Clinical Review Criteria Related to Oncotype DX® and MammaPrint Breast Cancer Assay

Oncotype DX and MammaPrint Breast Cancer Assay testing is for newly diagnosed women with Node negative or Node positive, ER positive, HER2-negative and to determine recurrence risk for deciding whether or not to undergo adjuvant chemotherapy. This may be **Medically Necessary** in women with primary, invasive breast cancer meeting all of the following:

I. Criteria for Approval

A. 0-3 ipsilateral axillary nodes involved.

B. Breast tumor is hormone receptor positive.

C. The test will help in the decision of whether to have chemotherapy in addition to hormonal therapy following surgical resection.

CPT Code
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.
This code cannot be used for Ductal Carcinoma in Situ (DCIS) diagnosis.

II. What is Not Covered

A. The use of gene expression assays in Men with breast cancer is considered investigational.

MHI also considers the below tests experimental/investigational:

- BluePrint™ Molecular Subtyping Profile
- Breast Cancer Index SM/Breast Cancer Gene Expression Ratio (i.e., 2-Gene Ratio, Theros H: I, HOXBI3/IL17BR)
- BreastOncPX™ (Breast Cancer Gene Expression Prognosis Profile)
- Combimatrix™ Breast Cancer Profile
- eXagen®
- FoundationOne™
- HERmark® Breast Cancer Assay
- Clarient Insight DX™ MammaStrat™
- Invasiveness Signature™
- MammaPrint 70-gene signature
- NuvoSelect™ eRx 200-Gene Assay
- Oncotype DX Breast Cancer Assay for DCIS

HNE Review Dates: 10/14/2014, 12/8/2015,12/13/2016 10/14/14, , Reinstated 12/8/15, 12/13/16
MHI Review Dates: 2/2/2016, 2/9/2017

- PAM 50, formerly Breast Bioclassifier™
- Prosigna™ Breast Cancer Prognostic Gene Signature Assay
- Randox Assay
- Rotterdam Signature 76-Panel
- Symphony™ Personalized Breast Cancer Genomic Profile (MammaPrint®, BluePrint™, TargetPrint®)
- TargetPrint®
- TheraPrint™

References:

NCQA Standard, UM 2, Clinical Criteria for Utilization Management Decisions, Element A

Winifred S. Hayes, Inc., Oncotype DX® for Prognosis of Breast Cancer Recurrence, published Dec 11, 2012
(Last Accessed 11/1/16)

Harris L, Fritsche H, Mennel R, et al. American Society of Clinical Oncology 2007 update of recommendations for the use of tumor markers in breast cancer. J Clin Oncol. 2007 Nov 20; 25 (33):5287-312. Epub 2007 Oct 22.
(Last Accessed 11/1/16)

Breast Cancer. NCCN Clinical Practice Guidelines in Oncology. Version 3. 2015 Available at: http://www.nccn.org/professionals/physician_gls/pdf/breast.pdf
(Last Accessed 11/1/16)

http://www.oncotypedx.com/en-US/Breast/HealthcareProfessional/Guidelines.aspx
(Last Accessed 11/1/16)

http://www.agendia.com/pages/mammaprint/21.php

(Last Accessed 11/1/16)

Summary of Changes:
02/09/2017

- I., Criteria for Approval, removed:
  A. Breast tumor is HER2- receptor negative or HER2 -receptor positive
  B. Axillary node status is negative or any axillary node micrometastasis is no greater than 2.0 millimeters in size

  Added the underlined below:
  A. 0-3 ipsilateral axillary nodes involved

- Source/Citation Section:
  Updated Last Accessed dates.