Breast Cancer Gene Expression Assays

DESCRIPTION

Laboratory tests have been developed to detect the expression of different genes in breast tumor tissue and combine the results into a prediction of distant recurrence risk (return of detectable cancer in another part of the body) for individuals with early-stage breast cancer. Test results may help determine whether to include adjuvant chemotherapy in post-surgical management of breast cancer. In addition to guiding treatment decisions related to chemotherapy, Breast Cancer index™ has been validated to predict late distant recurrence risk and endocrine responsiveness when considering extension of endocrine therapy.

Most individuals with newly diagnosed, early-stage or nonmetastatic breast cancer are disease-free after initial local and regional treatment; however, almost a third of women develop metastasis by the 5 – 10 year follow-up.

Examples of Gene Expression Assays for Breast Cancer:

Test	Description
Breast Cancer Index ™	6-11 gene predictor for risk of late recurrence at 5 to 10 years; Predictive of benefit of extended adjuvant endocrine therapy
EndoPredict®	12-gene molecular score for early and late recurrence
MammaPrint®	70 gene analysis; provides low – high risk classification for 10 year prognosis
Oncotype DX® for Breast Cancer	21-gene assay; Recurrence Score® of 0 – 100 provides 10 year prognosis information
Prosigna® (PAM 50)	Digital analysis system based on prediction of 50 gene microarray; giving a numerical value of 0-100 that correlates with the probability of recurrence within 10 years.

POLICY

- Breast cancer gene expression assay is considered ***medically necessary*** if the medical appropriateness criteria are met. **(See Medical Appropriateness below.)**

- Breast cancer gene expression assay is considered ***investigational*** for other indications including, but not limited to, the following**:**

  - Noninvasive ductal carcinoma in situ (i.e., Oncotype DX® Breast DCIS Score)
  - When performed using BluePrint® 80-gene molecular subtyping assay
  - When performed using InsightTNBCType®

MEDICAL APPROPRIATENESS

- Breast cancer gene expression assay is considered **medically appropriate** if **ANY ONE** of the following are met:

  - Test results will guide decision-making regarding adjuvant chemotherapy and **ALL** of the following:

- Newly diagnosed carcinoma of breast
- Primary, invasive breast cancer
- Human epidermal growth factor receptor 2 (HER2) negative
- Indicated when **ANY ONE** of the following tests is used:
  - MammaPrint® when **ALL** of the following are met:
    - Female breast cancer
    - Tumor size > 0.5 cm (5mm) in greatest dimension (T1b-T3)
    - Estrogen receptor positive (ER+)
    - Lymph node status is **ANY ONE** of the following:
      - No regional lymph node metastasis (pN0)
      - Involvement of 1-3 positive ipsilateral axillary lymph nodes
  - Oncotype DX® when **ALL** of the following are met:
    - Male or Female breast cancer
    - Tumor size > 0.5 cm (5mm) in greatest dimension (T1b-T3)
    - Estrogen receptor positive (ER+)
    - Lymph node status is **ANY ONE** of the following:
      - No regional lymph node metastasis (pN0)
      - Involvement of 1-3 positive ipsilateral axillary lymph nodes
  - EndoPredict® when **ALL** of the following are met:
    - Female breast cancer
    - Unilateral tumor
    - Tumor size > 0.5 cm (5mm) in greatest dimension (T1b-T3)
    - Hormone receptor positive (ER+ or PR+)
    - Lymph node status is **ANY ONE** of the following:
      - No regional lymph node metastasis (pN0)
      - Involvement of 1-3 positive ipsilateral axillary lymph nodes
  - Breast Cancer Index™ when **ALL** of the following are met:
    - Female breast cancer
    - Unilateral tumor
    - Tumor size > 0.5cm (5mm) in greatest dimension (T1b-T3)
    - Hormone receptor positive (ER+ or PR+)
    - Lymph node status is **ANY ONE** of the following:
      - Individual has no regional lymph node metastasis (pN0)
      - Micrometastases (pN1mi, malignant cells in regional lymph node(s) not greater than 2.0mm)
  - Prosigna® when **ALL** of the following are met:
    - Female breast cancer
    - Tumor size equal to or greater than 0.4 cm (4mm) in greatest dimension (T1b-T3)
    - Hormone receptor positive (ER+/PR+)
    - No regional lymph node metastasis
- Test results will predict benefit of extended endocrine therapy beyond five years when **ALL** of the following are met:
  - Test performed using Breast Cancer Index™
  - Female breast cancer
  - Unilateral tumor
  - Tumor size > 0.5cm (5mm) in greatest dimension (T1b-T3)
  - Hormone receptor positive (ER+ or PR+)
  - Lymph node status is 0 – 3 positive nodes

Approved Revision: Do Not Implement Until 6/2/21

IMPORTANT REMINDERS

- Any specific products referenced in this policy are just examples and are intended for illustrative purposes only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available. These examples are contained in the parenthetical e.g. statement.

- We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits, or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the Medical Policy and a health plan, the express terms of the health plan will govern.

ADDITIONAL INFORMATION

Tests intended to assess estrogen receptor, progesterone receptor and *HER2* status, such as TargetPrint®, and tests that do not provide a specific recurrence risk are outside the scope of this policy.

SOURCES

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EFFECTIVE DATE 6/2/2021

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