



MEDICAL POLICY

Date Reviewed: 05/16/08, 04/24/09, 04/28/10, 04/15/11

Subject: Gene Expression Profiling for the Management of Breast Cancer (Amsterdam Signature, Breast Cancer Gene Expression Ratio, Breast Cancer Index, HOXB13:IL17BR, H/I, Insight DX Breast Cancer Profile, MammaPrint, Mammostrat, Oncotype DX, Rotterdam Signature)

Description: Gene expression profiling evaluates breast cancer cells to establish the likelihood that breast cancer will respond to chemotherapy, calculates the probability that breast cancer will recur, and estimates the likelihood of overall survival. These tests, which evaluate genes from tumor cells, are used in conjunction with other conventional tests in an attempt to identify those individuals who would be likely to receive additional benefit from the addition of chemotherapy to the treatment regimen.

Indications of Coverage:

Oncotype DX testing is considered medically necessary when all of the following criteria are met:

When ordered by an oncologist to assess the need for adjuvant (assisting) chemotherapy in individuals with recently diagnosed (less than six months) stage I or II non-metastatic (node negative) breast cancer

Adjuvant chemotherapy is not contraindicated (for example, due to comorbidities)

Pathological evaluation of the tumor cells is estrogen receptor positive and HER2 receptor negative

Management of the disease is dependent on the results of the test

Limitations of Coverage:

Review contract and endorsements for exclusions and prior authorization or benefit requirements.

If used for a condition/diagnosis other than is listed in the Indications of Coverage, deny as experimental or investigative.

If used for a condition/diagnosis that is listed in the Indications of Coverage, but the criteria are not met, deny as not medically necessary.

Amsterdam Signature, MammaPrint, Rotterdam Signature, and Breast Cancer Gene Expression Ratio, Breast Cancer Index, HOXB13:IL17BR, H/I, Insight DX Breast Cancer Profile, and Mammostrat testing are considered investigational as there is insufficient peer-reviewed scientific literature supporting the effectiveness of these tests over standard evaluation and management techniques.

Documentation required:

Office notes

Pathology report

Test report

Rationale: Treatment of breast cancer depends upon the type of cancer that is found, whether it has spread to other parts of the body, and the individual's overall health status. Treatment may include one or more of the following: chemotherapy (either prior to removal of the tumor, after removal of the tumor, or as the sole therapy), hormone therapy, removal of the tumor (for example, lumpectomy or mastectomy), and radiation therapy. Some studies have shown that many individuals would remain disease free using only hormone therapy (for example, tamoxifen). Since there is uncertainty regarding a process for identifying individuals who would benefit from chemotherapy, it is likely that there are both individuals prescribed chemotherapy who will not benefit from it and individuals who were not prescribed chemotherapy where it may be of benefit. Gene expression profiling may be helpful to identify those individuals unlikely to benefit from chemotherapy, thus preventing the significant and debilitating effects of chemotherapy for those individuals.

There is minimal peer-reviewed literature from controlled clinical trials evaluating the impact of gene expression profiling on clinical outcomes. A clinical trial evaluating the Oncotype DX test (TAILORx) is currently ongoing, but is not expected to be completed before 2014. A similar clinical trial evaluating other gene expression profiling tests (MINDACT) carries an estimated completion date of 2019. However, one study (National Surgical Adjuvant Breast and Bowel Project) identified a correlation between the results of the Oncotype DX test and the response to adjuvant chemotherapy. Individuals with a high score from the Oncotype DX test were found to have received significant benefit from the use of adjuvant chemotherapy.

Due to the lack of literature supporting the efficacy of the other tests, such as the Amsterdam Signature, MammaPrint, and Rotterdam Signature, only the Oncotype DX test is currently covered.

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Approved by the Medical Director