LCD Database ID Number

L36499

Contractor Name

First Coast Service Options, Inc.

Contractor Number

09101 - Florida
09201 – PR/USVI
09102 – Florida
09202 – Puerto Rico
09302 – Virgin Islands

Contractor Type

MAC – Part A/B

LCD Title

BRCA1 and BRCA2 Genetic Testing

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CMS National Coverage Policy

Language quoted from CMS National Coverage Determination (NCDs) and coverage provisions in interpretive manuals are italicized throughout the Local Coverage Determination (LCD). 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.

Unless otherwise specified, italicized text represents quotation from one or more of the following CMS sources:

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.
BRCA1 and BRCA2 Genetic Testing A/B

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”

Primary Geographic Jurisdiction

Florida
Puerto Rico/Virgin Islands

Oversight Region

Region IV

Original Determination Effective Date

04/11/2016

Original Determination Ending Date

N/A

Revision Effective Date

N/A

Revision Ending Date

N/A

Indications and Limitations of Coverage and/or Medical Necessity

Covered 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 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;
BRCA1 and BRCA2 Genetic Testing A/B

- 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.

Medicare will cover BRCA-testing for an adopted individual with breast or ovarian cancer diagnosed ≤45 y or ≤60 y with triple negative breast cancer, or has a personal history of an "other" cancer (see above) that is suspicious of being a BRCA-related cancer. Individuals with little known family health history, come from small families, and in the case of sex-specific conditions, have few female/male relatives at risk of developing a particular condition, 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.
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 olaparib therapy is not reasonable and necessary and will not be covered by Medicare.

Any test must also meet the indication and limitations of coverage in Molecular Pathology Procedures LCD (L34519) including the following criteria.

- 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.

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.
BRCA1 and BRCA2 Genetic Testing A/B

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, olaparib, 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 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
BRCA1 and BRCA2 Genetic Testing A/B

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.\textsuperscript{18,20} 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.\textsuperscript{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%,\textsuperscript{18} 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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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 service. 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.\textsuperscript{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.\textsuperscript{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. 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 Olaparib is recommended.

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).

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. Results are considered inconclusive if the individual is a carrier of an alteration that currently has no known clinical significance (variant of uncertain significance).

**Type of Bill Code**

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:**
BRCA1 and BRCA2 Genetic Testing A/B

81162  
BRCA1, BRCA2 (breast cancer 1 and 2) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis and full duplication/deletion analysis

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

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 14 genes, including ATM, BRCA1, BRCA2, BRIP1, CDH1, MLH1, MSH2, MSH6, NBN, PALB2, PTEN, RAD51C, 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

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:

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
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 unspecified 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
BRCA1 and BRCA2 Genetic Testing A/B

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 right male 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 unspecified 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   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
Z85.43   Personal history of malignant neoplasm of ovary
Z85.46   Personal history of malignant neoplasm of prostate
BRCA1 and BRCA2 Genetic Testing A/B

Diagnoses that Support Medical Necessity

N/A

ICD-10 Codes that DO NOT Support Medical Necessity

N/A

Diagnoses that DO NOT Support Medical Necessity

N/A

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


Start Date of Comment Period
10/08/2015

End Date of Comment Period
11/22/2015

Start Date of Notice Period
02/25/2016

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LCR A/B2016-043

Related Documents
N/A

LCD Attachments
N/A

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