

IHCP *bulletin*

INDIANA HEALTH COVERAGE PROGRAMS BT201406 FEBRUARY 25, 2014



Oncotype DX[®] genetic testing for breast cancer to be an IHCP covered service

Effective April 1, 2014, the Indiana Health Coverage Programs (IHCP) will add Oncotype DX genetic testing of breast cancer tumors as a covered service. This service may be billed with procedure code S3854 – *Gene expression profiling panel for use in the management of breast cancer treatment*. Coverage applies to all IHCP programs, subject to limitations established for certain benefit packages. Coverage applies to dates of service on or after April 1, 2014, in accordance with the following policies and procedures.

Coverage parameters

The IHCP covers Oncotype DX when it is considered medically necessary for managing the treatment of breast cancer. The 21-gene RT-PCR assay should only be ordered after surgery and subsequent pathological examination of the tumor have been completed. The test should be ordered in the context of a provider-patient discussion regarding risk preferences when the test result will aid in making decisions regarding chemotherapy.

Gene expression profiling as a technique of managing the treatment of breast cancer is considered **investigational and not medically necessary** when a gene profiling test other than the Oncotype DX Breast Cancer Assay is being used, including but not limited to:

- Breast Cancer Gene Expression Ratio (also known as Theros H/ISM)
- Breast Cancer IndexSM
- Insight[®] DX Breast Cancer Profile
- MammaPrint[®] (also referred to as the "Amsterdam signature" or "70-gene signature")
- Mammostrat

- Oncotype DX DCIS
- PAM50 Breast Cancer Intrinsic Classifier™
- The 41-gene signature assay
- The 76-gene "Rotterdam signature" assay
- THEROS Breast Cancer IndexSM

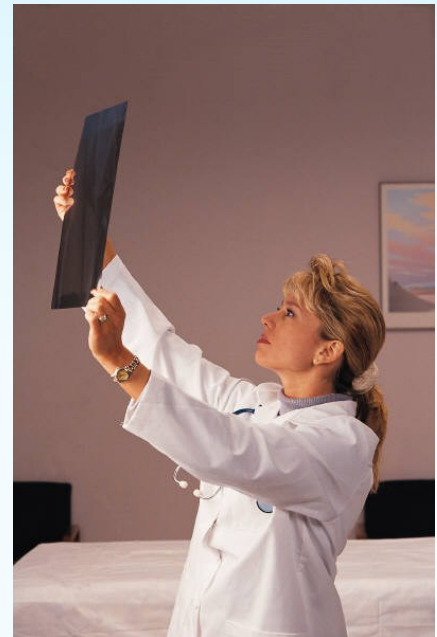
Gene expression profiling as a technique of managing the treatment of ductal carcinoma in situ (DCIS) is considered **investigational and not medically necessary** under all circumstances.

Repeat gene expression profiling with the Oncotype DX Breast Cancer Assay for the same tumor, such as a metastatic focus, or from more than one site when the primary tumor is multifocal is considered **investigational and not medically necessary**.

Prior authorization requirements

The IHCP requires prior authorization (PA) for Oncotype DX. To obtain PA for code S3854, **all** the following criteria must be met:

- Individual has had surgery and full pathological evaluation of the specimen has been completed.
- Histology is ductal, lobular, mixed, or metaplastic.
- Histology is not tubular or colloid.
- Estrogen receptor is positive (ER+), or progesterone receptor is positive (PR+), or both.
- HER2 receptor is negative.
- pN0 (node negative) or pN1mi with axillary lymph node micrometastasis is less than or equal to 2mm.
- Individual has one of the following:
 - Tumor size 0.6-1.0 cm moderate/poorly differentiated
 - Tumor size 0.6-1.0 cm well-differentiated with any of the following unfavorable features: angiolymphatic invasion, or high nuclear grade, or high histologic grade
 - Tumor size greater than 1.0 cm and less than or equal to 4.0 cm
- Individual does not have a pT4 lesion.
- Chemotherapy is a therapeutic option being considered and will be supervised by the practitioner ordering the gene expression profile.



Gene expression profiling with the Oncotype DX Breast Cancer Assay as a technique of managing the treatment of breast cancer is considered **not medically necessary** when the criteria listed have not been met.

Reimbursement

Pricing: Manually priced.

Billing guidance: This procedure is linked to revenue codes 300, 301, 309, 310, and 319. See [Chapter 8](#) of the *IHCP Provider Manual* for standard billing guidance.

The provider [Fee Schedule](#) at indianamedicaid.com will be updated to reflect coverage and reimbursement information. Reimbursement and billing information applies to services delivered under the fee-for-service delivery system. Individual managed care entities (MCEs) establish and publish reimbursement and billing criteria within the risk-based managed care (RBMC) delivery system.

QUESTIONS?

If you have questions about this publication, please contact Customer Assistance at (317) 655-3240 in the Indianapolis local area or toll-free at 1-800-577-1278.

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