



## ONCOTYPE DX™

Number: 200410-0017

Effective date: 09/28/2004

Revision date: 06/10/2009

### Overview

Oncotype DX™ is a patented breast cancer assay (Genomic Health, Inc., Redwood City, CA) that has been shown predict the likelihood of distant recurrence (metastasis) in preserved tumor tissue from women who participated in clinical trials from 1988 to 1993. The assay is conducted on routine paraffin-embedded breast cancer tissue. Oncotype Dx™ analyzes the expression of a panel of 21 genes via reverse transcription polymerase chain reaction (RT-PCR). A recurrence score (RS) is calculated from the gene expression using a proprietary algorithm. The RS is based on a scale of 1-100. Oncologists use the results of Oncotype Dx™ as a complementary decision making tool in combination with tumor characteristics to assess a woman's likely benefit from adjuvant chemotherapy. Women with low RS scores (1 to 17) respond well to hormone treatment and gain very little, if any, benefit from chemotherapy. Women with high RS scores (31 or higher) gain a great deal of benefit from chemotherapy. If the RS score is in the intermediate range, it is unclear whether chemotherapy is beneficial.

A multicenter Phase III prospective, randomized, clinical trial (TAILORx; NCT00310180) evaluating Oncotype DX™ as a predictor of distant recurrence is currently enrolling women from 18 to 75 years of age with ER positive, HER2 negative, axillary node negative breast cancer. The TAILORx trial will determine whether hormone therapy is not inferior to adjuvant chemotherapy for women with intermediate RS scores.

### Policy

**Oncotype DX™ requires preauthorization by FCHP, except for Fallon Senior Plan™ members who are enrolled in the TAILORx clinical trial. <sup>1</sup> The ordering physician is required to obtain preauthorization.**

FCHP will consider coverage for Oncotype Dx™ when all of the following criteria are met:

1. Breast cancer is newly diagnosed (Oncotype DX™ is not covered when more than six months have elapsed since initial diagnosis because the role of Oncotype Dx™ relative to delayed adjuvant chemotherapy has not been established), and
2. The results of the Oncotype DX™ assay will be used as a complementary decision making tool in combination with tumor characteristics to assess a woman's likely benefit from adjuvant chemotherapy, and

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<sup>1</sup> When a Fallon Senior Plan™ is enrolled in a Medicare-qualified clinical trial, claims for routine patient care services related to the clinical trial are submitted to Medicare contractors that process fee-for-service claims. For more information on Medicare coverage of clinical trials, refer to the National Coverage Determination for Routine Costs in Clinical Trials at [www.cms.hhs.gov/mcd/index\\_list.asp?list\\_type=ncd](http://www.cms.hhs.gov/mcd/index_list.asp?list_type=ncd).

3. Documentation of the following tumor characteristics is submitted to FCHP by the ordering physician:
  - a. Stage I or II
  - b. Axillary node negative
  - c. Estrogen receptor positive
  - d. HER2 negative
4. Documentation exists of the plan member's willingness to entertain hormone therapy if test outcome so directs.

### Exclusions

1. Oncotype DX™ is not covered when the decision to proceed with chemotherapy has already been made.
2. Oncotype DX™ testing to predict the likelihood of distant recurrence in male breast cancer is considered experimental/investigational.
3. Repeat Oncotype Dx™ testing or testing of multiple tumor sites in the same person has no proven value and is not covered.
4. Other assays to predict the likelihood of distant recurrence of breast cancer are considered experimental/investigational, including, but not limited to MammaPrint® and the Rotterdam Signature 76-Genes Panel.

### Codes

Codes	Number	Description
HCPCS	S3854	Gene expression profiling panel for use in the management of breast cancer treatment

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### References

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2. National Breast Cancer Coalition. Fact Sheets. Gene-Expression Profile Testing. Updated March 2007. Available at: <http://www.natlbcc.org/bin/index.asp?strid=733&depid=9&btid=2>.
3. National Breast Cancer Coalition. Fact Sheets. Prediction of Recurrence Using the Oncotype DX™ Test. Updated March 2007. Available at: <http://www.natlbcc.org/bin/index.asp?strid=732&depid=9&btid=2>.
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12. Ahmed AA, Brenton JD. Microarrays and Breast Cancer Clinical Studies: Forgetting What We Have Not Yet Learnt *Breast Cancer Res* 2005 May;7(3):96-9.
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14. Hayes Profile. Oncotype DX™ (Genomic Health, Inc.) Genetic Assay for Breast Cancer. © 2007 Winifred S. Hayes, Inc.

## PRODUCTS TO WHICH THIS POLICY APPLIES

- ⊕ FCHP Direct & Select Care
- ⊕ Major Medical
- ⊕ Fallon Preferred Care
- ⊕ MassHealth
- ⊕ Commonwealth Care
- ⊕ Fallon Senior Plan™

## COMMITTEE REVIEW DATES

Technology Assessment Subcommittee: 09/28/04, 09/25/07, 10/23/2007, 03/24/09

Technology Assessment Committee: 12/7/04, 04/08/08, 06/10/09

### IMPORTANT NOTE

**Not all services are covered for all commercial products or employer groups.** Even though this policy may indicate that a particular service or supply is considered covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. You need to consult the Evidence of Coverage to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and your plan of benefits, the provisions of your benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Medicare and Medicaid members, this policy will apply unless Medicare and Medicaid policies extend coverage beyond this Medical Policy & Criteria Statement.