Gene Expression Profiling for Breast Cancer — Oncotype DX® Breast Cancer Assay

Last Review Date: June 15, 2015  Number: MG.MM.LA.07d

Medical Guideline Disclaimer

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Definitions

Oncotype DX is a multiparameter gene expression assay that predicts the likelihood of breast cancer recurrence in members with newly diagnosed early stage invasive breast cancer. The test is used to guide use of adjuvant tamoxifen and adjuvant chemotherapy.

Guideline

Members with breast cancer are eligible for Oncotype DX coverage when all of the following criteria are met:

1. Newly diagnosed (< 6 months)
2. Stage I or II
3. Node-negative or with 1–3 involved ipsilateral axillary lymph nodes
4. Micrometastases < 2mm in size (considered node-negative [Stage pN1])
5. Estrogen receptor-positive
6. Human epidermal growth factor receptor 2 (HER-2/neu) negative
7. Member will receive Tamoxifen or Tamoxifen and adjuvant chemotherapy
Limitations/Exclusions

1. Repeat testing and indications other than those listed above (e.g., colon cancer) are not considered medically necessary.

2. Tests for genetic expression profiling other than Oncotype are not considered medically necessary** (i.e., BluePrint™, HerMark® [covered for Medicare members only], H:I ratio, Rotterdam/Veridex 76-gene prognostic signature, HOX13:IL17BR [two-gene signature]).


Applicable Procedure Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Use for Medicare</th>
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<tbody>
<tr>
<td>81519</td>
<td>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 (New code effective 01-01-2015)</td>
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<tr>
<td>83854</td>
<td>Gene expression profiling panel for use in the management of breast cancer treatment</td>
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References


Specialty-matched clinical peer review.