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Local Coverage Determination (LCD): MolDX: BRCA1 and BRCA2 Genetic Testing (L36082)

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Palmetto GBA (/medicare-coverage-database/staticpages/contractor-details.aspx?ContrId=381&ver=1)	A and B and HHH MAC	11502 - MAC B	J - M	North Carolina

– **LCD Information**

Document Information

LCD ID

L36082

LCD Title

MolDX: BRCA1 and BRCA2 Genetic Testing

Proposed LCD in Comment Period

N/A

Source Proposed LCD**AMA CPT / ADA CDT / AHA NUBC****Copyright Statement**

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file of UB-04 Data Specifications, contact Tim Carlson at (312) 893-6816 or Laryssa Marshall at (312) 893-6814. You may also contact us at ub04@healthforum.com.

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”

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

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

Indications and Limitations of Coverage

Nationally Covered Indications

This policy covers testing for the BRCA 1 and BRCA 2 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 one 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.

BRCA 1 and BRCA 2 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 BRCA 1 and BRCA 2 testing are covered by Medicare:

Criteria for Testing

- Individual with breast, ovarian¹, 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 relatives⁵ with breast cancer at any age, or
 - ≥1 first, second, or third degree relatives⁵ with prostate cancer (Gleason score ≥7), or
 - An unknown or limited family history³
 - Breast cancer diagnosed at any age, and
 - ≥1 first, second, or third degree relatives⁵ with breast cancer ≤50 y, or
 - ≥1 first, second, or third degree relatives⁵ with ovarian cancer at any age, or
 - ≥1 first, second, or third degree relatives⁵ 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 relatives⁵, 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 Jewish⁴) 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 relatives⁵ with ovarian cancer at any age, or
 - ≥1 first, second, or third degree relatives⁵ with breast cancer ≤50 y, or
 - ≥1 first, second, or third degree relatives⁵ pancreatic cancer at any

age, or

- o ≥ 1 first, second, or third degree relatives⁵ with metastatic prostate cancer at any age, or
 - o ≥ 2 first, second, or third degree relatives⁵ with breast cancer and/or pancreatic cancer and/or prostate cancer (any grade) at any age, or
 - o 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

*¹Includes fallopian tube and primary peritoneal cancers. BRCA – related ovarian cancers are associated with epithelial, non-mucinous histology.

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

³Medicare 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.

⁴Testing 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.

⁵NCCN 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 Section 90.2 B describes specific coverage criteria for nationally covered tests, Section 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 Section 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 Section 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 ONE hereditary cancer syndrome for which NCCN guidelines provide clear testing criteria and management recommendations, including but not limited to 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 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.

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 estrogen receptor (ER) negative, progesterone receptor (PR) negative, and human epidermal growth factor receptor 2 (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 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 three 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.

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 three 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 three 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 hereditary ovarian and breast cancer (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 one 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 salpingo-oophorectomy, 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 three 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 one 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

- 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:

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)
81163	BRCA1 (BRCA1, DNA REPAIR ASSOCIATED), BRCA2 (BRCA2, DNA REPAIR ASSOCIATED) (EG, HEREDITARY BREAST AND OVARIAN CANCER) GENE ANALYSIS; FULL SEQUENCE ANALYSIS
81164	BRCA1 (BRCA1, DNA REPAIR ASSOCIATED), BRCA2 (BRCA2, DNA REPAIR ASSOCIATED) (EG, HEREDITARY BREAST AND OVARIAN CANCER) GENE ANALYSIS; FULL DUPLICATION/DELETION ANALYSIS (IE, DETECTION OF LARGE GENE REARRANGEMENTS)
81165	BRCA1 (BRCA1, DNA REPAIR ASSOCIATED) (EG, HEREDITARY BREAST AND OVARIAN CANCER) GENE ANALYSIS; FULL SEQUENCE ANALYSIS
81166	BRCA1 (BRCA1, DNA REPAIR ASSOCIATED) (EG, HEREDITARY BREAST AND OVARIAN CANCER) GENE ANALYSIS; FULL DUPLICATION/DELETION ANALYSIS (IE, DETECTION OF LARGE GENE REARRANGEMENTS)

CODE	DESCRIPTION
81167	BRCA2 (BRCA2, DNA REPAIR ASSOCIATED) (EG, HEREDITARY BREAST AND OVARIAN CANCER) GENE ANALYSIS; FULL DUPLICATION/DELETION ANALYSIS (IE, DETECTION OF LARGE GENE REARRANGEMENTS)
81212	BRCA1 (BRCA1, DNA REPAIR ASSOCIATED), BRCA2 (BRCA2, DNA REPAIR ASSOCIATED) (EG, HEREDITARY BREAST AND OVARIAN CANCER) GENE ANALYSIS; 185DELAG, 5385INSC, 6174DELT VARIANTS
81215	BRCA1 (BRCA1, DNA REPAIR ASSOCIATED) (EG, HEREDITARY BREAST AND OVARIAN CANCER) GENE ANALYSIS; KNOWN FAMILIAL VARIANT
81216	BRCA2 (BRCA2, DNA REPAIR ASSOCIATED) (EG, HEREDITARY BREAST AND OVARIAN CANCER) GENE ANALYSIS; FULL SEQUENCE ANALYSIS
81217	BRCA2 (BRCA2, DNA REPAIR ASSOCIATED) (EG, HEREDITARY BREAST AND OVARIAN CANCER) GENE ANALYSIS; KNOWN FAMILIAL VARIANT
81432	HEREDITARY BREAST CANCER-RELATED DISORDERS (EG, HEREDITARY BREAST CANCER, HEREDITARY OVARIAN CANCER, HEREDITARY ENDOMETRIAL CANCER); GENOMIC SEQUENCE ANALYSIS PANEL, MUST INCLUDE SEQUENCING OF AT LEAST 10 GENES, ALWAYS INCLUDING BRCA1, BRCA2, CDH1, MLH1, MSH2, MSH6, PALB2, PTEN, STK11, AND TP53
81445	TARGETED GENOMIC SEQUENCE ANALYSIS PANEL, SOLID ORGAN NEOPLASM, DNA ANALYSIS, AND RNA ANALYSIS WHEN PERFORMED, 5-50 GENES (EG, ALK, BRAF, CDKN2A, EGFR, ERBB2, KIT, KRAS, NRAS, MET, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), INTERROGATION FOR SEQUENCE VARIANTS AND COPY NUMBER VARIANTS OR REARRANGEMENTS, IF PERFORMED

CODE	DESCRIPTION
81455	TARGETED GENOMIC SEQUENCE ANALYSIS PANEL, SOLID ORGAN OR HEMATOLYMPHOID NEOPLASM, DNA ANALYSIS, AND RNA ANALYSIS WHEN PERFORMED, 51 OR GREATER GENES (EG, ALK, BRAF, CDKN2A, CEBPA, DNMT3A, EGFR, ERBB2, EZH2, FLT3, IDH1, IDH2, JAK2, KIT, KRAS, MLL, NPM1, NRAS, MET, NOTCH1, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), INTERROGATION FOR SEQUENCE VARIANTS AND COPY NUMBER VARIANTS OR REARRANGEMENTS, IF PERFORMED
81479	UNLISTED MOLECULAR PATHOLOGY PROCEDURE

ICD-10 Codes that Support Medical Necessity

Group 1 Paragraph:

N/A

Group 1 Codes:

ICD-10 CODE	DESCRIPTION
C25.0	Malignant neoplasm of head of pancreas
C25.1	Malignant neoplasm of body of pancreas
C25.2	Malignant neoplasm of tail of pancreas
C25.3	Malignant neoplasm of pancreatic duct
C25.4	Malignant neoplasm of endocrine pancreas
C25.7	Malignant neoplasm of other parts of pancreas
C25.8	Malignant neoplasm of overlapping sites of pancreas
C25.9	Malignant neoplasm of pancreas, unspecified

ICD-10 CODE	DESCRIPTION
C48.1	Malignant neoplasm of specified parts of peritoneum
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
C50.021	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
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
C50.121	Malignant neoplasm of central portion of right male breast
C50.122	Malignant neoplasm of central portion of left male breast
C50.129	Malignant neoplasm of central portion of unspecified male breast
C50.211	Malignant neoplasm of upper-inner quadrant of right female breast

ICD-10 CODE	DESCRIPTION
C50.212	Malignant neoplasm of upper-inner quadrant of left female breast
C50.219	Malignant neoplasm of upper-inner quadrant of unspecified female breast
C50.221	Malignant neoplasm of upper-inner quadrant of right male breast
C50.222	Malignant neoplasm of upper-inner quadrant of left male breast
C50.229	Malignant neoplasm of upper-inner quadrant of unspecified male 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
C50.321	Malignant neoplasm of lower-inner quadrant of right male breast
C50.322	Malignant neoplasm of lower-inner quadrant of left male breast
C50.329	Malignant neoplasm of lower-inner quadrant of unspecified 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
C50.419	Malignant neoplasm of upper-outer quadrant of unspecified female breast

ICD-10 CODE	DESCRIPTION
C50.421	Malignant neoplasm of upper-outer quadrant of right male breast
C50.422	Malignant neoplasm of upper-outer quadrant of left male breast
C50.429	Malignant neoplasm of upper-outer quadrant of unspecified 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
C50.519	Malignant neoplasm of lower-outer quadrant of unspecified 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
C50.529	Malignant neoplasm of lower-outer quadrant of unspecified male breast
C50.611	Malignant neoplasm of axillary tail of right female breast
C50.612	Malignant neoplasm of axillary tail of left female breast
C50.619	Malignant neoplasm of axillary tail of unspecified female breast
C50.621	Malignant neoplasm of axillary tail of right male breast
C50.622	Malignant neoplasm of axillary tail of left male breast

ICD-10 CODE	DESCRIPTION
C50.629	Malignant neoplasm of axillary tail of unspecified male breast
C50.811	Malignant neoplasm of overlapping sites of right female breast
C50.812	Malignant neoplasm of overlapping sites of left female breast
C50.819	Malignant neoplasm of overlapping sites of unspecified female breast
C50.821	Malignant neoplasm of overlapping sites of right male breast
C50.822	Malignant neoplasm of overlapping sites of left male breast
C50.829	Malignant neoplasm of overlapping sites of unspecified male breast
C50.911	Malignant neoplasm of unspecified site of right female breast
C50.912	Malignant neoplasm of unspecified site of left female breast
C50.919	Malignant neoplasm of unspecified site of unspecified female breast
C50.921	Malignant neoplasm of unspecified site of right male breast
C50.922	Malignant neoplasm of unspecified site of left male breast
C50.929	Malignant neoplasm of unspecified site of unspecified male breast
C56.1	Malignant neoplasm of right ovary
C56.2	Malignant neoplasm of left ovary

ICD-10 CODE	DESCRIPTION
C56.9	Malignant neoplasm of unspecified ovary
C57.00	Malignant neoplasm of unspecified fallopian tube
C57.01	Malignant neoplasm of right fallopian tube
C57.02	Malignant neoplasm of left fallopian tube
C61	Malignant neoplasm of prostate
D05.11	Intraductal carcinoma in situ of right breast
D05.12	Intraductal carcinoma in situ of left breast
Z85.07	Personal history of malignant neoplasm of pancreas
Z85.3	Personal history of malignant neoplasm of breast
Z85.43	Personal history of malignant neoplasm of ovary
Z85.46	Personal history of malignant neoplasm of prostate

Showing 1 to 76 of 76 entries in Group 1

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ICD-10 Codes that DO NOT Support Medical Necessity

N/A

Additional ICD-10 Information

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.

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N/A

– Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE

01/01/2019	R16	<p>Under CPT/HCPCS Code Group 1, deleted 81211, 81213, 81214 and added 81163, 81164, 81165, 81166, 81167. This revision is due to the 2019 Annual CPT/HCPCS updates and effective 1/1/19.</p> <p>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.</p>	<ul style="list-style-type: none">• Revisions Due To CPT/HCPCS Code Changes
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11/22/2018	R15	<p>Added "1" in two bullet points under "Personal History of prostate cancer (Gleason score \geq7) at any age with:" where it was erroneously omitted:</p> <ul style="list-style-type: none"> • \geq1 first, second, or third degree relative5 pancreatic cancer at any age, or • \geq1 first, second, or third degree relative5 with metastatic prostate cancer at any age, or 	<ul style="list-style-type: none"> • Typographical Error
08/23/2018	R14	<p>Updated "Criteria for Coverage" formatting and content to be consistent with newest version of the updated NCCN. Updated Bibliography #20 with the updated version.</p>	<ul style="list-style-type: none"> • Provider Education/Guidance

08/09/2018	R13	Updated Bibliography #20 to correct NCCN reference version to Version 1.2019. Last updated 7/11/18.	<ul style="list-style-type: none"> • Typographical Error
07/12/2018	R12	Updated "Criteria for Coverage" formatting and content to be consistent with the NCCN.	<ul style="list-style-type: none"> • Provider Education/Guidance
02/26/2018	R11	The Jurisdiction "J" Part B Contracts for Alabama (10112), Georgia (10212) and Tennessee (10312) are now being serviced by Palmetto GBA. The notice period for this LCD begins on 12/14/17 and ends on 02/25/18. Effective 02/26/18, these three contract numbers are being added to this LCD. No coverage, coding or other substantive changes (beyond the addition of the 3 Part B contract numbers) have been completed in this revision.	<ul style="list-style-type: none"> • Change in Affiliated Contract Numbers

01/29/2018	R10	<p>The Jurisdiction "J" Part A Contracts for Alabama (10111), Georgia (10211) and Tennessee (10311) are now being serviced by Palmetto GBA. The notice period for this LCD begins on 12/14/17 and ends on 01/28/18. Effective 01/29/18, these three contract numbers are being added to this LCD. No coverage, coding or other substantive changes (beyond the addition of the 3 Part A contract numbers) have been completed in this revision.</p>	<ul style="list-style-type: none"> • Change in Affiliated Contract Numbers
01/01/2018	R9	<p>2018 Annual CPT/HCPCS Updates: Description was changed for the following CPT/HCPCS codes, effective 1/1/2018: 81432 descriptor was changed in Group 1</p>	<ul style="list-style-type: none"> • Revisions Due To CPT/HCPCS Code Changes

11/30/2017	R8	Removed duplicate mention of "melanoma" in HBOC bulleted list. Corrected bullet formatting.	<ul style="list-style-type: none">• Typographical Error
11/02/2017	R7	Added ICD-10 C48.1 to ICD-10 Codes that Support Medical Necessity: Group 1	<ul style="list-style-type: none">• Provider Education/Guidance
10/26/2017	R6	Added additional bullet to Criteria for Testing section.	<ul style="list-style-type: none">• Provider Education/Guidance

08/31/2017	R5	<p>Clarified the Criteria for Testing to align with the reformatted NCCN Guidelines. Reformatted the References to correct the numbering typographical errors and added the newest NCCN reference.</p> <p><i>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</i></p>	<ul style="list-style-type: none">• Provider Education/Guidance
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		<i>as noted in this policy.</i>	
02/15/2016	R4	Created as a result of DL36082 being released to a Final LCD and 2016 CPT codes added	<ul style="list-style-type: none"> • Reconsideration Request
11/27/2015	R3	added ICD-10 code Z85.3	<ul style="list-style-type: none"> • Revisions Due To ICD-10-CM Code Changes
10/05/2015	R2	Additional ICD-10 codes supporting medical necessity were added to the policy.	<ul style="list-style-type: none"> • Revisions Due To ICD-10-CM Code Changes
10/05/2015	R1	Removed J11 MAC	<ul style="list-style-type: none"> • Change to Lettered Jurisdiction Designation

- **Associated Documents**

Attachments

N/A

Related Local Coverage Documents

Article(s)

A54338 - MolDX: Myriad's BRACAnalysis CDx™ Coding and Billing Guidelines

LCD(s)

DL36082 (http://localcoverage.cms.gov/mcd_archive/m_d.asp?id=36435&ver=7)
 - (MCD Archive Site)

Related National Coverage Documents

N/A

Public Version(s)

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