



**Subject:** BRCA Testing\*

**Effective Date:** May 28, 2002

**Department(s):** Utilization Management

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**Policy:** Genetic screening for mutations related to breast cancer (BRCA-1 and BRCA-2) in high-risk patients is reimbursable under QualCare, Inc. provided that conditions in the Procedure below are met.

**Objective:** To ensure proper & consistent reimbursement and to allow members who need to make decisions, which may be impacted by knowledge of genetic susceptibility to breast and ovarian cancer, to do so in the most informed manner possible.

**Procedure:** Implicit in this policy is that BRCA-1 and BRCA-2 testing will be covered only when the information will be used to manage the medical care of the QualCare member (*e.g.*, to aid in deciding on prophylactic mastectomy and/or prophylactic oophorectomy and/or prophylactic chemotherapy). Unless otherwise stated, when criteria for testing are met the covered CPT codes are 81211, 81214, 81216- comprehensive BRCA1/2 analysis and BRCA large gene rearrangement (duplication/deletion) analysis for common variants. Patients whose BRCA-1 and BRCA-2 tests will be covered must have pre-test genetic counseling recommending the testing by one of the following: a medical geneticist,, a certified genetic counselor who is not employed by a commercial genetic testing laboratory, a genetic clinical nurse or advanced nurse practitioner who is not employed by a commercial genetic testing laboratory, with intent for post-test follow-up counseling. In addition at least one of the criteria in sections 1, 2 or 3 below must be met:

**1. Personal history alone:**

- a. Breast cancer diagnosed  $\leq$  45 yrs of age
- b. Multiple primary or bilateral breast cancers diagnosed  $\leq$  50 yrs of age.

- c. Ovarian, fallopian tube or primary peritoneal cancer at any age.
- d. Male breast cancer.
- e. Ashkenazi Jewish descent- CPT code 81812 only for founder mutations.
- f. Breast cancer diagnosed  $\leq 50$  yrs of age and either a limited family history ( $< 2$  first degree female relatives) or unavailable family history due to adoption.
- g. Triple negative (estrogen, progesterone and Her2Neu receptor negative) breast cancer diagnosed  $\leq 60$  yrs of age.
- h. BRCA 1/2 mutation detected by tumor profiling in the absence of germline mutation analysis.

**2. Personal and family history:**

- a. Prostate cancer (Gleason score  $\geq 7$ ) at any age with one or more close blood relatives\* with breast, ovarian, fallopian tube, primary peritoneal, pancreatic or prostate cancer ( Gleason score  $\geq 7$ ) at any age.
- b. Pancreatic cancer at any age with one or more close blood relatives with breast ( $\leq 50$  yrs), ovarian, fallopian tube, primary peritoneal or pancreatic cancer at any age.
- c. pancreatic cancer at any age with Ashkenazi Jewish ancestry -CPT 81212 only for founder mutations.
- d. Breast cancer diagnosed at any age at least one close blood relative\* with breast cancer diagnosed  $\leq 50$  yrs of age.
- e. Breast cancer diagnosed at any age and there are at least two close blood relatives\* with breast cancer, pancreatic cancer or prostate cancer (Gleason score  $\geq 7$ ) at any age.
- f. Breast cancer diagnosed at any age with at least one close blood relative\* with epithelial ovarian cancer, fallopian tube, or primary peritoneal cancer.
- g. Breast cancer at any age and a close male blood relative\* with breast cancer.

**3. Family history alone- applies to first or second degree blood relatives\*\* only:**

- a. Breast cancer in at least one individual diagnosed  $\leq 50$  yrs of age with at least one additional close blood relative\* with breast cancer at any age.
- b. Multiple primary or bilateral breast cancers with first diagnosis  $\leq 50$  yrs of age.

- c. Breast cancer diagnosed  $\leq 45$  yrs of age.
- d. Triple negative (estrogen, progesterone, Her2Neu receptor negative) breast cancer diagnosed  $\leq 60$  yrs of age.
- e. Breast cancer diagnosed  $\leq 50$  yrs of age with a limited family history ( $< 2$  first degree female relatives)
- f. Breast cancer in an individual diagnosed at any age with at least two close blood relatives\* with breast cancer diagnosed at any age.
- g. Breast cancer in an individual diagnosed at any age with at least one close blood relative\* diagnosed  $\leq 50$  yrs of age
- h. Breast cancer in an individual diagnosed at any age with at least two close blood relatives\* with pancreatic or prostate cancer (Gleason score  $\geq 7$ ) diagnosed at any age.
- i. Breast cancer in an individual diagnosed at any age with at least one close blood relative\* with epithelial ovarian cancer, fallopian tube, or primary peritoneal cancer.
- j. Breast cancer in an individual with a close male blood relative\* with breast cancer.
- k. Breast cancer in an individual of Ashkenazi Jewish descent-CPT code 81212 only for founder mutations.
- l. Ovarian, fallopian tube or primary peritoneal cancer in an individual at any age.
- m. Breast cancer in a male.
- n. Prostate cancer (Gleason score  $\geq 7$ ) at any age with one or more close blood relatives\* with breast, ovarian, fallopian tube, primary peritoneal, pancreatic, or prostate cancer (Gleason score  $\geq 7$ ) at any age.
- o. Pancreatic cancer at any age with one or more close blood relatives\* with breast, ovarian, fallopian tube, primary peritoneal or pancreatic cancer at any age.
- p. Pancreatic cancer at any age with Ashkenazi Jewish descent -CPT 81212 only for founder mutations.
- q. A known BRCA1/2 mutation in a biologically related individual-CPT codes 81215, 81217 only for the known familial variant.
- r. No first or second degree blood relative involved but a third degree blood relative with breast and/or epithelial ovarian/fallopian tube/primary peritoneal cancer with two or more close blood relatives\* with breast and/or ovarian cancer (with at least one close blood relative diagnosed with breast cancer  $\leq 50$  yrs of age).

\* A close blood relative includes first-, second-, and third-degree relatives on the same side of family.

\*\* A first-degree relative is defined as a blood relative with whom an individual shares approximately 50% of his/her genes, including the individual's parents, full siblings, and children.

A second-degree relative is defined as a blood relative with whom an individual shares approximately 25% of his/her genes, including the individual's grandparents, grandchildren, aunts, uncles, nephews, nieces and half-siblings.

A third-degree relative is defined as a blood relative with whom an individual shares approximately 12.5% of his/her genes, including the individual's great-grandparents and first-cousins.

4. Separate from the criteria in sections 1-3 above, comprehensive BRCA1/2 analysis and BRCA large gene rearrangement (duplication/deletion) analysis for common variants( CPT 81211,81214, 81216) is covered for individuals with a  $\geq 10\%$  predicted BRCA1/2 mutation prevalence based on a validated risk-assessment model (i.e.BRCAPRO, IBIS, BOADICEA, University of Pennsylvania[UPenn I or UPenn II], or Tyrer-Cusick).
5. For individuals meeting criteria from sections 1-3 above who previously underwent BRCA1/2 testing without analysis for common large genomic rearrangements, testing for the common large gene rearrangements is reimbursable.
6. Uncommon large rearrangement duplication/deletion testing ( CPT 81213) is considered medically necessary when any criteria in sections 1-4 above are met and standard BRCA1/2 testing (CPT 81211,81214,81216) is negative.
7. BRCA1 and BRCA2 genetic testing for susceptibility to breast or ovarian cancer with multi-gene next-generation sequencing panels is considered medically necessary when applicable criteria in sections 1-4 is met, the test panel addresses only genes relevant to the personal and family history of the individual and the individual meets criteria for one of the following hereditary cancer syndromes- Li Fraumeni Syndrome, Cowden Syndrome/PTEN Hamartoma Tumor Syndrome(PHTS).
8. Genetic testing for mutations related to breast cancer is considered **NOT MEDICALLY NECESSARY** for screening in the general population, for individuals with no personal history of breast or ovarian

cancer except as noted in sections 3-6 above, or for minors less than 18 years of age, due to lack of effective interventions to be applied during childhood.

9. Genetic testing for mutations related to breast cancer will only be covered if performed at a qualified (CLIA) laboratory.

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\*Consistent with Summary Plan Description (SPD). When there is discordance between this policy and the SPD, the provisions of the SPD prevail.

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