



## Gene Expression Profiling for Breast Cancer — Oncotype DX<sup>®</sup> Breast Cancer Assay

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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 ( $\leq$  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]).

\*\* Policies for covered exceptions: [Gene Expression Profiling for Breast Cancer — MammaPrint®](#), [Gene Expression Profiling for Breast Cancer — Breast Cancer Index](#).

### Applicable Procedure Codes

81519	Use for Medicare
	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)
S3854	Use for Commercial
	Gene expression profiling panel for use in the management of breast cancer treatment

### References

National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology™. Breast cancer. Version.2.2015. Available at: [http://www.nccn.org/professionals/physician\\_gls/pdf/breast.pdf](http://www.nccn.org/professionals/physician_gls/pdf/breast.pdf) . Accessed June 16, 2015.

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