

About this form

All BRCA tests require precertification. Failure to complete this form in its entirety may result in the delay of review. Effective June 20, 2016, this form replaces all other BRCA precertification information request documents and forms.

Once completed, this form contains confidential information. Only the individual or entity it's addressed to can use it. If you're not the intended recipient, or the employee or agent responsible for delivering the form to the intended recipient, you can't disseminate, distribute or copy the completed form. If you received the completed form in error, call us at **1-877-794-8720**.

How to fill out this form

As the patient's attending physician, you must complete all sections of the form. You can use this form with all Aetna health plans, including Aetna's Medicare Advantage plans. You can also use this form with health plans for which Aetna provides certain management services. This includes Innovation Health Plan, Inc., and Innovation Health Insurance Company.

When you're done

Once you've filled out the form, fax it and all requested medical documentation to us at **1-860-975-9126**. Or you can submit the completed form and the specimen sample to one of our network BRCA testing laboratories listed below. Then they'll submit the form to us.

- **Quest Diagnostics, Inc.:** Fax the precertification form to **1-855-422-5181**. Call BRCAVantage Concierge Services at **1-866-436-3463** or visit www.brcavantage.com for more information.
- **Ambry Genetics:** Fax the precertification form to **1-949-900-5501**. Order collection and transportation kits from by calling **1-866-262-7943** or online at www.ambrygen.com.
- **GeneDx, Genpath, Bio-Reference:** Order collection and transportation kits by calling **1-888-729-1206** or online at www.genedx.com/oncology.
- **Myriad Genetics Laboratories, Inc.:** Fax the precertification form to **1-801-584-3615**. If you have questions, call **1-800-469-7423**.
- **Medical Diagnostic Lab, LLC:** Fax the precertification form to **1-609-570-1062**. If you have questions, call **1-877-269-0090** or visit www.mdlab.com.
- **Counsyl:** For more information, call **1-888-COUNSYL (1-888-268-6795)**, send an e-mail to support@counsyl.com or visit www.counsyl.com.
- **Dynacare Northwest, Inc. (for members living in the states of Washington or West Virginia only):** Submit the precertification form with specimen sample to Dynacare Northwest, Inc. If you have questions about testing, call **1-800-533-0567**. If you have questions about insurance, billing or precertification call **1-877-415-0002**.

What happens next?

Once we receive the requested documentation, we'll perform a clinical review. Then we'll make a coverage determination and let you know our decision.

How we make coverage determinations

For our Medicare Advantage members, we use CMS benefit policies, including national coverage determinations (NCD) and local coverage determinations (LCD) when available, to make our coverage determinations. If there isn't an available NCD or LCD to review, then we'll use the Clinical Policy Bulletin referenced below to make the determination.

For all other members, we encourage you to review **Clinical Policy Bulletin #227: BRCA Testing, Prophylactic Mastectomy, and Prophylactic Oophorectomy** before you complete this form. You can find the policy by visiting the website on the back of the member's ID card.

Failure to complete this form in its entirety may result in the delay of review.

Fax to: BRCA Precertification Department

Fax number: 1-860-975-9126

Section 1: To be completed by ordering physician

Member name:

Member ID:

Member address:

Member phone #:

Member date of birth:

Gender: M F

Physician name:

Physician NPI number:

Physician phone number:

Physician status: Participating Non-participating

Physician address:

IPA name:

IPA NPI Number:

IPA address:

IPA phone #: 1- - -

Section 2: Provide the following general information

Laboratory name:

Laboratory phone number:

Laboratory status: Participating Non-participating

Date of specimen collection: / /

Section 3: Test menu

- BRCA 1 and BRCA 2 gene sequencing comprehensive testing (CPT 81211)
- BRCA 1/2 three gene mutation panel for Ashkenazi Jewish Ancestry (187delAG, 5385InsC, 6174delT) (CPT 81212)
- BRCA 1/2 three gene mutation panel for Ashkenazi Jewish Ancestry with reflex to comprehensive (CPT 81212, 81211)
- Large Rearrangement (BART) testing¹ (**Medicare members only**) (CPT 81213)
- BRCA 1 and BRCA 2 gene sequencing comprehensive and BART testing¹ (**Medicare members only**) (CPT 81162)
- BRCA 1 Single site testing (CPT 81215); specify relationship and mutation: _____
- BRCA 2 Single site testing (CPT 81217); specify relationship and mutation: _____
- BRCAAnalysis CDx™ (CPT 81211, 81213); include all failed lines of chemotherapy:
 1. _____ 2. _____ 3. _____

¹ Aetna does not cover large rearrangement testing (BART) unless the member is covered by Medicare and meets criteria for comprehensive testing. There is inadequate information regarding the frequency of large genomic re-arrangements in the United States populations to indicate that testing or re-testing for these specific mutations (e.g., the BART) is useful or effective in managing the care of members, including those with a strong family history of breast, ovarian or pancreatic cancer.

In addition, Aetna does not cover multigene hereditary breast cancer panels that accompany BRCA testing because there is insufficient published evidence of their clinical validity and utility. Information regarding this can be found in our Clinical Policy Bulletin (CPB): BRCA Testing, Prophylactic Mastectomy, and Prophylactic Oophorectomy available at www.aetna.com.

Member name:

Member date of birth:

Section 7: Risk criteria category for FEMALES

- Personal history of ovarian cancer**¹ Date of ovarian cancer diagnosis: Month ____ Year ____
- Personal history of breast cancer**² Date of breast cancer diagnosis: Month ____ Year ____
 - 1. Breast cancer² diagnosed at age 45 years or younger; or
 - 2. Breast cancer² diagnosed at age 50 years or younger, with any of the following:
 - a. At least one close blood relative³ with breast cancer² at age 50 years or younger; or
 - b. At least one close blood relative³ with epithelial ovarian cancer¹; or
 - c. Limited family structure⁴ or no family history available because member is adopted; or
 - d. Bilateral breast cancer² or two primaries⁵, with first diagnosis age 50 years or younger
 - 3. Breast cancer² is diagnosed at age 60 years or younger and is triple negative⁶
 - 4. Breast cancer² is diagnosed at any age, with any of the following:
 - a. At least two close blood relatives³ on the same side of the family with breast cancer² and/or epithelial ovarian cancer¹ at any age; or
 - b. Member has two breast primaries⁵ and has at least one close blood relative³ with either breast cancer diagnosed at age 50 or younger or with epithelial ovarian cancer¹; or
 - c. Close blood relative³ with either breast cancer² at age 50 or younger or with epithelial ovarian cancer¹ (**Medicare only**); or
 - d. At least two close blood relatives³ with pancreatic cancer or prostate cancer with Gleason score > 7 at any age (**Medicare only**); or
 - e. Close male blood relative³ with breast cancer²; or
 - f. First, second or third degree blood relative³ with a known BRCA1 or BRCA2 mutation⁷; or
 - g. Two close relatives³ on the same side of the family with pancreatic adenocarcinoma at any age; or
 - h. Ethnicity is associated with higher mutation frequency (Ashkenazi Jewish)⁸.
- Personal history of pancreatic adenocarcinoma at any age with two close relatives³ on the same side of the family with breast cancer², epithelial ovarian cancer¹, and/or pancreatic adenocarcinoma at any age**
- NO personal history of breast², ovarian cancer¹ or pancreatic adenocarcinoma (coverage excluded by Medicare)⁹**
 - 1. Women with three or more close blood relatives³ on the same side of the family with breast cancer; or
 - 2. Women with at least one close blood relative³ with:
 - a. male breast cancer; or
 - b. both breast² and epithelial ovarian cancer¹.
 - 3. Women with two close blood relatives³ on the same side of the family with:
 - a. and epithelial ovarian cancer¹; or
 - b. breast cancer², one of whom was diagnosed at age 50 years or younger; or
 - c. breast cancer² in one relative and epithelial ovarian cancer¹ in another relative
 - 4. Women with first degree relative with bilateral breast cancer⁵; or
 - 5. Women with one or more close blood relatives³ with both breast² and epithelial ovarian cancer¹; or
 - 6. Women of Ashkenazi Jewish descent with a first degree relative or two or more second degree relatives on the same side of the family with breast or epithelial ovarian cancer⁸; or
 - 7. Women with first, second or third degree blood relatives with a known BRCA1 or BRCA2 mutation⁹.
- Women who do not meet any of the above criteria but are determined through both independent formal genetic counseling and validated quantitative risk assessment tool⁷ to have at least a 10% pre-test probability of carrying a BRCA1 or BRCA2 mutation. Note: In this category only, a 3-generation pedigree and quantitative risk assessment results must be faxed directly to us at 1-860-975-9126. Pedigree template available on request.**
 - Formal genetic counseling Yes No
 - Genetic counselor name and location (state): _____

Member name:

Member date of birth:

Section 8: Risk criteria category for MALES

- Personal history of breast cancer; or
- First, second or third degree blood relative with a known BRCA1 or BRCA2 mutation, where the results will influence clinical utility (e.g., reproductive decision-making)¹⁰ **(coverage excluded by Medicare)**⁹

Section 9: Medical management (if patient tests positive)

- | | | | |
|--|------------------------------------|--|---|
| <input type="checkbox"/> Prophylactic oophorectomy | <input type="checkbox"/> Bilateral | <input type="checkbox"/> Tamoxifen chemoprevention | <input type="checkbox"/> Other, please specify: |
| <input type="checkbox"/> Prophylactic mastectomy | <input type="checkbox"/> Bilateral | <input type="checkbox"/> Increased breast surveillance | |

Section 10: Patient education

Consistent with the 1997 National Institutes of Health Consensus Statement on guidelines for care of patients with BRCA1 and BRCA2 mutations and American College of Medical Genetics guidelines, prior to testing and follow-up treatment, the patient must give informed consent in accordance with applicable law. Also consistent with such guidelines, such informed consent discussions should include at least the following:

- | | |
|--|--|
| 1. Clarification of the patient’s increased risk status | 5. Limited data regarding efficacy of methods for early detection and prevention |
| 2. Explanation of how genetics affects cancer susceptibility | 6. Possible psychological and social impact of testing |
| 3. Potential benefits, risk, and limitations of testing | 7. Counseling regarding therapeutic options, including limitations |
| 4. Possible outcomes of testing (e.g., positive, negative or uncertain test results) | |

Section 11: Read this important information

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties.

Section 12: Sign the form

By signing this form, I certify that the member listed above has given informed consent in accordance with the guidelines and risks above and that the BRCA analysis will be used to direct the medical management of this member.

Form completed by (please print):

Title:

Physician Signature (required) :

Contact Person:

Phone Number:

¹ For the purposes of these guidelines, fallopian tube and primary peritoneal carcinoma should be included.

² The term “breast cancer” includes both invasive and ductal carcinoma in situ (DCIS) breast cancers. Lobular carcinoma in situ (LCIS) is not included.

³ Close blood relatives include first-degree relatives (i.e., mother, sister, daughter) or second-degree relatives (i.e., aunt, grandmother, niece), all of whom are on the same side of the family. For affected Medicare members, close relatives would also include third-degree relatives (i.e. great grandmother, great aunt and first-degree cousin).

⁴ A limited family history is defined as a member who has fewer than two 1st or 2nd degree female relatives in the same lineage that lived to age 45. The “limited family history” can occur on either the maternal or paternal side of family. A three generation pedigree is needed for this category.

⁵ Two breast primaries in a single individual includes bilateral disease or cases where there are two or more clearly separate ipsilateral primary tumors.

⁶ Triple negative breast cancer is when the individual’s breast cancer cells test negative for estrogen receptors (ER-), progesterone receptors (PR-) and human epidermal growth factor receptors (HER2-).

⁷ Validated quantitative risk assessment tools include BRCAPRO, Yale, University of Pennsylvania (UPenn I or UPenn II), BOADICEA (Breast and Ovarian Analysis of Disease Incidence and Carrier Estimation Algorithm) and Tyrer-Cuzick (IBIS Breast Cancer Risk Evaluation Tool).

⁸ For screening of Ashkenazi Jewish women, a screening panel for the founder mutations common in the Ashkenazi Jewish population (multisite testing) is considered medically necessary. If founder mutation testing is negative, full gene sequencing (reflex testing) is considered medically necessary only if member meets any one of the criteria described above.

⁹ Medicare does not cover BRCA genetic testing in the absence of a personal history of breast or ovarian cancer, since it is considered to be screening and is specifically excluded by Medicare.

¹⁰ Testing in this scenario is for the specific identified mutation (single site testing).