# Local Coverage Determination (LCD): MolDX: Oncotype DX® Breast Cancer for DCIS (Genomic Health™) (L36941)

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# Contractor Information

| Contractor Name | Contract Type | Contract Number | Jurisdiction | State(s) |
|---|---|---|---|---|
| Noridian Healthcare Solutions, LLC | A and B MAC | 01111 - MAC A | J - E | California - Entire State |
| Noridian Healthcare Solutions, LLC | A and B MAC | 01112 - MAC B | J - E | California - Northern |
| Noridian Healthcare Solutions, LLC | A and B MAC | 01182 - MAC B | J - E | California - Southern |
| Noridian Healthcare Solutions, LLC | A and B MAC | 01211 - MAC A | J - E | American Samoa<br>Guam<br>Hawaii<br>Northern Mariana Islands |
| Noridian Healthcare Solutions, LLC | A and B MAC | 01212 - MAC B | J - E | American Samoa<br>Guam<br>Hawaii<br>Northern Mariana Islands |
| Noridian Healthcare Solutions, LLC | A and B MAC | 01311 - MAC A | J - E | Nevada |
| Noridian Healthcare Solutions, LLC | A and B MAC | 01312 - MAC B | J - E | Nevada |
| Noridian Healthcare Solutions, LLC | A and B MAC | 01911 - MAC A | J - E | American Samoa<br>California - Entire State<br>Guam<br>Hawaii<br>Nevada<br>Northern Mariana Islands |

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# LCD Information

## Document Information

Original Effective Date
For services performed on or after 03/27/2017

LCD ID
L36941

Revision Effective Date
For services performed on or after 07/01/2018

LCD Title
MolDX: Oncotype DX® Breast Cancer for DCIS (Genomic Health™)

Revision Ending Date
N/A

Proposed LCD in Comment Period
N/A

Retirement Date
N/A

Source Proposed LCD
DL36941

Notice Period Start Date
02/09/2017

AMA CPT / ADA CDT / AHA NUBC Copyright Statement

Notice Period End Date
03/26/2017

CMS National Coverage Policy
Title XVIII of the Social Security Act, §1862(a)(1)(A). Allows coverage and payment for only those services that are considered to be reasonable and necessary.

Title XVIII of the Social Security Act, §1833(e). Prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

42 Code of Federal Regulations (CFR) 410.32(a). Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.

CMS On-Line Manual, Publication 100-02, *Medicare Benefit Policy Manual,* Chapter 15, §§80.0, 80.1.1, 80.2. Clinical Laboratory services.

CMS Internet-Only Manuals, Publication 100-04, Medicare Claims Processing Manual, Chapter 16, §50.5 Jurisdiction of Laboratory Claims, 60.12 Independent Laboratory Specimen Drawing, 60.2. Travel Allowance.

CMS Internet Online Manual Pub. 100-04 (Medicare Claims Processing Manual), Chapter 23 (Section 10) "Reporting ICD Diagnosis and Procedure Codes"

Coverage Guidance
**Coverage Indications, Limitations, and/or Medical Necessity**

This contractor will provide limited coverage for the Oncotype DX® DCIS assay (Genomic Health, Inc., Redwood City, CA) for women diagnosed with DCIS who are planning on having breast conserving surgery and considering adjuvant radiation therapy.

**Summary of Evidence**

Ductal carcinoma *in situ* (DCIS) is a heterogeneous group of neoplastic lesions confined to the breast ducts and lobules. It is one of the most commonly diagnosed breast conditions, accounting for approximately 20% of newly diagnosed breast cancers in the United States[1]. Women diagnosed with DCIS are at risk for local recurrence, which may be either DCIS or progression to invasive breast carcinoma. The management of patients with DCIS is

an area of controversy and historically treatment has included both surgical excision and radiation therapy[2]. Following surgical excision alone local recurrences occur in approximately 25% to 30% of women by 10 years[3]. The addition of radiation therapy has been reported to reduce local recurrence risk by approximately 50% but has not been demonstrated to prolong overall or disease free-survival[3]. In an observational study of patients diagnosed with DCIS from 1988 to 2011, prevention of invasive in-breast recurrence with radiation therapy after lumpectomy did not improve 10-year breast cancer-specific mortality compared with lumpectomy alone[4]. Therefore, treating all women with radiation therapy following surgical excision may represent overtreatment for many, especially given that the majority of cases do not recur following surgery alone. Clinical and pathologic features do not reliably predict the risk of recurrence and therefore validated biomarkers are needed that identify patients at low risk of local recurrence for whom less treatment is indicated and conversely distinguish patients at high risk of progression to invasive disease for whom more intensive treatment regimens are appropriate.

**Oncotype DX® DCIS Score**

**Test Description**

The DCIS Score is an RNA based assay measuring the expression of five proliferation genes, progesterone receptor (PR), GSTM1 and five reference genes (Figure 1) with results reported as a numerical score along with accompanying interpretive information. The assay is performed on formalin fixed paraffin-embedded (FFPE) tissue blocks containing DCIS. The DCIS Score was developed based upon analyses of multiple correlative science studies comparing gene expression profiles between invasive and DCIS tumor samples[5]. An algorithm was developed using scaling and category cut-points based on the analysis of the DCIS Score result in a separate cohort of DCIS patients[6].

**Figure 1: Genes Comprising the DCIS Score.**

| Proliferation Group | Hormone Receptor Group | Reference Group |
|---|---|---|
| • Ki67<br>• STK15<br>• Survivin<br>• CCNB1 (cyclin B1)<br>• MYBL2 | • PR<br>• GSTM1 | • ACTB (β - actin)<br>• GAPDH<br>• RPLPO<br>• GUS<br>• TFRC |

**Test Performance**

Initial validation of the DCIS Score result was performed in a prospectively designed study of archived tumor specimens from 327 patients who participated in the previously described E5194 trial, a prospective cooperative group trial that evaluated 5- and 10-year ipsilateral breast event (IBE) rates after local excision alone in a selected population of patients with DCIS[7, 8]. The study met its primary objective as the DCIS Score result was predictive of the 10-year risk of any IBE. The DCIS Score result as a continuous variable was significantly associated with developing an IBE (hazard ratio [HR]/50 units=2.31, 95% CI = 1.15-4.49; p = 0.02. Using three pre-specified risk groups (low < 39, intermediate 39-54, and high ≥ 55), the 10-year risk of any IBE (DCIS or invasive carcinoma) was 10.6% in the low risk group compared to 26.7 in the intermediate risk group and 25.9% in the high risk group; the risk stratification between the three groups was significant (log rank p = 0.006). The risk for developing ipsilateral invasive carcinoma only was 3.7 % in the low risk group compared to 19.2% in the high risk group (log rank p = 0.003). Approximately 70% of all patients enrolled in the study were in the low risk group. In multivariable analyses, the DCIS Score result, tumor size, and menopausal status were identified to be statistically significant predictors of the risk of local recurrence (p ≤ 0.02). The HR for the score remained unchanged after adjusting for tumor size and menopausal status thereby demonstrating that the DCIS Score result provides independent prognostic information beyond these risk factors.

The second prospectively designed clinical validation study of the Oncotype DX Breast DCIS Score Assay was conducted in a population-based cohort of women diagnosed with DCIS and treated with breast conserving therapy alone from 1994-2003 in Ontario, Canada[9]. The final study cohort included 718 patients of whom 571 had negative surgical margins. Median follow-up was 9.6 years. The study found the DCIS Score result to independently predict and quantify local recurrence risk. In the primary analysis, the DCIS Score result was significantly associated with any local recurrence in estrogen receptor positive patients (HR/50 units = 2.26, 95% CI = 1.41-3.59; p < 0.001) as well as all patients regardless of estrogen receptor status (HR = 2.15; 95% CI = 1.43-3.22; p < 0.001). For the same pre-specified risk groups (low < 39, intermediate 39-54, and high ≥ 55), the 10-year risk of a local invasive carcinoma recurrence was 8.0% in the low risk group compared with 20.9% and 15.5% in the intermediate and high risk groups, respectively; the risk stratification between the three groups

was significant (p = 0.03). The risk of developing a DCIS local recurrence was 5.4% in the low risk group compared with 14.1% and 13.7% in the intermediate and high risk groups, respectively (p = 0.002). In multivariable analysis the DCIS Score result was a significant predictor of local recurrence (HR/50 units = 1.68, 95% CI = 1.08-2.62; p = 0.02) and provided independent recurrence risk information beyond clinical and pathologic measures including age at diagnosis, tumor size, grade, necrosis, multifocality, and subtype. The primary analyses were restricted to patients with clear margins; however, secondary analysis included all patients regardless of surgical margins. The HR in the expanded cohort, adjusting for margin status and other clinical and pathological features, was 2.11 (95% CI = 1.43-3.09; p < 0.001) indicating that the DCIS Score result effectively risk-stratifies patients regardless of margin status.

The analytical and clinical performance of the Oncotype DX® DCIS assay is summarized below.

| | |
|---|---|
| Intended Use | To assess the average 10 year rate for any ipsilateral breast event (DCIS or invasive carcinoma) in women diagnosed with DCIS who had breast conserving surgery with negative margins and are considering adjuvant radiation therapy. |
| Validated Specimen Type(s) | Formalin fixed paraffin-embedded (FFPE) tissue |

**Analytical Performance**

| Description | Results |
|---|---|
| Precision, within RNA extract (2 operator; 2 runs on different days; 2 manufacturing reagent lot; 5 PCR robots; 9 PCR detection systems; 75 paired RNA extracts run all in CLIA lab; expected score range 3-86*) | **Within RNA Extracts**<br>**DCIS Score Category** / **N** / **STD**<br>Low / 36 / 1.04<br>Int-High / 39 / 1.09 |
| Precision, between tumor block sections (2 operator; 2 runs on different days; 2 manufacturing reagent lot; 5 PCR robots; 9 PCR detection systems; 39 unique tumor blocks run all in CLIA lab; expected score range 3-86*) | **Between Consecutive Tumor Block Sections**<br>**DCIS Score Category** / **N** / **STD**<br>Low / 19 / 2.11<br>Int-High / 20 / 3.96 |
| Analytical sensitivity: Minimum input | Total RNA: 110 ng extracted from tumor tissue |
| Critical reagent closed/shelf-life stability (GHI conducted shelf-life stability unless stated otherwise) | Reverse Transcription Kit<br>Stability from date of receipt through the manufacturer's labeled expiration date with 12 months of on-site storage at -20 °C ± 5 °C<br>GSP pool (gene specific primers for reverse transcription)<br>9 months at -20 °C ± 5 °C<br>Reverse Transcription Positive control<br>2 years at -80 °C ± 10 °C<br>P3 Plate<br>9 months -80 °C ± 10 °C<br>Human gDNA (quantitative PCR positive control)<br>6 months at +5 °C ± 3 °C<br>Quantitative PCR Master Mix<br>18 months from date of manufacturing at -20 °C ± 5 °C |
| Critical reagent open/in use stability (GHI conducted operational stability unless stated otherwise) | Reverse Transcription Kit |

| | |
|---|---|
| | Use within 2 shifts after opening kit and prior to manufacturer's labeled expiration date at -20 °C ± 5 °C |
| | GSP pool (gene specific primers for reverse transcription)<br>Freeze thaw no more 10x |
| | Reverse Transcription Positive control<br>Single Use Tube |
| | P3 Plate<br>Freeze thaw no more than 10x<br>Use within 1 day 5 °C ± 3 °C |
| | Human gDNA (quantitative PCR positive control)<br>6 months at +5 °C ± 3 °C |
| | Quantitative PCR Master Mix<br>3 months after thaw at 5 °C ± 3 °C<br>Up to 3 hours prior to qPCR plate assembly at room temperature (18 °C to 25 °C) |
| | Assembled Quantitative PCR plates<br>24 hours at room temperature (18 °C to 25 °C) |
| Specimen stability, primary | FPET slice in tube 6 months at room temperature<br>(18 °C to 25 °C) |
| Specimen stability, intermediate (extracted RNA) | Within 1 day 5 °C ± 3 °C<br>Within 5 days -20 °C ± 5 °C<br>Within 365 days at -80 °C ± 10 °C |
| Specimen stability, intermediate (cDNA Sample plate) | Within 3 months at -20 °C ± 5 °C |

* DCIS Score risk groups were specified prior to first clinical validation study (DCIS Score: Low <39, Intermediate 39-54, High ≥54). Actual range of DCIS scores for samples used for precision studies were DCIS Score Low 3-37 and DCIS Score Int-High 40-86.

**Clinical Performance**

The Oncotype DX DCIS Score is a continuous measure that provides predicted risks of an ipsilateral breast event for individual patients over a continuum of gene expression, reflecting the continuous nature of tumor biology. Statistics such as sensitivity and specificity were designed to evaluate the general predictive ability of binary (dichotomous) predictors of the presence or absence of a disease or condition, rather than prediction of the risk of a future event, and have limitations in the assessment of continuous predictors of risk[10, 11, 12]. A more appropriate statistical assessment of the predictive accuracy of the DCIS Score for risk groups is demonstrated by the width of the 95% confidence intervals for estimates of 10-year risk of an IBE within each risk group, shown in the table below.

The Oncotype DX DCIS Score was validated in two clinical studies encompassing the indicated patient population. Both clinical validation studies were conducted under IRB-approved protocols with pre-specified analytical and quality acceptance criteria, statistical analysis plans, and endpoints. All clinical studies were conducted on the platform (device) after assay performance requirements (above) were specified and independently validated.

**Results**

| Description | Solin et al., 2013[8]<br>(n = 327 patients) | Rakovitch et al., 2015[9]<br>(n = 571 patients) |
|---|---|---|
| Hazard ratio/50 units | 2.31[a]<br>(95% CI = 1.15 - 4.49)<br>p = 0.02 | 2.15[b]<br>(95% CI = 1.43 - 3.22)<br>p < 0.001 |

| | | |
|---|---|---|
| **Number (%) of patients** | | |
| Low DCIS Score | 230 (70%) | 355 (62%) |
| Intermediate/High DCIS Score | 97 (30%) | 216 (38%) |
| **10-year Risk of Local Recurrence (95% CI)** | | |
| Low DCIS Score | 10.6% (6.9-16.2%) | 12.7% (9.5-16.9%) |
| Intermediate/High DCIS Score | 26.2% (18.1-37.0%) | 30.1% (23.9-37.5%) |
| Overall Proportion with IBE[c] | 46/327 (14.1%) | 100/571 (17.5%) |

[a]Adjusted for tamoxifen use (pre-specified primary analysis)
[b]No covariate adjustment; all patients (irrespective of ER status) with negative resection margins
[c]Ipsilateral breast event (DCIS or invasive carcinoma)

**Decision Impact and Health Economic Studies**

A prospective multicenter clinical utility study evaluating the impact of the DCIS Score result upon treatment recommendations for radiation therapy (XRT) has been reported[13]. Eligible women had newly diagnosed histologically documented DCIS and were candidates for breast conserving therapy. Physicians completed standardized questionnaires that captured their estimates of local recurrence risk and treatment recommendations for XRT, prior to and after receiving the DCIS Score results. A total of 115 evaluable patients from 10 US centers were included in final analyses. Study results found a significant change in the proportion of patients receiving recommendations for XRT pre- vs post-DCIS Score result (P = 0.008; McNemar's test). Pre-assay, 73.0% of patients were recommended to receive XRT; this was reduced to 59.1% post-assay. Overall integration of the DCIS Score result into clinical management decisions resulted in a 31.3% change in XRT recommendations. Changes in treatment were bidirectional, indicating that the information was useful both for identifying patients at lower risk of recurrence for whom XRT may be omitted, as well as those at higher risk who may be appropriate candidates for more intensive modalities.

In a second prospective multicenter clinical utility study[14], 27 surgeons and 27 radiation oncologists at 13 US centers provided estimates of local recurrence risk and XRT recommendations for 127 patients, before and after DCIS Score results were known. Baseline characteristics of this patient cohort were similar to those of the first clinical utility study. Post-assay, 26.4% of recommendations changed overall , representing 22.0% of recommendations by radiation oncologists and 30.7% of recommendations by surgeons. The DCIS Score result was the most frequently cited reason for post-assay treatment recommendations.

Young et al reported a retrospective health economic study from a single center involving 38 patients for whom the DCIS Score assay had been ordered[15]. In this cohort, 26 patients (68%) had DCIS Score results and local recurrence risk considered low enough to omit radiation from their course of therapy. The authors concluded that the assay has the potential to be cost-saving to the healthcare system and spare many patients from the adverse effects associated with radiation therapy. A cost-effectiveness modeling study comparing the Oncotype DX Breast DCIS Score Assay to standard clinical assessment to determine treatment recommendation for radiation therapy has been reported by Alvarado et al[16]. The study found that on average, the assay was more cost-effective than the clinical assessment strategy by approximately $1000/patient, with similar life expectancies (17.15 vs 17.11, respectively) and quality-adjusted life-years (QALYs) (16.777 vs 16.789).

**Criteria for Coverage**

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.

**Analysis of Evidence**
**(Rationale for Determination)**

*Level of Evidence*

Quality – Moderate

Strength – Limited

Weight - Limited

This contractor recognizes that evidence of clinical utility for the Oncotype DX® DCIS assay for women diagnosed with DCIS who are planning on having breast conserving surgery and considering adjuvant radiation therapy is promising at the current time. However, this contractor believes the ongoing collection studies with data elements identified below will generate sufficient data to demonstrate the utility of this assay in women with DCIS. Continued coverage is dependent bi-annual data submission and defined endpoints.

The MolDX Contractor expects Genomic Health to:

- Ensure that healthcare providers who order the DCIS Score understand the appropriate patient population for testing and how to interpret test results; **and**
- Report utilization by DCIS Score risk category on a bi-annual basis; **and**
- Continue data development providing further evidence of clinical utility for the DCIS Score. During coverage with data development, evidence will be generated from Medicare patients receiving the DCIS Score. The nature and extent of this data is dependent on the volume of testing, specific disease context, and data elements required to support the test's utility. De-identified data should be collected through HIPAA-compliant mechanisms.
- For the DCIS Score, collected data elements include:
    - Date of DCIS diagnosis
    - DCIS pathology including:
        - Histologic subtype
        - Pathological grade
        - Size
        - Presence of necrosis
        - Multi-focality as reported on pathology report
        - ER, PR and Her-2 Neu Status as reported on pathology report
- Treatment received (local: surgery +/- radiation, systemic: hormonal therapy)
- Any ipsilateral recurrence during the period of data development (DCIS and/or Invasive cancer recurrences).

Provide bi-annual data updates to include:

- Number of tested patients for which data is being collected
    - Completeness of the collected data elements
    - Updates on the analysis supporting test utility including:
        - Proportion of DCIS score Low Risk patients receiving breast conserving surgery alone
        - Proportion of High-Risk and Intermediate-Risk DCIS score receiving radiation therapy.
        - 3-year ipsilateral recurrence rates in DCIS score Low Risk patients receiving breast-conserving surgery alone
        - 3-year ipsilateral recurrence rates for DCIS score Intermediate and High Risk patients receiving breast-conserving surgery plus radiation.
        - Clinical management (i.e., adjuvant radiation procedures) for patients who are low or high risk by the DCIS assay is consistent with the post-test strategy described below for at least 80% of tested patients

| Oncotype DX® DCIS assay | Post-Test Diagnostic Strategy to Consider |
|---|---|
| Low Risk | No XRT |
| High Risk | XRT |

- Analysis of collected data to demonstrate that:
  - Ipsilateral breast recurrence at 3 years is ≤ 6% in DCIS Low Risk patients treated with breast conserving surgery alone, and
  - Local recurrence rate in DCIS Low Risk patients after treatment with breast conserving surgery alone is not statistically significantly greater than breast cancer recurrences from the DCIS Intermediate and High risk groups receiving radiation
- Data analysis described above should be:
  - Independently verified;
  - Made public, either in a peer reviewed publication or online, within one year of completion.

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# Coding Information

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

N/A

Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the policy, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

N/A

CPT/HCPCS Codes
**Group 1 Paragraph:** N/A

**Group 1 Codes:**

| | |
|---|---|
| 0045U | ONCOLOGY (BREAST DUCTAL CARCINOMA IN SITU), MRNA, GENE EXPRESSION PROFILING BY REAL-TIME RT-PCR OF 12 GENES (7 CONTENT AND 5 HOUSEKEEPING), UTILIZING FORMALIN-FIXED PARAFFIN-EMBEDDED TISSUE, ALGORITHM REPORTED AS RECURRENCE SCORE |

ICD-10 Codes that Support Medical Necessity
**Group 1 Paragraph:** N/A

**Group 1 Codes:**

| ICD-10 Codes | Description |
|---|---|
| D05.11 | Intraductal carcinoma in situ of right breast |
| D05.12 | Intraductal carcinoma in situ of left breast |

# General Information

Associated Information

No comments were received for this draft LCD for comment period ending 12/30/2016.

Sources of Information

N/A

Bibliography

1. Ward EM, DeSantis CE, Lin CC, et al. Cancer Statistics: Breast cancer in situ. CA Cancer J Clin. 2015;65(6):481-495.

2. Zujewski JA, Harlan LC, Morrell DM, et al. Ductal carcinoma in situ: trends in treatment over time in the US. Breast Cancer Res Treat. 2011;127(1):251-257.

3. Correa C, McGale P, Taylor C, et al. Overview of the randomized trials of radiotherapy in ductal carcinoma in situ of the breast. J Natl Cancer Inst Monogr. 2010;(41):162-177.

4. Narod SA, Iqbal J, Giannakeas V, Sopik V, Sun P. Breast cancer mortality after a diagnosis of ductal carcinoma in situ. JAMA Oncol. 2015;1(7):888-896.

5. Baehner FL, Sangli C, Anderson J, et al. Quantitative gene expression analysis using Oncotype DX in ductal carcinoma in situ that is adjacent to invasive ductal carcinoma. Poster presented: San Antonio Breast Cancer Symposium; December 2008; San Antonio, TX.

6. Baehner FL, Yoshizawa CN, Butler SM, et al. The development of the DCIS Score: scaling and normalization in the Marin Medical Laboratories cohort. Poster presented: ASCO Breast Cancer Symposium; September 2012; San Francisco, CA.

7. Hughes LL, Wang M, Page DL, et al. Local excision alone without irradiation for ductal carcinoma in situ of the breast: a trial of the Eastern Cooperative Oncology Group. J Clin Oncol. 2009;27(32):5319-5324.

8. Solin L, Gray R, Baehner FL, et al. A multigene expression assay to predict local recurrence risk for ductal carcinoma in situ of the breast. J Natl Cancer Inst. 2013;105(10):701-710.

9. Rakovitch E, Nofech-Mozes S, Hanna W, et al. A population-based validation study of the DCIS Score predicting recurrence risk in individuals treated by breast-conserving surgery alone. Breast Cancer Res Treat. 2015;152(2):389-398.

10. Cook NR. Use and misuse of the receiver operating characteristic curve in risk prediction. Circulation 2007;115:928-35.

11. Moons KGM, Harrell FE. Sensitivity and specificity should be de-emphasized in diagnostic accuracy studies. Acad Radiol 2003;10:670-2.

12. Pepe MS, Feng Z, Huang Y, et al. Integrating the predictiveness of a marker with its performance as a classifier. Am J Epidemiology 2008;167:362-8.

13. Alvarado M, Carter DL, Guenther MJ, et al. The impact of genomic testing on the recommendation for radiation therapy in patients with ductal carcinoma in situ: A prospective clinical utility assessment of the 12-gene DCIS Score result. J Surg Oncol. 2015 Jun;111(8):935-940.

14. Manders JB, Kuerer HM, Smith BD, et al. The 12-gene DCIS Score Assay: Impact on radiation treatment (XRT) recommendations and clinical utility. Poster presented: San Antonio Breast Cancer Symposium; December 2015; San Antonio, TX.

15. Young R, Kalnicki S, Fox JL, et al. The DCIS Score - Potential for healthcare savings? Poster presented: San Antonio Breast Cancer Symposium; December 2014; San Antonio, TX.

16. Alvarado M, Harrison B, Howe R, et al. Cost-effectiveness of gene expression profiling for DCIS. Poster presented: San Antonio Breast Cancer Symposium; December 2012; San Antonio, TX.

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# Revision History Information

| Revision History Date | Revision History Number | Revision History Explanation | Reason(s) for Change |
|---|---|---|---|
| 07/01/2018 | R3 | Replaced HCPCS code 81479 with 0045U. | • Creation of Uniform LCDs With Other MAC Jurisdiction<br>• Revisions Due To CPT/HCPCS Code Changes |
| 08/18/2017 | R2 | LCD is revised to remove CDD from the title and to add Summary of Evidence, Analysis of Evidence and Bibliography. There were no changes in coverage. | • Creation of Uniform LCDs With Other MAC Jurisdiction |
| 03/27/2017 | R1 | LCD is revised to include D05.12 as a covered diagnosis, effective 3/27/17. The draft LCD (DL36912) issued by the primary MolDX Contractor did not have CPT or ICD-10 codes included; however, a sticky note was later placed on the draft indicating CPT 81479 and ICD-10 codes D05.11 and D05.12 would be added. D05.12 was not included in that final LCD in error. | • Creation of Uniform LCDs With Other MAC Jurisdiction<br>• Revisions Due To ICD-10-CM Code Changes |

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# Associated Documents

Attachments N/A

Related Local Coverage Documents LCD(s) DL36941 - (MCD Archive Site)

Related National Coverage Documents N/A

Public Version(s) Updated on 09/23/2018 with effective dates 07/01/2018 - N/A Updated on 08/09/2017 with effective dates 08/18/2017 - 06/30/2018 Some older versions have been archived. Please visit the MCD Archive Site to retrieve them. Back to Top

# Keywords

- MolDX
- oncotype
- DCIS
- Genomic
- ductal carcinoma
- breast
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