



OONCOTYPE DX, BREAST CANCER ASSAY: COVERAGE EFFECTIVE JULY 1, 2014

Effective with date of service July 1, 2014, Louisiana Medicaid covers Oncotype DX Breast Cancer Assay via Genomic Health, Inc. to assist providers in the determination of breast cancer prognosis.

Coverage Criteria for the treating physician ordering the assay:

- Oncotype DX Breast Cancer Assay should be done within six months of the initial diagnosis of breast cancer.
- Oncotype DX Breast Cancer Assay should be considered for individuals only after surgery and subsequent pathological examination of the tumor has been completed.
- Histology indicates the cancer is ductal, lobular, mixed, or metaplastic.
- Histology shows the cancer is not tubular or colloid.
- Estrogen receptor is positive (ER+), or progesterone receptor is positive (PR+) or both.
- Human epidermal growth factor receptor 2 (HER2) is negative.
- Chemotherapy is a therapeutic option being considered for treatment and will be supervised by the practitioner ordering the gene expression profile.
- Node negative or
- Node positive (1-3 nodes only) on individuals who are post-menopausal.

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**.

Billing Information:

- In order for Genomic Health, Inc. to receive reimbursement for Oncotype DX Breast Cancer Assay, providers should only order this assay for an appropriate breast cancer diagnosis that meets the coverage criteria.
- To receive reimbursement for claims related to Oncotype DX Breast Cancer Assay, Genomic Health, Inc. should include one of the following ICD-9 diagnosis codes in addition to V86.0 (Estrogen receptor positive status): 174.0-174.6, 174.8, 174.9, 233.0, 238.3, 239.3.

- Genomic Health, Inc. should submit claims using HCPCS code S3854, gene expression profiling panel for use in the management of breast cancer treatment.