Medical Coverage Policy
Policy Number – MP22-025E
Original review date – 08/01/22
Effective date – 11/19/2025

Oncotype DX® breast cancer assay

Background

Oncotype Dx® Breast Cancer Recurrence Score test is a gene expression profiling test done on tumor samples. RNA from the tumor is extracted and the expression of 21 genes (16 cancer-related and five reference genes) is analysed using RT-PCR. The result is reported as a Recurrence Score, which estimates the risk of metastasis and predicts the likelihood of benefit from chemotherapy and/or hormone therapy.

Policy statement

Disclaimer: This policy is applicable to TRICARE Prime and Select beneficiaries and may not apply to Active Duty Service Members (ADSM) under Supplemental Health Care Program (SHCP) or TRICARE Prime Remote (TPR) in accordance with TRICARE Operations Manual (TOM) Chapter 17, Section 3. Please review TOM Chapter 17, Section 3, Paragraph 2.0 onwards, regarding SHCP coverage and any TRICARE-specific exclusions included in this coverage policy to accurately determine the benefit for ADSMs.

Oncotype DX Recurrence Score test (81519) may be approved per criteria described in the TOM, Chapter 18, Section 3, detailed below:

I. Management of breast cancer is dependent on result of the test i.e. decision to use chemotherapy in addition to hormone therapy will be made based on the recurrence score AND one of the following criteria are met:
   a. Tumor is estrogen receptor positive, human EGFR 2 (HER2) negative, and lymph node negative; OR
   b. Tumor is estrogen receptor positive, human EGFR 2 (HER2) negative, with one to three involved ipsilateral axillary lymph nodes

Limitations of coverage

I. Oncotype DX Breast Cancer Recurrence Score test will not be covered for any indications other than those listed above per the TOM

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(TOM) Chapter 18, Section 3, Figure 18.3-1

TEST NAME:	**Oncotype DX® Breast Cancer Assay (Oncotype DX®)**
Effective Date:	January 1, 2013
Coverage Guidelines:	Oncotype DX® gene testing is covered for the following indications:

	· Estrogen Receptor (ER) positive (+), Lymph Node (LN) negative (-), human EGFR 2 negative (HER2-) breast cancer patients who are considering whether to use adjuvant chemotherapy in addition to standard hormone therapy. · ER+, HER2- breast cancer patients with one to three involved ipsilateral axillary lymph nodes who are considering whether to use adjuvant chemotherapy in addition to hormonal therapy.

Chapter 18, Section 3, 7.0 Contractor Responsibilities
The contractor shall:
Preauthorize the demonstration approved Laboratory Developed Tests (LDT) as required and verify medical necessity according to all indications detailedon the approved LDT list published on the TRICARE Rates and Reimbursement web page.The contractor shall consider only the indications listed in the Coverage Guidelines for cost-sharing. The contractor shall issue the notification of decision to authorize use of the LDT in writing to both the applicant provider and the beneficiary receiving the LDT.

Coding information

Code	Description
81519	Oncology (breast), mRNA, gene expression profiling by real-time RT-PCR of 21 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as recurrence score

References

1. TRICARE Operations Manual Chapter 18, Section 3 TRICARE Manuals - Display Chap 18 Sect 2 (Change 50, Sep 17, 2025)

Revision history

December 2023: Updated references

November 2024: No changes

November 2025: Updated references

Approved by:

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Chief Medical Officer

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