Local Coverage Determination (LCD):
MolDX: EndoPredict® Breast Cancer Gene Expression Test (L37311)

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Contractor Information

Contractor Name	Contract Type	Contract Number	Jurisdiction	State(s)
Noridian Healthcare Solutions, LLC	A and B MAC	02101 - MAC A	J - F	Alaska
Noridian Healthcare Solutions, LLC	A and B MAC	02102 - MAC B	J - F	Alaska
Noridian Healthcare Solutions, LLC	A and B MAC	02201 - MAC A	J - F	Idaho
Noridian Healthcare Solutions, LLC	A and B MAC	02202 - MAC B	J - F	Idaho
Noridian Healthcare Solutions, LLC	A and B MAC	02301 - MAC A	J - F	Oregon
Noridian Healthcare Solutions, LLC	A and B MAC	02302 - MAC B	J - F	Oregon
Noridian Healthcare Solutions, LLC	A and B MAC	02401 - MAC A	J - F	Washington
Noridian Healthcare Solutions, LLC	A and B MAC	02402 - MAC B	J - F	Washington
Noridian Healthcare Solutions, LLC	A and B MAC	03101 - MAC A	J - F	Arizona
Noridian Healthcare Solutions, LLC	A and B MAC	03102 - MAC B	J - F	Arizona
Noridian Healthcare Solutions, LLC	A and B MAC	03201 - MAC A	J - F	Montana
Noridian Healthcare Solutions, LLC	A and B MAC	03202 - MAC B	J - F	Montana
Noridian Healthcare Solutions, LLC	A and B MAC	03301 - MAC A	J - F	North Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03302 - MAC B	J - F	North Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03401 - MAC A	J - F	South Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03402 - MAC B	J - F	South Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03501 - MAC A	J - F	Utah
Noridian Healthcare Solutions, LLC	A and B MAC	03502 - MAC B	J - F	Utah
Noridian Healthcare Solutions, LLC	A and B MAC	03601 - MAC A	J - F	Wyoming
Noridian Healthcare Solutions, LLC	A and B MAC	03602 - MAC B	J - F	Wyoming

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LCD Information

Document Information

LCD ID
L37311

LCD Title
MolDX: EndoPredict® Breast Cancer Gene Expression
Test

Proposed LCD in Comment Period
N/A

Source Proposed LCD
DL37311

AMA CPT / ADA CDT / AHA NUBC Copyright Statement

Original Effective Date
For services performed on or after 01/30/2018

Revision Effective Date
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Revision Ending Date
N/A

Retirement Date
N/A

Notice Period Start Date
12/14/2017

Notice Period End Date
01/29/2018

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 Medicare contractor will provide limited coverage for the EndoPredict® breast cancer gene expression test (Myriad Genetic Laboratories Inc., Salt Lake City, UT) for the management of post-menopausal women diagnosed with early-stage (TNM stage T1-3, N0-1) estrogen-receptor (ER) positive, Her2-negative breast cancer, who are either lymph node-negative or who have 1-3 positive nodes, and for whom treatment with adjuvant endocrine therapy (e.g., tamoxifen or aromatase inhibitors) is being considered. The test is used by physicians in the management of these patients by identifying those who have sufficiently low risk of distant recurrence (DR) at 10 years and may safely forego chemotherapy.

Summary of Evidence

In 2016, approximately 247,000 cases of breast cancer were diagnosed in the United States.[1] Approximately 54% of early-stage breast cancers are estrogen receptor (ER)-positive and HER2-negative, leading to treatment with adjuvant endocrine therapy (e.g., tamoxifen or aromatase inhibitors) that significantly improves prognosis.[2,3] Determining which patients with ER+/Her2- breast cancer will have a low enough risk of DR after 5 years of endocrine therapy to forgo adjuvant chemotherapy is a priority for physicians who manage these patients.

A 2012 meta-analysis by the Early Breast Cancer Trialist's Collaborative Group demonstrated that all clinical risk groups of patients with early breast cancer experience a ~30% benefit from chemotherapy, in terms of decrease in DR rate.[4] Therefore, patients with a low underlying risk of DR will have a lower absolute benefit from chemotherapy, compared to patients with a high underlying risk of DR. For each patient, the expected absolute benefit of chemotherapy needs to be weighed against the 2-3% chance of treatment-related toxicity and long-term side effects.

Tumor size, grade, and nodal status are currently used for assessment of a patient's distant recurrence risk to make decisions about the addition of chemotherapy to endocrine therapy. However, molecular tests have been shown to improve prognostic accuracy compared to standard clinical features and have become increasingly important for patients with ER+/Her2- breast cancer. These assays have become standard of care in the treatment of early stage breast cancer, to identify patients who have a low risk of DR such that chemotherapy would not provide an overall benefit, to directly predict chemotherapy benefit, and to help curtail costly overtreatment.

In determining the cutoff to identify low risk patients, breast cancer prognostic tests commonly use a threshold of a 10% risk of DR at 10 years. Patients with a risk under 10% are categorized as low risk. This 10% cutoff is a well-accepted standard used by many currently available breast prognostic tests and accepted by the American Society of Clinical Oncology (ASCO).[5]

Test Description and Intended Use

EndoPredict was developed in a training cohort of 964ER-positive and HER2-negative breast tumor samples.[10] The EndoPredict test is composed of a 12 gene molecular score as well as clinicopathological features (tumor size and nodal status). Eight genes were selected as relevant for therapeutic decision making; they include proliferation-associated genes as well as estrogen receptor signaling-associated genes. The signature also includes three RNA normalization genes and one DNA contamination control gene. The 12 gene molecular score is calculated by the weighted expression of the 8 target genes, as normalized by the 3 normalization genes, as measured in formalin-fixed paraffin-embedded (FFPE) breast tumor tissue. The 12 gene molecular score is then combined with clinicopathologic features including tumor size and lymph node status to produce the EndoPredict (EPclin) score. Patients with an EPclin score of ≤3.3 are classified as low risk and those with an EPClin score >3.3 are classified as high risk. In addition to a clear bimodal result (low- or high-risk), the test report includes the personalized risk of 10-year distant recurrence based on each patient's individual tumor.

EndoPredict is intended for use in FFPE breast tumor tissue from postmenopausal women diagnosed with early-stage (TNM stage T1-3, N0-1) ER-positive, Her2-negative breast cancer, who are either lymph node-negative or who have 1-3 positive nodes, and for whom treatment with adjuvant endocrine therapy (e.g., tamoxifen or aromatase inhibitors) is being considered. The test is used by physicians in the management of early-stage breast cancer by identifying those patients with a low-risk EPClin score, for whom the absolute benefit of adjuvant chemotherapy is unlikely to outweigh the risks.

Analytical Validation

This assay's analytical validation is consistent with industry standards and MolDX criteria.

Clinical Validation

The prognostic ability of EndoPredict has been validated by prospectively designed-retrospective studies in three different cohorts from phase III trials [The Austrian Breast & Colorectal Cancer Study Group (ABCSG)-6 and-8, and Arimidex, Tamoxifen, Alone or in Combination (ATAC)] involving more than 2,600 patients,[7,10] satisfying a 1B level of evidence according to the classification for prognostic biomarkers proposed by Simon et al.[11] These studies

collectively demonstrate the ability of EndoPredict to predict the primary endpoint of distant metastases in both early and late time periods, to accurately classify patients into a low or high risk group, and to identify a low risk group with excellent 10 year outcomes after treatment with 5 years of endocrine therapy only.[7,10,12-13] EndoPredict was determined to provide independent prognostic information compared to clinical and pathologic features alone.[9]

Filipits et al. (2011) described the initial development and clinical validation of the 12 gene molecular score and EPclin scores.[10] The 12 gene molecular score and EPclin scores were developed in a training cohort of 964 ER-positive, HER2-negative tumors from both node-positive and -negative patients treated with adjuvant endocrine therapy only. The design and calculation of the 12 gene molecular score and EPclin scores was prespecified. The threshold for EPclin to discriminate patients into low and high risk of distant recurrence was pre-defined at 3.3 which corresponded to a 10% DR risk at 10 years. Scores were then independently validated on 1702 patients from two large randomized phase III trials (ABCSG-6 and -8 trials), with ER+, HER2- breast cancer who received endocrine therapy only for 5 years, and included both node-positive and node-negative patients. In Kaplan-Meier analysis, EPclin low risk patients had a 4% distant recurrence rate (both ABCSG cohorts), while EPclin high risk patients had a 28% (ABCSG-6) or 22% (ABCSG-8) rate of distant recurrence (HR= 7.97 (ABCSG-6) or 4.27 (ABCSG-8), both P<0.001), demonstrating the ability of EPclin to accurately classify patients into low and high risk groups.

Buus et al. (2016) published a clinical validation study of EndoPredict in a third cohort of patients using the same pre-defined EPclin threshold of 3.3 to discriminate low risk from high risk patients (as described in Filipits et al.).[7] The study included 928 women from the ATAC trial who had ER-positive, HER2-negative breast cancer, both node-negative and node-positive, chemotherapy-naïve, treated with endocrine therapy. The EPclin score classified high and low risk patients with both node negative disease (5.9% DR for low risk vs. 20.0% DR for high risk, HR=3.9 (2.33-6.52) p<0.001) and node positive disease (5.0% vs. 36.9%, HR=9.49 (2.33-38.75) p<0.001). Overall, the EPclin score classified 58.8% of patients as low risk in this study. The authors concluded that the superior performance of EPclin compared with another widely used breast cancer prognostic test was partly due to the inclusion of clinical variables (nodal status and tumor size) in the EPclin score, but also due to an improved molecular signature that better predicts late events in years 5-10 ($x2=59.3$, p<0.001).

Dubsky et al. conducted two secondary analyses to evaluate the performance of EndoPredict in different subsets of the 1702 ER-positive, HER2-negative breast cancer patients from the ABCSG-6 and ABCSG-8 phase III trials.[12-13] The EPclin score improved the classification of breast cancer compared to the prognosis assigned by standard guidelines that use clinical and pathological features (i.e., NCCN, German S3 and St. Gallen).[12] Using clinical guidelines, 6-19% of patients were classified as low risk; however, EPclin classified 63% of all patients as low risk. Furthermore, 58-61% of patients classified as high- or intermediate-risk according to clinical guidelines were reclassified by EPclin as low risk; this group of patients had a 5% rate of distant metastasis at 10 years, confirming the accuracy of EndoPredict's assessment of risk. Finally, EndoPredict was compared to standard clinical parameters for predicting distant metastases in both early (0-5y) and late (5-10y) time periods, which is an important consideration based on the fact that 50% of recurrences in women with ER+, Her2- breast cancer occur after 5 years.[13] The EPclin low risk group had significantly improved clinical outcomes compared to the EPclin high risk group in both the early (0-5y; HR 4.82, p<.001)) and late (5-10y; HR 6.25, p<.001) timeframes. The EPclin score identified 64% of patients at risk after 5 years into a low-risk subgroup with an absolute 1.8% risk of late distant metastasis at 10 years.

Clinical Utility

A retrospective analysis of the prospective use and impact of the EndoPredict assay in a clinical setting was published in 2013 by Müller et al.[14] Samples from 167 women with primary invasive ER+, HER2- breast cancer were analyzed by EndoPredict performed at the molecular pathology laboratory (Institute of Pathology) at the Charite´ University Hospital in Berlin. The impact of EndoPredict on changes in therapy decisions was evaluated for 130 of the 167 patients, of whom 47.7% had low EPclin scores and 52.3% had high EPclin scores. There was a change in pre-test versus post-test therapy for 37.7% of patients with most of the changes due to reduction from combination therapy (chemotherapy plus endocrine) to endocrine therapy alone. Before the EndoPredict assay, 47 (36.2%) of patients had been scheduled for endocrine therapy alone and 83 (63.8%) had been scheduled for a combination of endocrine therapy and chemotherapy. After the EndoPredict results were available, the number of patients with endocrine therapy alone increased to 67 (51.5%). Changes in therapy were directionally aligned with the EPclin result as low or high risk.

A 2013 meta-analysis of Oncotype DX decision data determined that the test changed adjuvant chemotherapy treatment decisions in 33.4 % of patients (8 studies, 1,437 patients).[16] The observed change in treatment recommendations for

37.7% and 35.8% of patients after use of EndoPredict is therefore consistent with the expected clinical utility of similar established tests.

Summary of Analytical and Clinical Performance

General

Intended Use	EndoPredict is intended for use in FFPE breast tumor tissue from postmenopausal women diagnosed with early stage (TNM stage T1-3, N0-1) ER-positive, Her2-negative breast cancer, who are either lymph node-negative or who have 1-3 positive nodes, and for whom treatment with adjuvant endocrine therapy (e.g., tamoxifen or aromatase inhibitors) is being considered.
Validated Specimen Type (s)	Invasive primary female breast cancer resection FFPE tumors.

Analytical Performance

Description	Results (with 95% Confidence Intervals if applicable)
Intermediate precision (between run precision)12 samples (2 low, 10 high, score range 2.1-5.9) were run 3 times for the inter-batch reproducibility. Each set of 12 samples was run on different days, in batches of 2 samples. Each time a set of 12 samples was run, the samples were randomly assigned into the batches of 2 samples. Thus, 6 batches were run for each set of samples, for a total of 18 batches. 2 QuantStudio instruments (for qRT-PCR) and 7 technicians (3 within the anatomic pathology laboratory and 4 within the RNA extraction and qRT-PCR laboratory) were involved. These samples were tested over a 17 day period, with each sample replicate tested on a different day than the other replicates for that sample. Two different lots of 96-well plates and positive control were utilized, and a single lot of mastermix and extraction reagents were utilized.	Qualitative: 100% (36/36; 95% CI = 90.3-100%) Quantitative: Standard deviation = 0.06 EPclin score units (upper 95% CI: 0.07)
Reproducibility (between sites)	N/A. This test is only performed in one laboratory.
Minimum input quantity	There is no minimum RNA concentration required for testing as determined by UV spectroscopy. Instead, a functional quantification of the RNA is performed by measuring the average Ct values of the 3 housekeeper genes. This average value must be between 19.0 and 27.0 for an EPclin score to be generated.
Limit of blank (LOB)	Not empirically determined.
Limits of quantitation (LOQ)	There is no pre-specified upper or lower limit for Ct values for any target or housekeeper gene. However, there is both an upper and lower limit for the averaged Ct value of the housekeeper genes (19.0-27.0).
Reportable range	For the EPclin score, the reportable range of scores was determined in a cohort of 1,324 samples and is from 1.1 to 6.2.10
Interfering substances	

	Contamination of ≤70% normal tissue did not significantly alter the EPclin score.[18] Additionally, there are no known PCR inhibitors in breast resection tissue.
Specimen stability, primary (FFPE)	Archival FFPE samples were tested in the validation studies of this assay, with samples over 10 years old tested and producing passing results.[10]
Specimen stability, intermediate (Isolated RNA) 6 samples (1 low risk, 5 high risk; score range 2.0 to 6.8) were tested over 4 weeks when stored at -80 °C, acceptance criteria = ±0.6 EP score units)	4 weeks at -80 °C
Reagent closed/shelf-life stability	4 reagents are considered critical: Versant Tissue Prep Kit (Siemens Healthcare Diagnostics); TaqPath 1-step RT-qPCR Master Mix (ThermoScientific); Positive control RNA (Agilent Technologies); and EndoPredict 96-well plate (Myriad GMBH). Manufacturer's guidelines are followed for all reagent expirations.
Reagent open/in use stability	

The prognostic ability of EndoPredict has been validated in three different cohorts from phase III trials (ABCSG-6 and-8, and ATAC), involving more than 2,600 patients with ER-positive, HER2-negative, node-positive and–negative invasive breast cancer treated with endocrine therapy only.

Cohort	Patient Subset	No. Patients	EPclin Low Risk Group		EPclin High Risk Group	HR and p-value
			10-yr risk of DR (95% CI)	10-yr risk of DR (95% CI)	10-yr risk of DR (95% CI)	(Between EPclin low/high risk groups)
ABCSG-6[10] ABCSG-8[10] ATAC[7]	All (Node Negative & Node Positive)	378	4% (1 – 8%)	55%	28% (20 – 36%)	7.97(3.56-17.83 p<0.001
		1324	4% (2 – 5%)	65%	22% (15 – 29%)	4.27(2.74-6.67) p<0.001
		928	5.8% (4.0 – 8.3)	59%	28.8% (24.3 – 33.9)	5.99(3.94-9.11) p<0.001
ABCSG-6&8[10]* ATAC[7]	Node Negative	1165	5% (2.5 – 6.8)	78%	16% (10.0 – 22.8)	3.92(2.35-6.54) p<0.001
		680	5.9% (4.0 – 8.6)	73%	20.0% (14.6 – 27.0)	3.90 (2.33-6.52) p<0.001
ABCSG-6&8[10]* ATAC[7]	Node Positive	527	5.2% (1.0 – 9.2)	30%	28% (21.1 – 34.4)	4.70(2.16-10.22) p<0.001
		248	5.0% (1.2 – 18.9)	19%	36.9% (30.2 – 44.5)	9.49 (2.33-38.75) p<0.001

*Subset analysis from Filipits et al. 2011

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

Level of Evidence

Quality of Evidence – Moderate

Strength – High

Weight - Moderate

The EndoPredict assay is reasonable and necessary to assist physicians in the management of early stage breast cancer by identifying those patients with a sufficiently low risk of 10-year distant recurrence who may safely forgo chemotherapy. The assay is covered for women with T1-3, N0-1 breast cancer when the following criteria are met:

- Patient is post-menopausal, and
- Pathology reveals invasive carcinoma of the breast that is ER-positive, Her2-negative, and
- Patient is either lymph node-negative or has 1-3 positive lymph nodes, and
- Patient has no evidence of distant metastasis, and
- Test result will be used to determine treatment choice between endocrine therapy alone vs. endocrine therapy plus chemotherapy.

Note: The EndoPredict test should not be ordered if a physician does not intend to act upon the test result.

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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:
81599 UNLISTED MULTIANALYTE ASSAY WITH ALGORITHMIC ANALYSIS

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

Group 1 Codes:

ICD-10 Codes	Description
C50.011	Malignant neoplasm of nipple and areola, right female breast
C50.012	Malignant neoplasm of nipple and areola, left female breast
C50.111	Malignant neoplasm of central portion of right female breast
C50.112	Malignant neoplasm of central portion of left female breast
C50.211	Malignant neoplasm of upper-inner quadrant of right female breast
C50.212	Malignant neoplasm of upper-inner quadrant of left female breast
C50.311	Malignant neoplasm of lower-inner quadrant of right female breast

ICD-10 Codes	Description
C50.312	Malignant neoplasm of lower-inner quadrant of left female breast
C50.411	Malignant neoplasm of upper-outer quadrant of right female breast
C50.412	Malignant neoplasm of upper-outer quadrant of left female breast
C50.511	Malignant neoplasm of lower-outer quadrant of right female breast
C50.512	Malignant neoplasm of lower-outer quadrant of left female breast
C50.611	Malignant neoplasm of axillary tail of right female breast
C50.612	Malignant neoplasm of axillary tail of left female breast
C50.811	Malignant neoplasm of overlapping sites of right female breast
C50.812	Malignant neoplasm of overlapping sites of left female breast
C50.911	Malignant neoplasm of unspecified site of right female breast
C50.912	Malignant neoplasm of unspecified site of left female breast

ICD-10 Codes that DO NOT Support Medical Necessity N/A
ICD-10 Additional Information Back to Top

General Information

Associated Information
N/A

Sources of Information
N/A
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Revision History Information

Revision History Date	Revision History Number	Revision History Explanation	Reason(s) for Change
01/30/2018	R1	Corrected the link in the first bibliography entry.	• Creation of Uniform LCDs With Other MAC Jurisdiction

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Associated Documents

Attachments N/A

Related Local Coverage Documents Article(s) A55794 - Response to Comments: MolDX: EndoPredict® Breast Cancer Gene Expression Test LCD(s) DL37311 - MolDX: EndoPredict® Breast Cancer Gene Expression Test

Related National Coverage Documents N/A

Public Version(s) Updated on 08/16/2018 with effective dates 01/30/2018 - N/A Updated on 11/30/2017 with effective dates 01/30/2018 - N/A Back to Top

Keywords

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- EndoPredict
- breast
- estrogen
- Myriad
- Her-2
- MolDX
- endocrine
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