

Breast DCIS Prognostic Algorithmic Tests

- I. Breast DCIS prognostic algorithmic tests are considered **medically necessary** when:
 - A. The member has ductal carcinoma in situ (DCIS), **AND**
 - B. The tumor specimen contains at least 0.5 mm of DCIS, **AND**
 - C. The result of testing would aid in treatment decision-making (i.e., pursuing additional surgery or radiation therapy), **AND**
 - D. The member's DCIS was not removed via mastectomy (i.e., there is residual ipsilateral breast tissue).
- II. Breast DCIS prognostic algorithmic tests are considered **investigational** for all other indications.

RATIONALE AND REFERENCES

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Centers for Medicare and Medicaid Services (CMS)

The CMS local coverage determination (LCD) entitled "MoIDX: Oncotype DX Breast Cancer for DCIS (Genomic Health)" includes the following coverage criteria for OncotypeDX DCIS:

"The Oncotype DX DCIS assay is covered only when the following clinical conditions are met:

- Pathology (excisional or core biopsy) reveals ductal carcinoma in situ of the breast (no pathological evidence of invasive disease), and
- FFPE specimen with at least 0.5 mm of DCIS length, and
- Patient is a candidate for and is considering breast conserving surgery alone as well as breast conserving surgery combined with adjuvant radiation therapy, and
- Test result will be used to determine treatment choice between surgery alone vs. surgery with radiation therapy, and
- Patient has not received and is not planning on receiving a mastectomy."

Centers for Medicare & Medicaid Services. Medicare Coverage Database: Local Coverage Local Coverage Determination MolDX: Oncotype DX Breast Cancer for DCIS (Genomic Health) (L36912). Effective Date 11/25/2021. Available at:
<https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=36912>

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This single center prospective clinical trial aimed to study whether adjuvant radiation therapy recommendations would change for women with DCIS based on results of Oncotype DX Breast DCIS testing. The paper found that “in 28% of patients (20/71), the RT [radiotherapy] recommendation changed as a result of the Oncotype test, with the majority of the change being from recommending RT to omitting RT” (p. 5).

Muktar S, Kirby A, Locke I, et al. Oncotype DX Breast DCIS Score® Test: Impact on Radiotherapy Recommendations and Patient Decisional Anxiety. Clin Oncol (R Coll Radiol). 2025 Jun;42:103839. Published online April 4, 2025. doi:10.1016/j.clon.2025.103839