

Local Coverage Article: Billing and Coding: MolDX: Myriad's BRACAnalysis CDx™ (A55294)

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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

Article Information

General Information

Article ID

Original Effective Date

A55294

10/15/2017

Article Title

Billing and Coding: MoIDX: Myriad's BRACAnalysis CDx™

Revision Effective Date

11/01/2019

Article Type

Billing and Coding

Revision Ending Date

N/A

AMA CPT / ADA CDT / AHA NUBC Copyright Statement

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Retirement Date

N/A

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CMS National Coverage Policy

N/A

Article Guidance

Article Text:

The following coding and billing guidance is to be used with its associated Local coverage determination.

The FDA has approved Lynparza® (olaparib), as a treatment for women with advanced ovarian cancer or women or men with metastatic breast cancer, and the companion diagnostic BRCAAnalysis CDx®, the laboratory test to detect mutated BRCA genes.

Lynparza, a poly ADP-ribose polymerase (PARP) inhibitor, blocks enzymes involved in repairing damaged DNA and is intended for women with heavily pretreated ovarian cancer or HER-2 negative metastatic breast associated with defective BRCA genes. BRCAAnalysis CDx™ detects the presence of BRCA1 and BRCA2 gene mutations. According to the FDA, "results of the test are used as an aid in identifying breast and ovarian cancer patients with deleterious or suspected deleterious germline BRCA variants, who are or may become candidates for treatment with Lynparza® (olaparib)." BRCAAnalysis CDx™ is only covered for women diagnosed with ovarian or breast cancer and who have not been previously tested for BRCA mutations.

To report a BRCAAnalysis CDx™ service, please submit the following claim information:

- One (1) unit of service
- Enter DEX Z-Code™ identifier adjacent to the CPT code in the comment/narrative field for the following Part B claim field/types:
 - Loop 2400 or SV101-7 for the 5010A1 837P
 - Item 19 for paper claim
- Enter DEX Z-Code™ identifier adjacent to the CPT code in the comment/narrative field for the following Part A claim field types:
 - Line SV202-7 for 837I electronic claim
 - Block 80 for the UB04 claim form
- Select at least one ICD-10-CM diagnosis code.

Only one BRCA testing per beneficiary lifetime will be considered reasonable and necessary. If a patient received BRCA testing prior to Lynparza treatment consideration, regardless of the performing lab, additional testing would not be considered a reasonable and necessary service.

BRCA1/BRCA2 genetic testing is not reasonable and necessary, thus it is non-covered, for the following indications:

- Genetic screening in the general population. Such testing is considered screening and is excluded by Medicare statute. An ABN must be obtained for BRCA 1 and BRCA 2 testing for individuals without signs and symptoms of breast, ovarian or other hereditary cancer syndromes as indicated in this policy.
- Testing of individuals with no personal history of breast, ovarian, fallopian tube, primary peritoneal, pancreatic, or prostate cancer. Such testing is considered screening and is excluded by Medicare statute. An ABN must be obtained for BRCA 1 and BRCA 2 testing for individuals without signs and symptoms of breast, ovarian or other hereditary cancer syndromes as indicated in this policy
- Testing of individuals under 18 years of age.

Coding Information

CPT/HCPCS Codes

Group 1 Paragraph:

N/A

Group 1 Codes:

CODE	DESCRIPTION
81162	BRCA1 (BRCA1, DNA REPAIR ASSOCIATED), BRCA2 (BRCA2, DNA REPAIR ASSOCIATED) (EG, HEREDITARY BREAST AND OVARIAN CANCER) GENE ANALYSIS; FULL SEQUENCE ANALYSIS AND FULL DUPLICATION/DELETION ANALYSIS (IE, DETECTION OF LARGE GENE REARRANGEMENTS)

CPT/HCPCS Modifiers

N/A

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

N/A

Group 1 Codes:

ICD-10 CODE	DESCRIPTION
C48.0	Malignant neoplasm of retroperitoneum
C48.1	Malignant neoplasm of specified parts of peritoneum
C48.2	Malignant neoplasm of peritoneum, unspecified
C48.8	Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum
C50.011	Malignant neoplasm of nipple and areola, right female breast
C50.012	Malignant neoplasm of nipple and areola, left female breast
C50.021	Malignant neoplasm of nipple and areola, right male breast
C50.022	Malignant neoplasm of nipple and areola, left male breast
C50.111	Malignant neoplasm of central portion of right female breast
C50.112	Malignant neoplasm of central portion of left female breast
C50.121	Malignant neoplasm of central portion of right male breast
C50.122	Malignant neoplasm of central portion of left male 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
C50.221	Malignant neoplasm of upper-inner quadrant of right male breast
C50.222	Malignant neoplasm of upper-inner quadrant of left male breast
C50.311	Malignant neoplasm of lower-inner quadrant of right female breast

ICD-10 CODE	DESCRIPTION
C50.312	Malignant neoplasm of lower-inner quadrant of left female breast
C50.321	Malignant neoplasm of lower-inner quadrant of right male breast
C50.322	Malignant neoplasm of lower-inner quadrant of left male 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
C50.421	Malignant neoplasm of upper-outer quadrant of right male breast
C50.422	Malignant neoplasm of upper-outer quadrant of left male 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
C50.521	Malignant neoplasm of lower-outer quadrant of right male breast
C50.522	Malignant neoplasm of lower-outer quadrant of left male breast
C50.611	Malignant neoplasm of axillary tail of right female breast
C50.612	Malignant neoplasm of axillary tail of left female breast
C50.621	Malignant neoplasm of axillary tail of right male breast
C50.622	Malignant neoplasm of axillary tail of left male breast
C50.811	Malignant neoplasm of overlapping sites of right female breast
C50.812	Malignant neoplasm of overlapping sites of left female breast
C50.821	Malignant neoplasm of overlapping sites of right male breast
C50.822	Malignant neoplasm of overlapping sites of left male breast
C50.911	Malignant neoplasm of unspecified site of right female breast
C50.912	Malignant neoplasm of unspecified site of left female breast
C50.921	Malignant neoplasm of unspecified site of right male breast
C50.922	Malignant neoplasm of unspecified site of left male breast
C56.1	Malignant neoplasm of right ovary
C56.2	Malignant neoplasm of left ovary
C56.9	Malignant neoplasm of unspecified ovary
C57.01	Malignant neoplasm of right fallopian tube
C57.02	Malignant neoplasm of left fallopian tube
C79.61	Secondary malignant neoplasm of right ovary
C79.62	Secondary malignant neoplasm of left ovary
C79.9	Secondary malignant neoplasm of unspecified site
Z85.3	Personal history of malignant neoplasm of breast

ICD-10 CODE	DESCRIPTION
Z85.43	Personal history of malignant neoplasm of ovary
Z85.44	Personal history of malignant neoplasm of other female genital organs

ICD-10 Codes that DO NOT Support Medical Necessity

N/A

Additional ICD-10 Information

N/A

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

Other Coding Information

N/A

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
11/01/2019	R4	relating LCD to Article

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
11/01/2019	R3	This article was converted to a Billing and Coding type article. No other changes were made.
02/21/2019	R2	Revised the first paragraph to include men in the treatment for metastatic breast cancer and included non-coverage indications. Effective 1/1/2019, 81479 is replaced with CPT code 81162.
07/05/2018	R1	Revised opening paragraphs and added the following ICD-10 codes: C48.0, C48.1, C48.2, C48.8, C50.011, C50.012, C50.021, C50.022, C50.111, C50.112, C50.121, C50.122, C50.211, C50.212, C50.221, C50.222, C50.311, C50.312, C50.321, C50.322, C50.411, C50.412, C50.421, C50.422, C50.511, C50.512, C50.521, C50.522, C50.611, C50.612, C50.621, C50.622, C50.811, C50.812, C50.821, C50.822, C50.911, C50.912, C50.921, C50.922, C57.01, C57.02, Z85.3, Z85.43, Z85.44. Removed ICD-10 C79.60

Associated Documents

Related Local Coverage Document(s)

LCD(s)

L35160 - MolDX: Molecular Diagnostic Tests (MDT)

Related National Coverage Document(s)

N/A

Statutory Requirements URL(s)

N/A

Rules and Regulations URL(s)

N/A

CMS Manual Explanations URL(s)

N/A

Other URL(s)

N/A

Public Version(s)

Updated on 10/17/2019 with effective dates 11/01/2019 - N/A

Updated on 10/17/2019 with effective dates 11/01/2019 - N/A

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Updated on 07/05/2018 with effective dates 07/05/2018 - N/A

Updated on 08/13/2017 with effective dates 10/15/2017 - N/A

Keywords

- MoIDX
- Myriad's
- BRAVAnalysis
- CDx
- Lynparza
- 81162