Subject: Breast Cancer Gene Expression Assays*

Effective Date: December 11, 2007

Department(s): Utilization Management

Policy: Tumor tissue gene expression assays (CPT 81519) used to determine prognosis in patients with breast cancer are reimbursable under Plans administered by QualCare, Inc., as delineated in this policy.

Objective: To assure proper and consistent reimbursement and to limit coverage of breast cancer gene expression assays to those whose validity is adequately supported by peer-reviewed literature.

Procedure:

1. The Oncotype DX ® assay is reimbursable in patients who are recently diagnosed with breast cancer and meet all of the following criteria:

   - Tumor is estrogen-receptor positive
   - Tumor is HER2-receptor negative or HER2-receptor positive but less than 1 cm in diameter
   - There is no evidence of metastasis and axillary nodes are negative for breast cancer
   - OR the individual is postmenopausal with estrogen receptor positive tumor and 1-3 ipsilateral axillary lymph nodes are positive for metastatic disease.

Adjuvant chemotherapy is not contraindicated by any other factor (including but not limited to advanced age or significant comorbidities)
Note: gene expression profiling is not recommended for micro-invasive disease (pN1mi- <2mm axillary lymph node metastasis).

2. Oncotype DX® is not reimbursable for ductal carcinoma in situ (DCIS) or any other condition not listed in section 1 above as it is considered investigational or unproven due to inadequate documentation in the medical literature.

3. Breast cancer gene expression assays that are NOT reimbursable because they are deemed to be experimental, investigational, or unproven because of insufficient support in peer-reviewed literature, include but are not limited to:

- Mammaprint®
- Rotterdam Signature 76-Panel
- Breast Cancer Gene Expression Ratio

References

National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology-Breast Cancer Version 1.2016, accessed online at nccn.org on 01/25/16


Paik S. Is gene array testing to be considered routine now? Breast.2011;20(S3):S87-91


Conlin AK, Seidman AD. Use of the Oncotype DX 21-gene assay to guide adjuvant decision making I early-stage breast cancer. Mol Diagn Ther 2007;11(6):355-360 (Jan)


*Consistent with Summary Plan Description (SPD). When there is discordance between this policy and the SPD, the provisions of the SPD prevail.