Local Coverage Determination (LCD): Pathology and Laboratory: BRCA1 and BRCA2 Genetic Testing (L36741)

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Contractor Information

Contractor Name	Contract Type	Contract Number	Jurisdiction	State(s)
Cahaba Government Benefit Administrators®, LLC	A and B MAC	10101 - MAC A	J - J	Alabama
Cahaba Government Benefit Administrators®, LLC	A and B MAC	10102 - MAC B	J - J	Alabama
Cahaba Government Benefit Administrators®, LLC	A and B MAC	10201 - MAC A	J - J	Georgia
Cahaba Government Benefit Administrators®, LLC	A and B MAC	10202 - MAC B	J - J	Georgia
Cahaba Government Benefit Administrators®, LLC	A and B MAC	10301 - MAC A	J - J	Tennessee
Cahaba Government Benefit Administrators®, LLC	A and B MAC	10302 - MAC B	J - J	Tennessee

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LCD Information

Document Information

LCD ID
L36741

Previous Proposed LCD
DL36741

LCD Title
Pathology and Laboratory: BRCA1 and BRCA2 Genetic Testing

Original Effective Date
For services performed on or after 10/01/2016

Revision Effective Date
N/A

Revision Ending Date
N/A

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N/A

Notice Period Start Date
08/07/2016

Notice Period End Date
09/21/2016

CMS National Coverage Policy

- CMS Internet-Only Manual, Publication 100-02, Medicare Benefit Policy Manual, Chapter 15, §§80.0, 80.1.1, 80.2. Clinical Laboratory services.
- CMS Internet-Only Manuals, Publication 100-02, Medicare Benefit Policy Manual, Chapter 15, §80.6, Requirements for Ordering and Following Orders for 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 ICD -9-CM Coding for Diagnostic Tests
- CMS Internet-Only Manuals, Publication 100-08, Medicare Program Integrity Manual, Chapter 3, §3.4.1.3, Diagnosis code requirements.
- 42 CFR 410.32(a). Order diagnostic tests.
- 42 CFR 411.15(k)(1). Particular Services excluded from coverage
- NCDs and coverage provisions in interpretive manuals are not subject to the LCD Review Process (42 CFR 405.860[b] and 42 CFR 426 [Subpart D]). In addition, an administrative law judge may not review an NCD. See §1869(f)(1)(A)(i) of the Social Security Act.
- Title XVIII of the Social Security Act, Section 1833(e) prohibits Medicare payment for any claim which lacks the necessary information to process the claim.
- Title XVIII of the Social Security Act, Section 1862(a)(1)(A) allows coverage and payment for services considered medically reasonable and necessary.

Coverage Guidance
Coverage Indications, Limitations, and/or Medical Necessity

Background

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. 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. 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. 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. 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.

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. 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. Based on this USPSTF recommendation, the Patient Protection and Affordable Care Act (ACA) requires that private group and individual health plans provide coverage for genetic counseling and, if appropriate, genetic testing for women

at risk for hereditary breast ovarian cancer syndrome (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.

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% 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. 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. 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 followup care and access to additional resources.

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. 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. Nonetheless, Medicare does not cover testing for patients without signs and symptoms of breast or ovarian cancer.

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 inter dependent); 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 inter dependent).

Indications

This is a limited coverage policy for BRCA 1 and BRCA 2 genetic testing. 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 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) 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.

Limitations

Any test must also meet:

- Availability of a clinically valid test, based on published peer reviewed medical literature; AND
- Testing assay(s) are Food and Drug Administration (FDA) approved/cleared or if LDT (lab developed test) or LDT protocol or FDA modified test(s) the laboratory documentation should support assay(s) analytical validity and clinical utility.

  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.
- Generic (not disease specific) genomic sequence panels (NGS comprehensive definitive cancer testing panel/s) of 51 or greater genes are non-covered at this time (specific testing of 51 or greater genes as expressed by disease specific coding, e.g. Prosigna breast cancer assay, can be medically necessary).

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Coding Information

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

014x Hospital - Laboratory Services Provided to Non-patients

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, 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
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: ICD-10 codes must be coded to the highest level of specificity. Consult the 'Official ICD-10-CM Guidelines for Coding and Reporting' in the current ICD-9-CM book for correct coding guidelines. This LCD does not take precedence over the Correct Coding Initiative (CCI).

Group 1 Codes:

ICD-10 Codes	Description
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
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

ICD-10 Codes	Description
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
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 - D05.82	Other specified type of carcinoma in situ of unspecified breast - Other specified type of carcinoma in situ of left breast
D05.90 - D05.92	Unspecified type of carcinoma in situ of unspecified breast - Unspecified type of carcinoma in situ of left breast
Z85.07	Personal history of malignant neoplasm of pancreas
Z85.43	Personal history of malignant neoplasm of ovary

ICD-10 Codes	Description
Z85.46	Personal history of malignant neoplasm of prostate

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

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General Information

Associated Information
Documentation Requirements

Documentation must support CMS 'signature guidelines, as described in the Medicare Program Integrity Manual (Pub. 100-08), Chapter 3.

The patient's medical record must contain documentation that fully supports the medical necessity for services included within this LCD. This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures.

Utilization Guidelines

BRCA testing is limited to once-in-a-lifetime.

Sources of Information and Basis for Decision

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- National Accreditation Program for Breast Centers. NAPBC Standards Manual: 2014 Edition.
- National Cancer Institute (NCI) Genetics of Breast and Gynecologic Cancers (PDQ®): High-Penetrance Breast and/or Gynecologic Cancer Susceptibility Genes. Last updated February 2015.
- 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.
- 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.
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- Other Contractor's Policies
  - FCSO DL36499, BRCA1 and BRCA2 Genetic Testing
  - Noridian DL36161, BRCA1 and BRCA2 Genetic Testing
  - Novitas DL36715, BRCA1 and BRCA2 Genetic Testing

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Revision History Information

N/A Back to Top

Associated Documents

Attachments N/A

Related Local Coverage Documents Article(s) A55303 - LCD - Comment/Response - Pathology and Laboratory: BRCA1 and BRCA2 Genetic Testing (L36741) LCD(s) DL36741 - Pathology and Laboratory: BRCA1 and BRCA2 Genetic Testing

Related National Coverage Documents N/A

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Keywords

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