

Local Coverage Determination (LCD): MoIDX: Breast Cancer Assay: Prosigna (L36380)

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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 Guam Hawaii Northern Mariana Islands
Noridian Healthcare Solutions, LLC	A and B MAC	01212 - MAC B	J - E	American Samoa Guam Hawaii 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 California - Entire State Guam Hawaii Nevada Northern Mariana Islands

LCD Information

Document Information

LCD ID

Original Effective Date

L36380

For services performed on or after 05/03/2016

LCD Title

MoIDX: Breast Cancer Assay: Prosigna

Revision Effective Date

For services performed on or after 11/01/2019

Proposed LCD in Comment Period

N/A

Revision Ending Date

N/A

Source Proposed LCD

DL36380

Retirement Date

N/A

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Notice Period Start Date

03/17/2016

Notice Period End Date

05/02/2016

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CMS National Coverage Policy

Title XVIII of the Social Security Act (SSA), §1862(a)(1)(A), states that no Medicare payment shall be made for

items or services that “are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.”

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

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

This policy provides limited coverage of the Prosigna breast cancer gene signature assay to patients that meet the following criteria consistent with the FDA indications for use:

- Post-menopausal female **either**
 - ER+, lymph node-negative, stage I or II breast cancer; **or**
 - ER+, lymph node-positive (1-3 positive nodes), stage II breast cancer.

Claims for Prosigna testing will be denied when testing does not meet all of the above criteria.

Background

Women with early breast cancer and up to 3 locally positive lymph nodes whose tumor is estrogen-receptor positive will usually receive anti-hormonal therapy such as tamoxifen or aromatase inhibitors. U.S. (NCCN) and international (St. Gallen) guidelines predicate the decision for adjuvant chemotherapy on the size and grade of the breast cancer and other factors including genomic assays that provide additional information on risk of recurrence (Hernandez-Ava et al., 2013). According to a 2014 review, “Prognostic factors provide an indication of whether a patient needs subsequent therapy.” (Paoletti & Hayes, 2014). Similarly, another 2014 review article states, “Efforts should be focused on reducing chemotherapy in patients unlikely to benefit.” (Rampurwala et al., 2014). Accordingly, Medicare has covered breast cancer gene signature prognostic/predictive tests since 2006.

The PAM50 breast cancer gene signature test was developed in the late 1990s and initial studies showed a strong correlation with breast cancer recurrence and with complete pathologic response to neoadjuvant chemotherapy (Parker et al., 2009). While test results are reported on a scale of 1-100 as a Risk of Recurrence (ROR) score, the underlying algorithm is also able to classify cases into the luminal A and B, Her2neu, and triple-negative subtype classifications.

The Nanostring nCounter® nucleic acid analysis system replicates the PAM50 algorithm, as an FDA cleared kit, the Prosigna Breast Cancer Gene Signature Assay (FDA, 2013). The Prosigna package insert was most recently updated in January, 2015 (FDA, 2015) reflecting additional studies (Sestak et al., 2014). Notably, the Prosigna platform and the original PAM50 platform have a 0.997 correlation (Dowsett et al., 2013).

For the FDA, the Prosigna test was validated in a large population of post-menopausal, estrogen-receptor positive women based on 1,017 cases of the TransATAC study (Dowsett et al., 2013). The study showed a strong correlation with long-term breast cancer recurrence and added substantial additional prognostic information over a clinical

treatment score based on standard clinical variables. This study was replicated in an independent population, also on the Prosigna test, using 1,620 samples from the ABCSG8 trial (Gnant, 2014). A separate analysis of these trials validated prediction of distant recurrence in years 5-10 after initial diagnosis (Sestak et al., 2014) and has been incorporated in the FDA labeling (FDA, 2015). The Prosigna test is issued as separate reports, consistent with FDA review and labeling, for node-negative and node-positive (1-3 node) populations. Analytic performance, precision, reproducibility, and analysis of the clinical validations are provided in the FDA labeling (FDA, 2013; FDA, 2015).

Clinical utility of this breast cancer gene signature has also been assessed. The study of Martin et al. (2015) showed a 20% decision impact on decisions for or against adjuvant chemotherapy in an all-comers population of 200 new cases of incident breast cancer, when Prosigna test information became available after all other clinical information had been considered. The net rates of selecting adjuvant chemotherapy for low, intermediate, and high risk cases was similar to that observed in a meta-analysis of Oncotype DX decision data (Carlson & Roth, 2013). Additional support for the use of these test results in treatment decisions comes from Parker et al. (2009), in which there was a strong association with neoadjuvant chemotherapy response. Low-scoring cases have a very low change of complete pathological response to neoadjuvant chemotherapy, while high-scoring cases approach a 50% chance of complete pathological response. The same findings have been observed for other breast cancer gene signatures based on prognostic algorithms (Chang et al., 2008).

Summary of Evidence

NA

Analysis of Evidence (Rationale for Determination)

NA

General Information

Associated Information

Documentation Requirements

The patient's medical record must contain documentation that fully supports the medical necessity for services included within this LCD (see **Coverage Indications, Limitations, and/or Medical Necessity**). This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures.

Documentation supporting the medical necessity should be legible, maintained in the patient's medical record, and must be made available to the MAC upon request.

This final LCD, effective 05/03/2016, combines JEA DL36320 into the JEB LCD so that both JEA and JEB contract numbers will have the same final MCD LCD number.

No comments were received for comment period ending 12/07/2015.

Sources of Information

N/A

Bibliography

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4. FDA (2013). 510(k) Summary: K130010. Prosigna Breast Cancer Prognostic Gene Signature Assay.
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8. Martin M et al. (2015) Prospective study of the impact of the Prosigna assay on adjuvant clinical decision-making in unselected patients with estrogen receptor positive, human epidermal growth factor receptor negative, node negative early-stage breast cancer. *Curr Med Res Opin* 23:1-9.
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Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
11/01/2019	R4	<p>The LCD is revised to remove CPT/HCPCS codes in the Keyword Section of the LCD.</p> <p>At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a</p>	<ul style="list-style-type: none">• Other (The LCD is revised to remove CPT/HCPCS codes in the Keyword Section of the LCD.)

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.	
11/01/2019	R3	<p>11/01/2019: This LCD is being revised in order to adhere to CMS requirements per chapter 13, section 13.5.1 of the Program Integrity Manual.</p> <p>There has been no change in coverage with this LCD revision. Regulations regarding billing and coding were removed from the CMS National Coverage Policy section of this LCD and placed in the related Billing and Coding: MolDX: Breast Cancer Assay: Prosigna Article A57363.</p>	<ul style="list-style-type: none"> • Provider Education/Guidance
11/01/2019	R2	<p>As required by CR 10901, all billing and coding information has been moved to the companion article, this article is linked to the LCD.</p> <p>At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.</p>	<ul style="list-style-type: none"> • Revisions Due To Code Removal
01/01/2018	R1	<p>2018 Annual CPT/HCPCS updates: Added 81520 to CPT/HCPCS codes section.</p> <p>12/4/17: At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.</p>	<ul style="list-style-type: none"> • Creation of Uniform LCDs With Other MAC Jurisdiction • Revisions Due To CPT/HCPCS Code Changes

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Article(s)

A57363 - Billing and Coding: MolDX: Breast Cancer Assay: Prosigna

LCD(s)

DL36320

- (MCD Archive Site)DL36380

- (MCD Archive Site)

Related National Coverage Documents

N/A

Public Version(s)

Updated on 01/28/2020 with effective dates 11/01/2019 - N/A

Updated on 12/18/2019 with effective dates 11/01/2019 - N/A

Updated on 10/08/2019 with effective dates 11/01/2019 - N/A

Updated on 12/04/2017 with effective dates 01/01/2018 - 10/31/2019

Updated on 03/03/2016 with effective dates 05/03/2016 - N/A

Keywords

N/A