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

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Website.

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

Back to Top

LCD Information

Document Information

LCD ID
L36082

Original ICD-9 LCD ID
N/A

LCD Title
MolDX: BRCA1 and BRCA2 Genetic Testing

Original Effective Date
For services performed on or after 10/05/2015

Revision Effective Date
For services performed on or after 11/27/2015

Revision Ending Date
02/14/2016

Retirement Date
N/A

Notice Period Start Date
08/20/2015

Notice Period End Date
10/04/2015

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

Indications and Limitations of Coverage

Nationally Covered Indications

This is a limited coverage policy for BRCA 1 and BRCA 2 genetic testing. The covered indications specified in this policy apply only to BRCA testing that has undergone a technical assessment (TA) with MolDX and received a favorable outcome. In cases where the TA requirement has been fulfilled, BRCA 1 and BRCA 2 genetic testing has been found to be reasonable and necessary in the following instances:

1. Personal History of Female Breast Cancer

   BRCA1 and BRCA2 genetic testing for susceptibility to breast or ovarian cancer is covered in adults [by full sequence analysis and duplication/deletion analysis of common variants (CPT codes 81211 and 81213) as medically reasonable and necessary when there is a personal history of breast cancer (invasive breast cancer or ductal carcinoma in situ) and ANY of the following indications:

- Diagnosed at age 45 or younger;
- Diagnosed at age 50 or younger with at least one close blood relative* with breast cancer at any age;
- Diagnosed with two breast primaries (includes bilateral disease or cases where there are two or more clearly separate ipsilateral primary tumors) when the first breast cancer diagnosis occurred prior to age 50;
- Diagnosed at age 60 or younger with a triple negative breast cancer (estrogen receptor (ER) negative, progesterone receptor (PR) negative, and human epidermal growth factor receptor 2 (HER2) negative);
- Diagnosed at age 50 or younger with a limited family history (e.g., fewer than two first- or second degree female relatives or female relatives surviving beyond 45 years in the relevant maternal and/or paternal lineage);
- Diagnosed at any age and there are at least two close blood relatives* with breast cancer at any age;
- Diagnosed at any age with at least one close blood relative* with breast cancer at age 50 or younger;
- Diagnosed at any age and there are at least two close blood relatives* with pancreatic cancer or prostate cancer with Gleason score >7 at any age;
- Diagnosed at any age with at least one close blood relative* with epithelial ovarian cancer, fallopian tube, or primary peritoneal cancer;
- Close male blood relative* with breast cancer;
- Individual of Ashkenazi Jewish descent begin testing with Ashkenazi Jewish founder specific mutations (a gene mutation observed with high frequency in a group that is or was geographically or culturally isolated, in which one or more of the ancestors was a carrier of the mutant gene) (CPT code 81212). If negative, complete analysis (CPT 81211 and 81213). If negative, complete analysis (CPT 81211 and 81213) may be considered if ancestry also includes non-Ashkenazi Jewish relatives or other criteria for BRCA1/BRCA2 genetic testing are met.

*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.

Genetic testing for a known mutation in a family is a covered service for individuals with signs and/or symptoms of breast cancer. Testing of an unaffected Medicare eligible individual or family member is not a covered Medicare service.

2. Personal History of Other Cancer

BRCA1 and BRCA2 genetic testing for susceptibility to breast or ovarian cancer is covered in adults [by full sequence analysis and duplication/deletion analysis of common variants (CPT codes 81211) and uncommon duplication/deletion analysis (CPT 81213)] as medically necessary when there is a personal history of ANY of the following indications:

- Personal history of epithelial ovarian, fallopian tube, or primary peritoneal cancer;
- Personal history of male breast cancer;
- Personal history of pancreatic cancer or prostate cancer with Gleason score =7 at any age, =1 close blood relatives* with breast (=50 y), invasive ovarian, pancreatic cancer, or prostate cancer with Gleason score =7 at any age;
- Personal history of pancreatic cancer at any age with Ashkenazi Jewish ancestry (Begin testing with Ashkenazi Jewish founder specific mutations [CPT code 81212]. If negative, complete analysis (CPT 81211 and 81213) should be performed. Complete analysis (CPT 81211 and 81213) may be considered if ancestry also includes non-Ashkenazi Jewish relatives and other criteria for BRCA1/BRCA2 genetic testing are met.

Genetic testing for a known mutation in a family is a covered service for individuals with signs and/or symptoms of another inheritable cancer. Testing of an unaffected Medicare eligible individual or family member is not a covered Medicare service.

3. Multigene Panels

BRCA1 and BRCA2 genetic testing for susceptibility to breast or ovarian cancer with multi-gene next -generation sequencing (NGS) panels is covered as medically necessary when ALL of the following criteria are met:

- Pre-test genetic counseling by a cancer genetics professional independent of the laboratory has been performed and post-test genetic counseling by a cancer genetics professional independent of the laboratory is planned;
- All genes in the panel are relevant to the personal and family history for the individual being tested (large panels with genes that are not relevant to the individual's personal and family history are not reasonable and necessary);
- Criteria listed under Section 1, Personal History of Female Breast Cancer and/or Section 2 Personal History of Other Cancer are met.
- Individual also meets criteria for at least ONE other hereditary cancer syndrome for which NCCN guidelines provide clear testing criteria and management recommendations, including but not limited to Li-Fraumeni 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.

All tests must have been registered with the MolDX contractor and must have passed a Technical Assessment. Tests currently undergoing a Technical Assessment may be paid until such time as the final results of the TA are available.

Nationally Non-Covered Indications

BRCA1/BRCA2 genetic testing for susceptibility to breast or ovarian cancer is not covered for any other indication including any of the following because it is considered not medically reasonable and necessary for these 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, melanoma, 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 BRCA1or 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 post-test 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 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 pre-test 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 pre-test 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, post-test 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.

Multi-gene Panel Testing

Multi-gene 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 multi-gene 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 CA-125 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]

Back to Top

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:

81211	BRCA1, BRCA2 (BREAST CANCER 1 AND 2) (EG, HEREDITARY BREAST AND OVARIAN CANCER) GENE ANALYSIS; FULL SEQUENCE ANALYSIS AND COMMON DUPLICATION/DELETION VARIANTS IN BRCA1 (IE, EXON 13 DEL 3.835KB, EXON 13 DUP 6KB, EXON 14-20 DEL 26KB, EXON 22 DEL 510BP, EXON 8-9 DEL 7.1KB)
81212	BRCA1, BRCA2 (BREAST CANCER 1 AND 2) (EG, HEREDITARY BREAST AND OVARIAN CANCER) GENE ANALYSIS; 185DELAG, 5385INSC, 6174DELT VARIANTS
81213	BRCA1, BRCA2 (BREAST CANCER 1 AND 2) (EG, HEREDITARY BREAST AND OVARIAN CANCER) GENE ANALYSIS; UNCOMMON DUPLICATION/DELETION VARIANTS
81214	BRCA1 (BREAST CANCER 1) (EG, HEREDITARY BREAST AND OVARIAN CANCER) GENE ANALYSIS; FULL SEQUENCE ANALYSIS AND COMMON DUPLICATION/DELETION VARIANTS (IE, EXON 13 DEL 3.835KB, EXON 13 DUP 6KB, EXON 14-20 DEL 26KB, EXON 22 DEL 510BP, EXON 8-9 DEL 7.1KB)
81215	BRCA1 (BREAST CANCER 1) (EG, HEREDITARY BREAST AND OVARIAN CANCER) GENE ANALYSIS; KNOWN FAMILIAL VARIANT
81216	BRCA2 (BREAST CANCER 2) (EG, HEREDITARY BREAST AND OVARIAN CANCER) GENE ANALYSIS; FULL SEQUENCE ANALYSIS
81217	BRCA2 (BREAST CANCER 2) (EG, HEREDITARY BREAST AND OVARIAN CANCER) GENE ANALYSIS; KNOWN FAMILIAL VARIANT
81445	TARGETED GENOMIC SEQUENCE ANALYSIS PANEL, SOLID ORGAN NEOPLASM, DNA ANALYSIS, 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
81455	TARGETED GENOMIC SEQUENCE ANALYSIS PANEL, SOLID ORGAN OR HEMATOLYMPHOID NEOPLASM, DNA 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 Codes	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 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
C50.021	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
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
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
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
C56.9	Malignant neoplasm of unspecified ovary
C57.00	Malignant neoplasm of unspecified fallopian tube

ICD-10 Codes	Description
C57.01	Malignant neoplasm of right fallopian tube
C57.02	Malignant neoplasm of left fallopian tube
C61	Malignant neoplasm of prostate
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
D05.12	Intraductal carcinoma in situ of left breast
D05.80	Other specified type of carcinoma in situ of unspecified breast
D05.81	Other specified type of carcinoma in situ of right breast
D05.82	Other specified type of carcinoma in situ of left breast
D05.90	Unspecified type of carcinoma in situ of unspecified breast
D05.91	Unspecified type of carcinoma in situ of right breast
D05.92	Unspecified type of 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

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

Back to Top

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
References

1. ACOG Practice Bulletin No. 103: Hereditary breast and ovarian cancer syndrome. Obstet Gynecol. 2009 Apr;113(4):957--66. doi: 10.1097/AOG.0b013e3181a106d4. ACOG Guidelines for Managing Hereditary Breast and Ovarian Cancer Syndrome.

2. Alosp K, Fereday S, Meldrum C, et al. BRCA Mutation Frequency and Patterns of Treatment Response in BRCA Mutation–Positive Women With Ovarian Cancer: A Report From the Australian Ovarian Cancer Study Group. JCO 2012; 30:2654--63.

3. American College of Obstetricians and Gynecologists (ACOG). Breast--ovarian cancer screening. ACOG Committee Opinion Number 176. Washington, DC: ACOG; October 1996.

4. American College of Surgeons Commission on Cancer. Cancer Program Standards 2012, Version 1.2.1: Ensuring Patient--Centered Care.

5. Berchuck A, Cirisano F, Lancaster JM. Role of BRCA1 mutation screening in the management of familial ovarian cancer. Am J Obstet Gynceol. 1996;175:738-7-46.

6. Biesecker BB, Boehnke M, Calzone K, et al. Genetic counseling for families with inherited susceptibility to breast and ovarian cancer. JAMA. 1993;269:170--4.

7. Blackwood MA, Weber BL. BRCA1 and BRCA2: from molecular genetics to clinical medicine. J Clin Oncol. 1998 May;16(5):1969--77.

8. Castilla LH, Couch FJ, Erdos MR, et al. Mutations in the BRCA1 gene in families with early-onset breast and ovarian cancer. Nature Genetics. 1994;8:387--91.

9. Couch FJ, DeShano ML, Blackwood MA, et al. BRCA1 mutations in women attending clinics that evaluate the risk of breast cancer. N Engl J Med. 1997;336(20):1409--15.

10. FDA Prescribing information: LYNPARZA™ (olaparib). Downloaded February 26, 2015. http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/206162lbl.pdf

11. Fitzgerald MG, MacDonald DJ, Krainer M, et al. Germ-line BRCA1 mutations in Jewish and non-Jewish women with early onset breast cancer. N Engl J Med. 1996;334:143--9.

12. Foulkes WD. Inherited susceptibility to common cancers. N Engl J Med. 2008;359(20):2143--53.

13. Healy B. BRCA genes: Bookmarking, fortune telling, and medical care. NEJM. 1997;336:1448--9.

14. Lambert, M. Am Fam Physician. A COG Guidelines for Managing Hereditary Breast and Ovarian Cancer Syndrome. 2009;80(12):1505-7.

15. Langston AA, Malone KE, Thompson JD, et al. BRCA-1 mutations in a population-based sample of young women with breast cancer. N Engl J Med. 1996;334:137--42.

16. Lynch HT1, Watson P, Conway TA, Lynch JF. Clinical/genetic features in hereditary breast cancer. Breast Cancer Res Treat. 1990;15(2):63--71.

17. Metcalfe KA, Poll A, Royer R, et al. Screening for founder mutations in BRCA1 and BRCA2 in unselected Jewish women. J Clin Oncol. 2010;28(3):387--91

18. National Accreditation Program for Breast Centers. NAPBC Standards Manual: 2014 Edition.

19. National Cancer Institute (NCI) Genetics of Breast and Gynecologic Cancers (PDQ®): High-Penetrance Breast and/or Gynecologic Cancer Susceptibility Genes. Last updated February 2015.

20. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology: Genetics/Familial High-Risk Assessment: Breast and Ovarian. Version 1.2015. Last updated 3/30/2015.

21. Palma MD, Domchek SM, Stopfer J, Erlichman J, Siegfried JD, Tigges--Cardwell J, et al. The relative contribution of point mutations and genomic rearrangements in BRCA1 and BRCA2 in high--risk breast cancer families. Cancer Res. 2008;68(17):7006--14.

22. Pharoah PD, Day NE, Duffy S, Easton DF, Ponder BA. Family history and the risk of breast cancer: a systematic review and meta-analysis. Int J Cancer. 1997;71(5):800--9.

23. Pilarski R, Burt R, Kohlman W, Pho L, Shannon KM, Swisher E. Cowden syndrome and the PTEN hamartoma tumor syndrome: systematic review and revised diagnostic criteria. J Natl Cancer Inst. 2013 Nov 6;105(21):1607--16. doi: 10.1093/jnci/djt277. Epub 2013 Oct 17.

24. Szabo CI, King MC. Inherited breast and ovarian cancer. Hum Mol Genet. 1995;4 Spec No:1811--17.

25. U.S. Cancer Statistics Working Group. United States Cancer Statistics: 1999–2011 Incidence and Mortality Web--based Report. Atlanta: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Cancer Institute; 2014. Available at: www.cdc.gov/uscs.

26. U.S. Preventive Services Task Force. Screening for breast cancer: U.S. Preventive Services Task Force Recommendation Statement. Ann Intern Med 2009;151:716--26.

27. Unger MA, Nathanson KL, Calzone K, et al. Screening for Genomic Rearrangements in Families with Breast and Ovarian Cancer Identifies BRCA1 Mutations Previously Missed by Conformation- Sensitive Gel Electrophoresis or Sequencing. Am J Hum Genet. 2000 Oct; 67(4): 841–50. Published online 2000 Sep 7.

28. USPSTF Final Recommendation Statement: BRCA-Related Cancer: Risk Assessment, Genetic Counseling, and Genetic Testing. U.S. Preventive Services Task Force. December 2013.

29. Walsh T, Casadei S, Coats KH, Swisher E, Stray SM, Higgins J, et al. Spectrum of mutations in BRCA1, BRCA2, CHEK2, and TP53 in families at high risk of breast cancer. JAMA. 2006;295(12):1379--88.

30. Whittemore AS. Risk of breast cancer in carriers of BRCA gene mutations. N Engl J Med. 1997;337(11):78-8-9.

31. Wong-Brown MW1, Meldrum CJ, Carpenter JE, et. al. Prevalence of BRCA1 and BRCA2 germline mutations in patients with triple-negative breast cancer. Breast Cancer Res Treat. 2015 Feb 15.

32. Zugazagoitia J, Pérez-Segura P, Manzano A, et. al. Limited family structure and triple-negative breast cancer (TNBC) subtype as predictors of BRCA mutations in a genetic counseling cohort of early-onset sporadic breast cancers. Breast Cancer Res Treat. 2014;148(2):415--21.

Back to Top

Revision History Information

Please note: Most Revision History entries effective on or before 01/24/2013 display with a Revision History Number of "R1" at the bottom of this table. However, there may be LCDs where these entries will display as a separate and distinct row.

Revision History Date	Revision History Number	Revision History Explanation	Reason(s) for Change
11/27/2015	R3	added ICD-10 code Z85.3	• Revisions Due To ICD-10-CM Code Changes
10/05/2015	R2	Additional ICD-10 codes supporting medical necessity were added to the policy.	• Revisions Due To ICD-10-CM Code Changes
10/05/2015	R1	Removed J11 MAC	• Change to Lettered Jurisdiction Designation

Back to Top

Associated Documents

Attachments N/A

Related Local Coverage Documents Article(s) A54338 - MolDX: Myriad's BRACAnalysis CDx™ Coding and Billing Guidelines A54567 - Response to Comments for MolDX: BRCA1 and BRCA2 Genetic Testing

Related National Coverage Documents N/A

Public Version(s) Updated on 12/23/2015 with effective dates 02/15/2016 - N/A Updated on 11/17/2015 with effective dates 11/27/2015 - 02/14/2016
Updated on 09/03/2015 with effective dates 10/05/2015 - 11/26/2015 Updated on 08/13/2015 with effective dates 10/05/2015 - N/A Updated on 08/13/2015 with effective dates 10/05/2015 - N/A Back to Top

Keywords

N/A Read the **LCD Disclaimer** Back to Top