Gene Expression Profiling for Breast Cancer — MammaPrint®

Last Review Date: June 18, 2014	**Number:** MG.MM.LA.12c

Definitions

MammaPrint® is a qualitative in vitro diagnostic test service, performed in a central laboratory, using the gene expression profile of fresh breast cancer tissue samples to assess a patients' risk for distant metastasis (up to 10 years for patients less than 61 years old, up to 5 years for patients ≥ 61 years).

Guideline

Members with Stage 1 or Stage 2 invasive breast cancer breast cancer are eligible for MammaPrint coverage for recurrence risk prediction when the following criteria are met:

1. Tumor size < 5.0 cm
2. ER+ or ER-
3. 0–3 local lymph nodes involved with nodal micrometastases (< 2.0 mm [Stage pN1])

Limitations/Exclusions

1. MammaPrint is not considered medically necessary adjuvant therapy treatment planning.
2. Repeat testing and indications other than those listed above are not considered medically necessary.
3. Tests for genetic expression profiling *other* than the MammaPrint or Oncotype® DX Breast Cancer Assay (see EmblemHealth's Oncotype guideline) 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]).

4. The MammaPrint test is not considered reasonable and necessary ≥ 6 months post diagnosis, or if chemotherapy has been initiated, as clinical utility has not been established when chemotherapy is delayed.

Applicable Procedure Codes

	Use for Medicare
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 (New code effective 01/01/2015)
	Use for Commercial
S3854	Gene expression profiling panel for use in the management of breast cancer treatment

References

FDA. 510(k) Substantial Equivalence Determination Decision Summary. 2007. http://www.accessdata.fda.gov/cdrh_docs/reviews/K101454.pdf. Accessed July 11, 2013.

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 . Accessed June 2, 2015.

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