

# BRCA1/BRCA2 GENETIC TESTING: MEDICARE GUIDELINES

Genetic testing of *BRCA1/BRCA2* is effective in identifying individuals at increased risk for breast, ovarian, and other cancers. Individuals with a hereditary predisposition to cancer may benefit from screening and prevention strategies to reduce their risk. Guidelines aid in the identification of patients at risk for a hereditary cancer predisposition syndrome. The following is a summary of published CMS coverage indications for germline *BRCA1/BRCA2* testing in those with a personal history of breast, ovarian, pancreatic and prostate cancer.

## Indications for *BRCA1/BRCA2* Testing

1. Personal history of ovarian, fallopian tube, or primary peritoneal cancers
2. Personal history of male breast cancer
3. Individual with a history of breast, ovarian, pancreatic, or prostate cancer from a family with a known *BRCA1/BRCA2* pathogenic or likely pathogenic variant
4. Personal history of breast cancer and one or more of the following indications:
  - Diagnosed at age 45 or under
  - Diagnosed at age 50 or under with any of the following:
    - An additional breast cancer primary
    - At least one close blood relative\* with breast cancer at any age
    - Unknown or limited family history
  - Diagnosed at age 60 or under with a:
    - Triple negative breast cancer [estrogen receptor (ER) negative, progesterone receptor (PR) negative, and human epidermal growth factor receptor 2 (HER2) negative]
  - Individual of ethnicity associated with higher mutation frequency (e.g. Ashkenazi Jewish)\*\*
  - Diagnosed at any age with any of the following:
    - At least one close blood relative\* with breast cancer diagnosed at age 50 or under
    - At least two additional diagnoses of breast cancer in the patient and/or close blood relative(s)\* at any age
    - At least one close blood relative\* with ovarian, fallopian tube, or primary peritoneal cancers
    - At least one close blood relative\* with pancreatic cancer
    - At least one close blood relative\* with prostate cancer (Gleason score  $\geq 7$  or metastatic)
    - At least one close blood relative\* with male breast cancer
5. Personal history of pancreatic cancer
6. Personal history of prostate cancer (Gleason score  $\geq 7$ ) at any age with any of the following:
  - At least 1 close blood relative\* with ovarian/fallopian tube/primary peritoneal cancer, pancreatic cancer, or metastatic prostate cancer
  - At least 1 close blood relative\* with breast cancer at age 50 or under
  - At least 2 close blood relatives\* with breast cancer or prostate cancer (any grade)
  - Ashkenazi Jewish ancestry\*\*
7. Personal history of metastatic prostate cancer
8. Individual with a history of breast, ovarian, pancreatic, or prostate cancer and a *BRCA1/BRCA2* pathogenic variant detected by tumor profiling on any tumor type in the absence of germline variant analysis
9. Personal history of breast, ovarian, pancreatic, or prostate cancer with either of the following:
  - First- or second-degree blood relative meeting any of the above criteria
  - Third-degree blood relative who has breast cancer or ovarian/fallopian tube/primary peritoneal cancer and who has at least two close blood relatives\* with breast cancer (at least one who was diagnosed at age 50 or under) or ovarian/fallopian tube/primary peritoneal cancer

\* Close blood relative are defined 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 the same side (either maternal or paternal) of the family.

\*\* For individuals of Ashkenazi Jewish ancestry who only meet ancestry-related criteria, Medicare will only cover the *BRCA1/BRCA2* Ashkenazi Jewish Founder Panel (test code B361). For these individuals, testing beyond this test code may not be covered and requires a signed ABN.

**It is important to note that Medicare DOES NOT cover *BRCA1/BRCA2* testing without a personal diagnosis of cancer. Please visit the CMS website at [www.cms.gov](http://www.cms.gov) for the most up-to-date information and to view the complete coverage determination for *BRCA1/BRCA2* testing (LCD L36715).**

**It is important to provide accurate and specific ICD-10 diagnosis codes to the highest level of specificity when ordering genetic testing. Please refer to the reverse side for a guide to best coding practices when ordering tests that include the *BRCA1/BRCA2* genes.**

| BREAST        |  |         |   |         |  |
|---------------|--|---------|---|---------|--|
| Female Breast |  |         | Male Breast   |         |  |
| Left          |  |         | Right   |         |  |
| C50.012       | Malignant neoplasm of nipple and areola, left female breast      | C50.011 | Malignant neoplasm of nipple and areola, right female breast      | C50.022 | Malignant neoplasm of nipple and areola, left male breast      |
| C50.112       | Malignant neoplasm of central portion of left female breast      | C50.111 | Malignant neoplasm of central portion of right female breast      | C50.122 | Malignant neoplasm of central portion of left male breast      |
| C50.212       | Malignant neoplasm of upper-inner quadrant of left female breast | C50.211 | Malignant neoplasm of upper-inner quadrant of right female breast | C50.222 | Malignant neoplasm of upper-inner quadrant of left male breast |
| C50.312       | Malignant neoplasm of lower-inner quadrant of left female breast | C50.311 | Malignant neoplasm of lower-inner quadrant of right female breast | C50.322 | Malignant neoplasm of lower-inner quadrant of left male breast |
| C50.412       | Malignant neoplasm of upper-outer quadrant of left female breast | C50.411 | Malignant neoplasm of upper-outer quadrant of right female breast | C50.422 | Malignant neoplasm of upper-outer quadrant of left male breast |
| C50.512       | Malignant neoplasm of lower-outer quadrant of left female breast | C50.511 | Malignant neoplasm of lower-outer quadrant of right female breast | C50.522 | Malignant neoplasm of lower-outer quadrant of left male breast |
| C50.612       | Malignant neoplasm of axillary tail of left female breast        | C50.611 | Malignant neoplasm of axillary tail of right female breast        | C50.622 | Malignant neoplasm of axillary tail of left male breast        |
| C50.812       | Malignant neoplasm of overlapping sites of left female breast    | C50.811 | Malignant neoplasm of overlapping sites of right female breast    | C50.822 | Malignant neoplasm of overlapping sites of left male breast    |
| C50.912       | Malignant neoplasm of unspecified site of left female breast     | C50.911 | Malignant neoplasm of unspecified site of right female breast     | C50.922 | Malignant neoplasm of unspecified site of left male breast     |
| D05.02        | Lobular carcinoma in situ of left breast                         | D05.01  | Lobular carcinoma in situ of right breast                         | D05.02  | Lobular carcinoma in situ of left breast                       |
| D05.12        | Intraductal carcinoma in situ of left breast                     | D05.11  | Intraductal carcinoma in situ of right breast                     | D05.12  | Intraductal carcinoma in situ of left breast                   |
| D05.82        | Other specified type of carcinoma in situ of left 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       |
| D05.92        | Unspecified type of carcinoma in situ of left breast             | D05.91  | Unspecified type of carcinoma in situ of right breast             | D05.92  | Unspecified type of carcinoma in situ of left breast           |
| Z17.0**       | Estrogen receptor positive status [ER+]                          |         |   | Z17.0** | Estrogen receptor positive status [ER+]                        |
| Z17.1**       | Estrogen receptor negative status [ER-]                          |         |   | Z17.1** | Estrogen receptor negative status [ER-]                        |
| Z85.3*        | Personal history of malignant neoplasm of breast                 |         |   | Z85.3*  | Personal history of malignant neoplasm of breast               |

| GYNECOLOGIC |   |        |  |  |  |
|-------------|---|--------|--|--|--|
| Ovarian     |   |        | Uterine                                    |  |  |
| Left        |   |        | Right                                      |  |  |
| C56.2       | Malignant neoplasm of left ovary                | C56.1  | Malignant neoplasm of right ovary          |  |  |
| C57.02      | Malignant neoplasm of left fallopian tube       | C57.01 | Malignant neoplasm of right fallopian tube |  |  |
| Z85.43*     | Personal history of malignant neoplasm of ovary |        |  |  |  |

| GENITOURINARY |                                |         |  |  |  |
|---------------|--------------------------------|---------|--|--|--|
| C61           | Malignant neoplasm of prostate | Z85.46* | Personal history of malignant neoplasm of prostate |  |  |

| PANCREATIC |  |       |   |  |  |
|------------|--|-------|---|--|--|
| 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               |  |  |
| C25.7      | Malignant neoplasm of other parts of pancreas      | C25.8 | Malignant neoplasm of overlapping sites of pancreas |  |  |
| C25.9      | Malignant neoplasm of pancreas, unspecified        | C25.4 | Malignant neoplasm of endocrine pancreas            |  |  |
| Z85.07*    | Personal history of malignant neoplasm of pancreas |       |   |  |  |

\* Note that "Z" codes should be used only for a past history of a condition.  
 This is not a comprehensive list of ICD-10 codes. There are more codes available. Please visit [www.icd10data.com](http://www.icd10data.com) for a complete list of codes.

\*\* When using ICD-10-CM C50 codes, report applicable Z17 code for patients less than or equal to 60 years of age to identify estrogen-receptor status.

This list is intended to assist ordering healthcare providers in providing ICD-10 Diagnosis Codes as required by Medicare and other Insurers. It includes the most commonly found out-patient diagnoses (generally without complications), but is not complete.

This list was compiled from the 2019 ICD-10-CM [effective 10/1/18], as well as the Medicare Regulations and Manuals issued or authorized by the Centers for Medicaid and Medicare Services. An ICD-10-CM book should be used as a complete reference. The ultimate responsibility for correct coding belongs to the ordering healthcare provider.