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Department of Health and Hospitals

Louisiana Department of Health and Hospitals
Health Plan Advisory 14-10
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Coverage of Oncotype DX, Breast Cancer Assay for the Determination of Breast Cancer Prognosis:

Effective with date of service July 1, 2014, the Louisiana Medicaid Program covers Oncotype DX, Breast Cancer Assay to assist providers in the determination of breast cancer prognosis. The following policy was communicated to providers and Genomic Health, Inc.

Coverage Criteria:

- 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.
- HER2 receptor 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 breast cancer is considered **investigational and not medically necessary** when a gene profiling test other than Oncotype DX Breast Cancer Assay is being used, including but not limited to:

- Breast Cancer Gene Expression Ratio (also known as Theros H/I^{SM})
- Breast Cancer Index^{SM}
- Insight$^{®}$ DX Breast Cancer Profile
- MammaPrint$^{®}$
- Mammostrat

- Oncotype DX DCIS
- Pam50 Breast Cancer Intrinsic Classifier™
- The 41-gene signature assay
- The 76-gene "Rotterdam signature" assay
- THEROS Breast Cancer Index℠

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 :

- Providers ordering Oncotype DX Breast Cancer Assay should only request this assay for individuals who meet the coverage criteria and have an appropriate breast cancer diagnosis. There will not be any prior authorization requirements. However, Genomic Health, Inc. will not be reimbursed if this assay is completed for an individual who does not meet the coverage criteria and does not have an appropriate breast cancer diagnosis.
- Louisiana Medicaid will reimburse Genomic Health, Inc. for claims related to Oncotype DX Breast Cancer Assay, if the individual meets coverage criteria and there is an appropriate breast cancer diagnosis present on the claim. 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. may be reimbursed for claims related to Oncotype DX Breast Cancer Assay using HCPCS code S3854, gene expression profiling panel for use in the management of breast cancer treatment.