LCD - MolDX: BRCA1 and BRCA2 Genetic Testing (L36163)

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CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES
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
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LCD Information

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MolDX: BRCA1 and BRCA2 Genetic Testing

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CMS National Coverage Policy

Title XVIII of the Social Security Act, §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

CMS Internet-Only Manual, Pub. 100-02, Medicare Benefit Policy Manual, Chapter 15, §80 Requirements for Diagnostic X-Ray, Diagnostic Laboratory, and Other Diagnostic Tests

CMS Internet-Only Manual, Pub. 100-03, Medicare National Coverage Determinations Manual, Chapter 1, Part 2, §90.2 Next-Generation Sequencing (NGS) for Patients with Advanced Cancer which describes the criteria under which contractors may cover NGS laboratory tests for patients with cancer

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

Indications and Limitations of Coverage

Nationally Covered Indications

This policy covers testing for the BRCA1 and BRCA2 genes for patients suspected of hereditary breast and/or ovarian cancer syndromes. To be eligible for Medicare coverage, the individual being tested must have signs or symptoms of breast (invasive or ductal carcinoma in situ (DCIS)), ovarian cancer (including fallopian tube and primary peritoneal cancer), pancreatic cancer, or prostate cancer and meet 1 of the criteria below. Genetic testing for a known mutation in a family is a covered service for individuals with signs and/or symptoms of cancer. Testing of an unaffected Medicare eligible individual or family member is not a covered Medicare benefit.

BRCA1 and BRCA2 testing consists of full sequence and duplication/deletion analysis. Genetic testing for a known mutation in a family may be limited to the known familial variant.

The following indications for BRCA1 and BRCA2 testing are covered by Medicare:

Criteria for Testing

- Individual with breast, ovarian[1], pancreatic, or prostate cancer from a family with a known deleterious BRCA1 or BRCA2 gene mutation
- Individual with a personal history of ovarian[1*] cancer
- Individual with a breast cancer diagnosis meeting any of the following criteria:
    - Diagnosed ≤45 y
    - Triple negative breast cancer (estrogen receptor (ER) negative, progesterone receptor (PR) negative, and human epidermal growth factor receptor 2 (HER2) negative) breast cancer diagnosed ≤ 60 y
    - Diagnosed at 46-50 y with:
        - An additional breast cancer primary
        - ≥1 first, second, or third degree relative[5] with breast cancer at any age, or
        - ≥1 first, second, or third degree relative[5] with prostate cancer (Gleason score ≥7), or
        - An unknown or limited family history[3]
    - Breast cancer diagnosed at any age, and
        - ≥1 first, second, or third degree relative[5] with breast cancer ≤50 y, or
        - ≥1 first, second, or third degree relative[5] with ovarian cancer at any age, or
        - ≥1 first, second, or third degree relative[5] with metastatic prostate cancer or pancreatic cancer at any age, or
        - ≥2 additional diagnoses of breast cancer at any age in patient and/or in close blood relative5, or
        - A first, second, or third degree male relative with breast cancer
        - For an individual of ethnicity associated with higher mutation frequency (e.g. Ashkenazi Jewish[4]) no additional family history may be required.
    - Male breast cancer
- Personal history of prostate cancer (Gleason score≥7) at any age with:
    - ≥1 first, second, or third degree relative[5] with ovarian cancer at any age, or
    - ≥1 first, second, or third degree relative[5] with breast cancer ≤50 y, or
    - ≥1 first, second, or third degree relative[5] pancreatic cancer at any age, or
    - ≥1 first, second, or third degree relative[5] with metastatic prostate cancer at any age, or
    - ≥2 first, second, or third degree relatives[5] with breast cancer and/or pancreatic cancer and/or prostate cancer (any grad) at any age, or
    - Ashkenazi Jewish ancestry
- Personal history of pancreatic cancer at any age
- Personal history of metastatic prostate cancer (radiographic evidence of or biopsy-proven disease)
- *BRCA1/2* pathogenic mutation detected by tumor profiling on any tumor type in the absence of germline mutation analysis

[1]Includes fallopian tube and primary peritoneal cancers. BRCA – related ovarian cancers are associated with

epithelial, non-mucinous histology.

[2]Two breast cancer primaries includes bilateral (contralateral) disease or 2 or more clearly separate ipsilateral primary tumors either synchronously or asynchronously.

[3]Medicare will cover BRCA-testing for an adopted individual with breast cancer diagnosed ≤50 y, that is suspicious of being a BRCA-related cancer. Individuals with limited family history/structure, defined as fewer than 2 female first- or second-degree relatives having lived beyond age 45 in either lineage may also be eligible for BRCA gene testing. Similar to all testing, these situations require explanation of medical necessity for BRCA testing in the patient's medical record, and documentation of genetic counseling prior to BRCA testing.

[4]Testing for Ashkenazi Jewish founder-specific mutations should be performed first. Comprehensive BRCA1/2 testing may be considered if ancestry also includes non-Ashkenazi Jewish relatives or if any of the other BRCA-related criteria are met.

[5]National Comprehensive Cancer Network (NCCN) defines blood relative as first- (parents, siblings and children), second- (grandparents, aunts, uncles, nieces and nephews, grandchildren and half-siblings), and third degree-relatives (great-grandparents, great-aunts, great uncles, great grandchildren and first cousins) on same side of family.

Multigene Panels***

The indications and limitations of coverage listed in National Coverage Determination (NCD) §90.2 Next-Generation Sequencing (NGS) apply to genetic testing for susceptibility to breast or ovarian cancer. While the NGS NCD §90.2 B describes specific coverage criteria for nationally covered tests, §90.2 D permits coverage of other NGS as a diagnostic laboratory test for patients with cancer when performed and ordered according to the requirements described by the NCD. According to §90.2 D of the NGS NCD, AB Medicare Administrative Contractors (AB MACs) may cover next generation sequencing tests in patients with cancer. As such, genetic testing for susceptibility to breast or ovarian cancer with multi-gene NGS panels (not otherwise covered under NCD §90.2 B) may be covered by this AB MAC as reasonable and necessary when ALL of the NCD criteria are met in addition to the following:

- Pretest genetic counseling by a cancer genetics professional has been performed and posttest genetic counseling by a cancer genetics professional meeting NCCN accreditation criteria is planned;
- All genes in the panel are relevant to the personal and family history for the individual being tested (panels with genes that are not relevant to the individual’s personal and family history are not reasonable and necessary);
- Criteria listed under "Personal History of Female Breast Cancer" and/or "Personal History of Other Cancer" are met;
- Individual also meets criteria for at least 1 hereditary cancer syndrome for which NCCN guidelines provide clear testing criteria and management recommendations, including but not limited to Hereditary Breast and Ovarian Cancer Syndrome (HBOC), LiFraumeni Syndrome, Cowden Syndrome, or Lynch Syndrome.

*** While not required for payment, NCCN Guidelines recommend referral to a cancer genetics professional with expertise and experience in cancer genetics prior to genetic testing and after genetic testing. Examples of cancer genetics professionals with expertise and experience in cancer genetics include: an American Board of Medical Genetics or American Board of Genetic Counseling certified or board eligible Clinical Geneticist, Medical Geneticist or Genetic Counselor not employed by a commercial genetic testing laboratory (excludes individuals employed by or contracted with a laboratory that is part of an Integrated Health System which routinely delivers health care services beyond just the laboratory test itself as these individuals are also considered independent); medical oncologist,

obstetrician-gynecologist or other physician trained in medical cancer genetics, a genetic nurse credentialed as either a Genetic Clinical Nurse (GCN) or an Advanced Practice Nurse in Genetics (APGN) by either the Genetic Nursing Credentialing Commission (GNCC) or the American Nurses Credentialing Center (ANCC) who is not employed by a commercial genetic testing laboratory (excludes individuals employed by or contracted with a laboratory that is part of an Integrated Health System which routinely delivers health care services beyond just the laboratory test itself as these individuals are also considered independent).

Limitations

BRCA testing is limited to once-in-a-lifetime. If a patient has been previously tested for BRCA1 and BRCA2, repeat testing prior to Lynparza® therapy is not reasonable and necessary and will not be covered by Medicare.

Nationally Non-Covered Indications

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 Advance Beneficiary Notice of Non-coverage (ABN) must be obtained for BRCA1 and BRCA2 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 BRCA1 and BRCA2 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.

Background

General Overview

Cancer is the result of genetic alterations that often result in the deregulation of pathways that are important for various cellular functions including growth, maintenance of DNA integrity, cell cycle progression, and apoptosis (programmed cell death), among others. Among women in the United States, breast cancer is the most common cancer diagnosis, excluding squamous and basal cell skin cancers. Breast cancer is the second leading cause of cancer deaths among women, after lung cancer. [19,27] Epithelial ovarian cancer is the leading cause of death from gynecologic cancer in the United States and the fifth most common cause of cancer mortality in women.[19,27] Epithelial ovarian cancer comprises the majority of malignant ovarian neoplasms.[20]

While most breast cancers are considered sporadic, up to 10% are due to specific mutations in single genes that are passed down in families.[16,24] Similar rates are reported for ovarian cancer. [20] Specific patterns of breast and ovarian cancer are linked to the BRCA1 and BRCA2 genes, which cause hereditary breast and ovarian cancer syndrome HBOC.[7] HBOC is an inherited cancer-susceptibility syndrome characterized by the following: [1,27]

- Multiple HBOC-related cancers within a family (i.e., invasive ductal carcinoma, ductal carcinoma in situ, epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer, prostate cancer with Gleason score

≥7, pancreatic cancer and melanoma);

- Cancers typically occur at an earlier age than in sporadic cases (i.e., cancers not associated with inherited genetic risk);
- Two or more primary cancers in a single individual. This could be multiple primary cancers of the same type (e.g., bilateral breast cancer) or primary cancers of different types related to HBOC (e.g., breast and ovarian);
- Cases of male breast cancer.

In addition, there are some histopathologic features that have been noted to occur more frequently in breast cancers that are associated with BRCA1 or BRCA2 mutations. Multiple studies have demonstrated that BRCA1 breast cancer is more likely to be characterized as ER negative, PR negative, and HER2 negative, also referred to as triple negative breast cancer. [20,33,32] Studies indicate BRCA1 mutations are identified in 9% to 28% of patients with triple negative breast cancer.[20]

Recently, germline genetic testing of BRCA1 and BRCA2 has been shown to be informative for treatment considerations in patients with ovarian cancer.[2] Specifically, Lynparza®, a poly (ADP-ribose) polymerase (PARP) inhibitor has been Food and Drug Administration (FDA) approved for use as monotherapy in patients with ovarian cancer and with deleterious or suspected deleterious germline BRCA1 or BRCA2 mutation, who have been treated with 3 or more prior lines of chemotherapy.

BRCA1 and BRCA2 Testing Overview

Germline genetic testing of BRCA1 and BRCA2 is available to identify individuals at increased risk for breast and ovarian cancers, as individuals with an inherited cancer syndrome may benefit from screening and prevention strategies to reduce their risk.[1,20] The prevalence of BRCA mutations in the population is estimated between 1 in 300 and 1 in 800; however, specific mutations known as "founder mutations" occur more often in populations founded by a small ancestral group, including Ashkenazi (Eastern European) Jews, French Canadians, and Icelanders. The prevalence of BRCA mutations in the Ashkenazi Jewish population is approximately 1 in 40.[12,17,1,20] Three recurrent BRCA1 and BRCA2 mutations have been identified in Ashkenazi Jewish individuals (i.e., a genetically distinct population of Jewish people of eastern and central European ancestry) and make up the vast majority of BRCA mutations that occur in this population.[12,17]

Rearrangements, such as large genomic alterations including translocations, inversions, large deletions and insertions are believed to be responsible for 12% to 18% of BRCA1 inactivating mutations but are less common in BRCA2 and in individuals of Ashkenazi Jewish descent.[23,26,30,21] The NCCN guidelines note that comprehensive genetic testing includes full sequencing of BRCA1/BRCA2 and the detection of large genomic rearrangements. The NCCN recommends that since certain large genomic rearrangements are not detectable by a primary sequencing assay, additional testing may be needed in some cases.[20]

Evidence in the published, peer-reviewed scientific literature indicates that BRCA1 and BRCA2 genetic testing is appropriate for a specific subset of adult individuals who have been identified to be at high risk for hereditary breast and ovarian cancers. [25,8,10,5,15,13,9,6,20] Furthermore, several specialty organizations, including NCCN, American College of Medical Genetics (ACMG), and American Society of Clinical Oncology (ASCO), have issued statements recognizing the role of pre and posttest genetic counseling and BRCA testing in the management of at-risk patients. The U.S. Preventive Services Task Force (USPSTF) has published recommendations regarding genetic risk assessment, genetic counseling and BRCA mutation testing for breast and ovarian cancer susceptibility.[28,29] Based on this USPSTF recommendation, the Patient

Protection and Affordable Care Act requires that private group and individual health plans provide coverage for genetic counseling and, if appropriate, genetic testing for women at risk for HBOC as a preventive service with no out-of-pocket expense.

Lynparza® (olaparib) is a poly (ADP-ribose) polymerase (PARP) inhibitor approved by the FDA as monotherapy in patients with ovarian cancer, with deleterious or suspected deleterious germline BRCA1 or BRCA2 mutation who have been treated with 3 or more prior lines of chemotherapy. Testing of ovarian cancer patients in this clinical scenario is indicated to guide treatment.[2]

Mutations in the BRCA1 and BRCA2 genes are passed down in families through an autosomal dominant inheritance pattern meaning that the associated cancer predisposition can be inherited through either the mother's or father's side of the family and transmitted by a male or female. When a parent carries a BRCA mutation, there is a 50% chance of passing down the gene mutation with every pregnancy. Although the risk of inheriting the predisposition from a parent who carries a mutation is 50%, not everyone with an inherited mutation will develop cancer. The likelihood that a woman with a mutation will develop a related cancer (i.e., penetrance of a BRCA mutation) is estimated between 41% and 90%[20] and is much lower for men. The risk of developing cancer depends on numerous variables, including the penetrance of the specific mutation, the genetic makeup of the individual, environmental risk factors, the gender of the individual and their age.

Several national evidence-based and expert opinion guidelines and accrediting bodies recommend that genetic testing should be undertaken only in conjunction with independent pretest genetic counseling services in order to assist patients in complex clinical decision making. [18,14,20,28,29] Post-genetic testing counseling is also strongly recommended. The NCCN guidelines [2015] state that genetic counseling is a critical component of the cancer risk assessment process. In addition, the guidelines state that pretest counseling should include a discussion of why the test is being offered and how test results may impact medical management, cancer risks associated with the genes being tested, the significance of possible test results for the individual and family, the likelihood of a positive result, technical aspects and accuracy of the test, and economic considerations.[20] Per the guidelines, posttest counseling includes disclosure of results, discussion of the significance of the results for the individual and relevant family members, a discussion of the impact of the results on psychosocial aspects and on the medical management of the individual, and how and where the patient will receive follow-up care and access to additional resources.[20]

Medicare is a defined benefit program and requires that testing is only performed on patients with signs and symptoms of disease. Testing of unaffected individuals or family members is not a covered Medicare services. However, once a mutation is identified in the family, Medicare eligible relatives with signs and symptoms of breast cancer are typically tested for that specific mutation only.[5,9,20,10,13] For patients of Ashkenazi Jewish descent, initial testing is generally done for the 3 specific mutations that account for most hereditary breast and ovarian cancer in that population: 185delAG and 5382insC (also called 5385insC) in the BRCA1 gene and 6174delT in the BRCA2 gene. If the test results are negative, full analysis of the BRCA1 and BRCA2 genes is only considered if testing criteria for non-Jewish individuals are met.[17,20] Nonetheless, Medicare does not cover testing for patients without signs and symptoms of breast or ovarian cancer.

Multigene Panel Testing

Multigene panels for HBOC syndromes are available. In general, these panels test simultaneously for several genes associated with inherited breast and/or ovarian cancer, including but not limited to the BRCA1 and BRCA2 genes. The genes included and the methods used in multigene panels vary by laboratory. Some

cancer susceptibility testing panels include genes that have not been associated with hereditary breast or ovarian cancer and, in some cases, are not clinically actionable. Testing with a targeted panel may be indicated as a cost effective strategy when the individual's symptoms or family history meet testing criteria for more than 1 hereditary cancer syndrome. All genes included in the test should be relevant to the personal and family history for the individual being tested.

Test Results and Management

A positive BRCA test result reveals the presence of a mutation in either the BRCA1 or BRCA2 gene that prevents the translation of the full-sized protein or that is known to interfere with protein function in other ways and is associated with increased cancer risks.

Several strategies have been proposed for achieving the goal of reducing cancer risk for individuals with known BRCA mutations. The NCCN guidelines include detailed strategies and evidence review for at-risk patients.[20] For women these strategies include breast self-exams (BSE), clinical breast exams (CBE), mammograms, breast magnetic resonance imaging (MRI), risk-reducing bilateral salpingooophorectomy, discussion of risk-reducing bilateral mastectomy, and use of trans-vaginal ultrasound and CA125 in women who have not elected risk-reducing ovarian surgery. For men these include BSE and CBE starting at age 35 and consideration of mammography and prostate cancer screening starting at age 40. For both men and women recommendations include education regarding signs and symptoms of cancer(s), especially those associated with BRCA gene mutations, and screening may be individualized based on cancers observed in the family.

In patients with ovarian cancer with deleterious or suspected deleterious germline BRCA1 or BRCA2 mutation who have been treated with 3 or more prior lines of chemotherapy, consideration of treatment with the PARP inhibitor Lynparza® is recommended.[2,11]

A negative BRCA test result is interpreted within the context of a patient's individual and family cancer history, notably regarding whether any family member has previously been identified as carrying a mutation or not. An affected individual who has tested negative for a BRCA mutation may still have an inherited predisposing mutation in 1 of the BRCA genes that was not identified by testing, or a mutation in another gene that predisposes to breast or ovarian cancer. An individual in whom testing reveals they do not carry a BRCA1 or BRCA2 mutation that has been positively identified in another family member is considered to have a true negative result (i.e., they have not inherited the BRCA mutation nor associated increased cancer risks identified in other family members).[20]

A person is considered to have an indeterminate result if that person is not a carrier of a known cancer-predisposing gene mutation and the carrier status of all other biologic family members is either also negative or unknown.[20] Results are considered inconclusive if the individual is a carrier of an alteration that currently has no known clinical significance (variant of uncertain significance).[20]

Summary of Evidence

N/A

Analysis of Evidence (Rationale for Determination)

N/A

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

N/A

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Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
04/29/2021	R8	Under **CMS National Coverage Policy** added regulation CMS Internet-Only Manual, Pub. 100-02, Medicare Benefit Policy Manual, Chapter 15, §80 Requirements for Diagnostic X-Ray, Diagnostic Laboratory, and Other Diagnostic Tests. Under **Bibliography** changes were made to citations to reflect AMA citation guidelines. Formatting, punctuation and	• Provider Education/Guidance

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
		typographical errors were corrected throughout the LCD. Acronyms were defined and inserted where appropriate throughout the LCD. Lynparza® was inserted throughout the LCD where applicable.	
12/04/2019	R7	The LCD is revised to remove CPT/HCPCS codes in the Keyword Section of the LCD. 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.	• Other (The LCD is revised to remove CPT/HCPCS codes in the Keyword Section of the LCD.)
12/04/2019	R6	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. 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: BRCA1 and BRCA2 Genetic Testing A57355 article. Under **Sources of Information** references were moved to the **Bibliography** section. *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.*	• Provider Education/Guidance
11/01/2019	R5	As required by CR 10901, all billing and coding information has been moved to the companion article, this article is linked to the LCD. 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	• Revisions Due To Code Removal

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
		fields included on the LCD are applicable as noted in this policy.	
07/01/2019	R4	Added HCPCS codes 0102U, 0103U, 0104U per the 3rd Quarter CPT/HCPCS Code Update. 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.	• Creation of Uniform LCDs With Other MAC Jurisdiction • Revisions Due To CPT/HCPCS Code Changes
01/01/2019	R3	The following CPT codes are deleted 81211, 81213, 81214 and the following CPT codes are added 81163, 81164, 81165, 81166, 81167 per the 2019 Annual HCPCS Update. Revisions under Indications and Limitations of Coverage to Criteria for Testing for breast and prostate indications. Updated Bibliography #20 to update NCCN reference version to Version 2.2019. Added verbiage under Multigene Panels to align with the National Coverage Determination (NCD90.2): Next Generation Sequencing (NGS), which describes the criteria under which contractors may cover NGS laboratory tests for patients with cancer. 01/01/2019: 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.	• Creation of Uniform LCDs Within a MAC Jurisdiction • Revisions Due To CPT/HCPCS Code Changes
07/12/2018	R2	Substantial changes to Indications and Limitations of Coverage were made to be consistent with updated NCCN guidelines and updated Source of Information #20 to correct NCCN reference to Version 1.2019. Last updated 7/11/18. 07/23/2018: At this time, 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This	• Creation of Uniform LCDs With Other MAC Jurisdiction

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
		revision is not a restriction to the coverage determination; and, therefore not all the fields included in this LCD are applicable as noted in this policy.	
11/02/2017	R1	The policy is revised for the following: 2018 Annual CPT/HCPCS Updates: Description was changed for the following CPT/HCPCS codes, effective 01/01/2018: 81432. Added ICD-10 CM C48.1, effective 11/02/2017 Revisions made in Indications and Limitations and/or Medical Necessity section to be consistent with the MolDX Contractor. 12/21/2017: 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 in this LCD are applicable as noted in this policy.	• Creation of Uniform LCDs With Other MAC Jurisdiction • Revisions Due To ICD-10-CM Code Changes

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Articles

A57355 - Billing and Coding: MolDX: BRCA1 and BRCA2 Genetic Testing

A55295 - Billing and Coding: MolDX: Myriad's BRACAnalysis CDx®

A54898 - Response to Comments: MolDX: BRCA1 and BRCA 2 Genetic Testing

LCDs

DL36163 - (MCD Archive Site)

DL36165 - (MCD Archive Site)

Related National Coverage Documents

NCDs

90.2 - Next Generation Sequencing (NGS)

Public Versions

UPDATED ON	EFFECTIVE DATES	STATUS
01/10/2022	04/29/2021 - N/A	Currently in Effect (This Version)
01/29/2020	12/04/2019 - 04/28/2021	Superseded
12/05/2019	12/04/2019 - N/A	Superseded
Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.		

Keywords

N/A