

# Local Coverage Determination (LCD): MoIDX: Oncotype DX® Breast Cancer for DCIS (Genomic Health™) (L37199)

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## Contractor Information

<b>Contractor Name</b>	<b>Contract Type</b>	<b>Contract Number</b>	<b>Jurisdiction State(s)</b>
<a href="#">Wisconsin Physicians Service Insurance Corporation</a>	MAC - Part A	05101 - MAC A	J - 05 Iowa
<a href="#">Wisconsin Physicians Service Insurance Corporation</a>	MAC - Part B	05102 - MAC B	J - 05 Iowa
<a href="#">Wisconsin Physicians Service Insurance Corporation</a>	MAC - Part A	05201 - MAC A	J - 05 Kansas
<a href="#">Wisconsin Physicians Service Insurance Corporation</a>	MAC - Part B	05202 - MAC B	J - 05 Kansas
<a href="#">Wisconsin Physicians Service Insurance Corporation</a>	MAC - Part A	05301 - MAC A	J - 05 Missouri - Entire State
<a href="#">Wisconsin Physicians Service Insurance Corporation</a>	MAC - Part B	05302 - MAC B	J - 05 Missouri - Entire State
<a href="#">Wisconsin Physicians Service Insurance Corporation</a>	MAC - Part A	05401 - MAC A	J - 05 Nebraska
<a href="#">Wisconsin Physicians Service Insurance Corporation</a>	MAC - Part B	05402 - MAC B	J - 05 Nebraska
			Alaska Alabama Arkansas Arizona Connecticut Florida Georgia Iowa Idaho Illinois Indiana Kansas Kentucky Louisiana Massachusetts Maine Michigan Minnesota Missouri - Entire State Mississippi Montana North Carolina North Dakota Nebraska New Hampshire New Jersey Ohio Oregon Rhode Island South Carolina South Dakota Tennessee
<a href="#">Wisconsin Physicians Service Insurance Corporation</a>	MAC - Part A	05901 - MAC A	J - 05

Contractor Name	Contract Type	Contract Number	Jurisdiction	State(s)
<a href="#">Wisconsin Physicians Service Insurance Corporation</a>	MAC - Part A	08101 - MAC A	J - 08	Utah Virginia Virgin Islands Vermont Washington Wisconsin West Virginia Wyoming
<a href="#">Wisconsin Physicians Service Insurance Corporation</a>	MAC - Part B	08102 - MAC B	J - 08	Indiana
<a href="#">Wisconsin Physicians Service Insurance Corporation</a>	MAC - Part A	08201 - MAC A	J - 08	Michigan
<a href="#">Wisconsin Physicians Service Insurance Corporation</a>	MAC - Part B	08202 - MAC B	J - 08	Michigan
<a href="#">Back to Top</a>				

## LCD Information

### Document Information

LCD ID: L37199  
Original Effective Date: For services performed on or after 09/16/2017

LCD Title: MoIDX: Oncotype DX® Breast Cancer for DCIS (Genomic Health™)  
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Proposed LCD in Comment Period: N/A  
Revision Ending Date: N/A

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Retirement Date: N/A

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## CMS National Coverage Policy

Title XVIII of the Social Security Act (the "Act"), Section 1862(a)(1)(A). This section limits coverage and payment to those items and services that are reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Title XVIII of the Social Security Act, Section 1833(e). This section prohibits Medicare payment for any claim that lacks the necessary information to process the claim.

42 C.F.R. § 410.32 "Diagnostic X-ray tests, diagnostic laboratory tests, and other diagnostic tests: Condition."

Medicare Internet Online Manual Pub. 100-2 (Medicare Benefit Policy Manual), Chapter 15, Section 80, "Requirements for Diagnostic X-Ray, Diagnostic Laboratory, and Other Diagnostic Tests"

Medicare Internet Online Manual Pub. 100-4 (Medicare Claims Processing Manual), Chapter 16 Sections:  
50.5 Jurisdiction of Laboratory Claims:  
60.12 Independent Laboratory Specimen Drawing  
60.2 Travel Allowance

Medicare Internet Online Manual Pub. 100-4 (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<sup>1</sup>. 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<sup>2</sup>. Following surgical excision alone local recurrences occur in approximately 25% to 30% of women by 10 years<sup>3</sup>. 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<sup>3</sup>. 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<sup>4</sup>. 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<sup>5</sup>. 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<sup>6</sup>.

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

<b>Proliferation Group</b>	<b>Hormone Receptor Group</b>	<b>Reference Group</b>
Ki67	PR	ACTB ( $\beta$ -actin)
STK15		GAPDH
Surviv		RPLPO
CCNB1 (cyclin B1)	GSTM1	GUS
MYBL2		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<sup>7,8</sup>. 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  $\geq$  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  $\leq$  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<sup>9</sup>. 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 prespecified risk groups (low < 39, intermediate 39-54, and high  $\geq$  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.

### General

Intended Use	
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	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																		
<b>Analytical Performance</b>																			
<b>Description</b> 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* ) 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* )	<p><b>Results</b></p> <p><b>Within RNA Extracts</b></p> <table border="1"> <thead> <tr> <th>DCIS Score Category</th> <th>N</th> <th>STD</th> </tr> </thead> <tbody> <tr> <td>Low</td> <td>36</td> <td>1.04</td> </tr> <tr> <td>Int-High</td> <td>39</td> <td>1.09</td> </tr> </tbody> </table> <p><b>Between Consecutive Tumor Block Sections</b></p> <table border="1"> <thead> <tr> <th>DCIS Score Category</th> <th>N</th> <th>STD</th> </tr> </thead> <tbody> <tr> <td>Low</td> <td>19</td> <td>2.11</td> </tr> <tr> <td>Int-High</td> <td>20</td> <td>3.96</td> </tr> </tbody> </table>	DCIS Score Category	N	STD	Low	36	1.04	Int-High	39	1.09	DCIS Score Category	N	STD	Low	19	2.11	Int-High	20	3.96
DCIS Score Category	N	STD																	
Low	36	1.04																	
Int-High	39	1.09																	
DCIS Score Category	N	STD																	
Low	19	2.11																	
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 Stability from date of receipt through the manufacturer's labeled expiration date with 12 months of on-site storage at -20 °C ± 5 °C																		
	GSP pool (gene specific primers for reverse transcription) 9 months at -20 °C ± 5 °C																		
	Reverse Transcription Positive control 2 years at -80 °C ± 10 °C																		
	P3 Plate 9 months -80 °C ± 10 °C																		
	Human gDNA (quantitative PCR positive control) 6 months at +5 °C ± 3 °C																		
	Quantitative PCR Master Mix 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) Freeze thaw no more 10x																		
	Reverse Transcription Positive control Single Use Tube																		
	P3 Plate Freeze thaw no more than 10x Use within 1 day 5 °C ± 3 °C																		
	Human gDNA (quantitative PCR positive control) 6 months at +5 °C ± 3 °C																		
	Quantitative PCR Master Mix 3 months after thaw at 5 °C ± 3 °C Up to 3 hours prior to qPCR plate assembly at room temperature (18 °C to 25 °C)																		
	Assembled Quantitative PCR plates 24 hours at room temperature (18 °C to 25 °C)																		
Specimen stability, primary	FPET slice in tube 6 months at room Temperature (18 °C to 25 °C)																		
Specimen stability, intermediate (extracted RNA)	Within 1 day 5 °C ± 3 °C Within 5 days -20 °C ± 5 °C Within 365 days at -80 °C ± 10 °C																		

Specimen stability, intermediate (cDNA Sample plate)	Within 3 months at -20 °C ± 5 °C
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\* 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<sup>10,11,12</sup>.

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.

Description	Results	
	Solin et al., 2013 <sup>8</sup> (n = 327 patients)	Rakovitch et al., 2015 <sup>9</sup> (n = 571 patients)
Hazard ratio/50 units	2.31 <sup>a</sup> (95% CI = 1.15 - 4.49) p = 0.02	2.15 <sup>b</sup> (95% CI = 1.43 - 3.22) 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 <sup>c</sup>	46/327 (14.1%)	100/571 (17.5%)

<sup>a</sup>Adjusted for tamoxifen use (pre-specified primary analysis)

<sup>b</sup>No covariate adjustment; all patients (irrespective of ER status) with negative resection margins

<sup>c</sup>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<sup>13</sup>. 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<sup>14</sup>, 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<sup>15</sup>. 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<sup>16</sup>. 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 limited 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.

WPS GHA 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  $\leq 6\%$  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.

[Back to Top](#)

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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:**

81479 UNLISTED MOLECULAR PATHOLOGY PROCEDURE

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

ICD-10 Codes that DO NOT Support Medical Necessity N/A

ICD-10 Additional Information

NA

[Back to Top](#)

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## General Information

Associated Information

N/A

Sources of Information

N/A

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[Back to Top](#)

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## **Revision History Information**

N/A [Back to Top](#)

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## **Associated Documents**

Attachments N/A

Related Local Coverage Documents Article(s) [A55648 - Response to Comments: MoIDX: Oncotype DX® Breast Cancer for DCIS \(Genomic Health™\) \(DL37199\)](#). LCD(s) [DL37199 - MoIDX: Oncotype DX® Breast Cancer for DCIS \(Genomic Health™\)](#)

Related National Coverage Documents N/A

Public Version(s) Updated on 07/21/2017 with effective dates 09/16/2017 - N/A [Back to Top](#)

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## **Keywords**

N/A Read the [LCD Disclaimer](#) [Back to Top](#)