, Tufts Health Unify and Tufts Health RITogether. AIM Specialty Health® (AIM) will oversee medical necessity review for Tufts Health Public Plans.
- November 16, 2022: Reviewed by MPAC. Criteria updated to align with American Society for Clinical Oncology and National Comprehensive Cancer Network guidelines; limitations updated
- December 21, 2022: Reviewed by MPAC, renewed without changes
- July 19, 2023: Reviewed by MPAC; coverage expanded to include EndoPredict and Prosigna. Medical Necessity Guideline changed to Breast Cancer Gene Expression Tests; CPT codes 81520 and 81522 added effective September 1, 2023
- October 18, 2023: Reviewed by MPAC; renewed without changes
- November 2023: Unify name changed to One Care effective January 1, 2024
- November 21, 2024: Reviewed by MPAC; renewed without changes, effective January 1, 2025.

## Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.