

Local Coverage Determination (LCD): MoIDX: BREAST CANCER ASSAY: Prosigna (L36125)

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Contractor Information

| Contractor Name | Contract Type | Contract Number | Jurisdiction | State(s) |
|------------------------------|-----------------|-------------------|--------------|----------------|
| Palmetto GBA | A and B and HHH | MAC 11201 - MAC A | J - M | South Carolina |
| Palmetto GBA | A and B and HHH | MAC 11202 - MAC B | J - M | South Carolina |
| Palmetto GBA | A and B and HHH | MAC 11301 - MAC A | J - M | Virginia |
| Palmetto GBA | A and B and HHH | MAC 11302 - MAC B | J - M | Virginia |
| Palmetto GBA | A and B and HHH | MAC 11401 - MAC A | J - M | West Virginia |
| Palmetto GBA | A and B and HHH | MAC 11402 - MAC B | J - M | West Virginia |
| Palmetto GBA | A and B and HHH | MAC 11501 - MAC A | J - M | North Carolina |
| Palmetto GBA | A and B and HHH | MAC 11502 - MAC B | J - M | North Carolina |

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LCD Information

Document Information

LCD ID
L36125

Original Effective Date
For services performed on or after 10/01/2015

LCD Title
MoIDX: BREAST CANCER ASSAY: Prosigna

Revision Effective Date
For services performed on or after 10/17/2016

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Retirement Date
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Notice Period Start Date
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Notice Period End Date
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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."

Title XVIII of the Social Security Act, §1833(e), prohibits Medicare payment for any claim lacking the necessary documentation to process the claim.

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

CMS Internet Online Manual Pub. 100-02 (Medicare Benefit Policy Manual), Chapter 15, Section 80, "Requirements for Diagnostic X-Ray, Diagnostic Laboratory, and Other Diagnostic Tests"

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 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).

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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:

0008M ONCOLOGY (BREAST), MRNA ANALYSIS OF 58 GENES USING HYBRID CAPTURE, ON FORMALIN-FIXED PARAFFIN-EMBEDDED (FFPE) TISSUE, PROGNOSTIC ALGORITHM REPORTED AS A RISK SCORE

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 |
| C50.019 | Malignant neoplasm of nipple and areola, unspecified female breast |
| C50.111 | Malignant neoplasm of central portion of right female breast |
| C50.112 | Malignant neoplasm of central portion of left female breast |
| C50.119 | Malignant neoplasm of central portion of unspecified 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 |
| C50.219 | Malignant neoplasm of upper-inner quadrant of unspecified female breast |
| C50.311 | Malignant neoplasm of lower-inner quadrant of right female breast |
| C50.312 | Malignant neoplasm of lower-inner quadrant of left female breast |
| C50.319 | Malignant neoplasm of lower-inner quadrant of unspecified 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 |
| C50.419 | Malignant neoplasm of upper-outer quadrant of unspecified 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 |
| C50.519 | Malignant neoplasm of lower-outer quadrant of unspecified female breast |
| C50.611 | Malignant neoplasm of axillary tail of right female breast |
| C50.612 | Malignant neoplasm of axillary tail of left female breast |
| C50.619 | Malignant neoplasm of axillary tail of unspecified female breast |
| C50.811 | Malignant neoplasm of overlapping sites of right female breast |
| C50.812 | Malignant neoplasm of overlapping sites of left female breast |
| C50.819 | Malignant neoplasm of overlapping sites of unspecified female breast |
| C50.911 | Malignant neoplasm of unspecified site of right female breast |
| C50.912 | Malignant neoplasm of unspecified site of left female breast |
| C50.919 | Malignant neoplasm of unspecified site of unspecified female breast |
| D05.00 | Lobular carcinoma in situ of unspecified breast |
| D05.01 | Lobular carcinoma in situ of right breast |
| D05.02 | Lobular carcinoma in situ of left breast |
| D05.10 | Intraductal carcinoma in situ of unspecified breast |
| D05.11 | Intraductal carcinoma in situ of right breast |
| D05.80 | Other specified type of carcinoma in situ of unspecified breast |
| D05.90 | Unspecified type of carcinoma in situ of unspecified breast |

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

ICD-10 Additional Information

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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.

Sources of Information and Basis for Decision

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References

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Revision History Information

| Revision History Date | Revision History Number | Revision History Explanation | Reason(s) for Change |
|-----------------------|-------------------------|---|--|
| 10/17/2016 | R4 | DL36125 was presented at the 2016 June CAC because the male breast cancer codes were removed. This LCD version was created as a result of DL36125 being released to a Final LCD. | <ul style="list-style-type: none">• Other (DL36125 was presented at the 2016 June CAC because the male breast cancer codes were removed. This LCD version was created as a result of DL36125 being released to a Final LCD.) |
| 01/25/2016 | R3 | List of male breast cancer CPT codes removed for 1/25/2016 revision: C50.021 Malignant neoplasm of nipple and areola, right male breast C50.022 Malignant neoplasm of nipple and areola, left male breast C50.029 Malignant neoplasm of nipple and areola, unspecified male breast | <ul style="list-style-type: none">• Other (List of male breast cancer CPT codes removed for 1/25/2016 revision.) |

| Revision History Date | Revision History Number | Revision History Explanation | Reason(s) for Change |
|-----------------------------|-------------------------|--|---|
| | | <p>C50.121 Malignant neoplasm of central portion of right male breast</p> <p>C50.122 Malignant neoplasm of central portion of left male breast</p> <p>C50.129 Malignant neoplasm of central portion of unspecified male breast</p> <p>C50.221 Malignant neoplasm of upper-inner quadrant of right male breast</p> <p>C50.222 Malignant neoplasm of upper-inner quadrant of left male breast</p> <p>C50.229 Malignant neoplasm of upper-inner quadrant of unspecified male breast</p> <p>C50.321 Malignant neoplasm of lower-inner quadrant of right male breast</p> <p>C50.322 Malignant neoplasm of lower-inner quadrant of left male breast</p> <p>C50.329 Malignant neoplasm of lower-inner quadrant of unspecified male breast</p> <p>C50.421 Malignant neoplasm of upper-outer quadrant of right male breast</p> <p>C50.422 Malignant neoplasm of upper-outer quadrant of left male breast</p> <p>C50.429 Malignant neoplasm of upper-outer quadrant of unspecified male breast</p> <p>C50.521 Malignant neoplasm of lower-outer quadrant of right male breast</p> <p>C50.522 Malignant neoplasm of lower-outer quadrant of left male breast</p> <p>C50.529 Malignant neoplasm of lower-outer quadrant of unspecified male breast</p> <p>C50.621 Malignant neoplasm of axillary tail of right male breast</p> <p>C50.622 Malignant neoplasm of axillary tail of left male breast</p> <p>C50.629 Malignant neoplasm of axillary tail of unspecified male breast</p> <p>C50.821 Malignant neoplasm of overlapping sites of right male breast</p> <p>C50.822 Malignant neoplasm of overlapping sites of left male breast</p> <p>C50.829 Malignant neoplasm of overlapping sites of unspecified male breast</p> <p>C50.921 Malignant neoplasm of unspecified site of right male breast</p> <p>C50.922 Malignant neoplasm of unspecified site of left male breast</p> <p>C50.929 Malignant neoplasm of unspecified site of unspecified male breast</p> | |
| 01/25/2016 | R2 | Removed male breast cancer CPT codes | <ul style="list-style-type: none"> • Revisions Due To CPT/HCPCS Code Changes |
| 10/01/2015 | R1 | Removed reference to J11 MAC. | <ul style="list-style-type: none"> • Typographical Error |
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[Associated Documents](#)

Attachments N/A

Related Local Coverage Documents Article(s) [A55299 - Response to Comments: MolDX: Breast Cancer Assay-Prosigna](#) LCD(s) [DL36125](#) - (MCD Archive Site)

Related National Coverage Documents N/A

Public Version(s) Updated on 08/19/2016 with effective dates 10/17/2016 - N/A [Updated on 02/29/2016 with effective dates 01/25/2016 - 10/16/2016](#) [Updated on 12/03/2015 with effective dates 01/25/2016 - N/A](#) [Updated on 08/13/2015 with effective dates 10/01/2015 - 01/24/2016](#) [Updated on 08/03/2015 with effective dates 10/01/2015 - N/A](#) [Back to Top](#)

Keywords

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