#### **Medical Coverage Policy**

Policy Number – MP22-019E Original review date – 02/25/2022 Effective date – 10/20/2025

# BRCA1/2 genetic testing

#### **Background**

In the United States, breast cancer is the second leading cause of cancer related deaths in women. Epithelial ovarian cancer is the leading cause of death from gynecologic cancer in the United States. While most breast and ovarian cancers are sporadic in origin, there are certain specific familial mutations which increase the risk of these cancers.

BRCA1 and BRCA2 mutations in the general population have a prevalence estimated between 1 in 300 and 1 in 800. The prevalence of BRCA mutations in Ashkenazi Jewish population is about 1 in 40. Mutations in BRCA1 and BRCA2 genes are inherited in an autosomal dominant manner. The likelihood that a woman with an inherited BRCA mutation will develop a related cancer is estimated to be between 41% and 90% and is much lower in men. Based on this, BRCA1 and BRCA2 genetic testing is appropriate for a specific subset of adults identified to be at high risk for hereditary breast and ovarian cancers.

#### **Policy statement**

Disclaimer: This policy is applicable to TRICARE Prime and Select beneficiaries and may not apply to Active Duty Service Members (ADSM) under Supplemental Health Care Program (SHCP) or TRICARE Prime Remote (TPR) in accordance with TRICARE Operations Manual (TOM) Chapter 17, Section 3. Please review TOM Chapter 17, Section 3, Paragraph 2.0 onwards, regarding SHCP coverage and any TRICARE-specific exclusions included in this coverage policy to accurately determine the benefit for ADSMs.

Per <u>TRICARE</u> policy, BRCA1 and BRCA2 genetic testing criteria are based on the latest NCCN guidelines. This policy, with the effective date of 02/25/2022, is based on the guidelines detailed in the current version of Clinical Practice Guidelines in Oncology. Genetic/Familial High-Risk Assessment: Breast, Ovarian, and Pancreatic - Version 1.2022.

BRCA1 and BRCA2 genetic testing may be covered is the following criteria are met:

- A. Personal history of breast cancer and any of the following indications:
  - a. Diagnosed at age 50 or younger
  - b. Diagnosed at age 51 or older and any of the following indications:
    - i. Three or more total diagnoses of breast and/or prostate cancer in patient and/or close blood relative on the same side of the family
    - ii. One or more close blood relative with any of the following:
      - 1. Breast cancer at age 50 or less or male breast cancer at any age
      - 2. Ovarian cancer at any age
      - 3. Pancreatic cancer at any age





- 4. Metastatic, intraductal/cribriform histology, or high or very high-risk group prostate cancer at any age
- iii. Triple negative breast cancer
- iv. Multiple primary breast cancers (synchronous or metachronous)
- v. Lobular breast cancer with personal or family history of diffuse gastric cancer
- vi. Male breast cancer
- vii. One or more blood relatives with male breast cancer
- viii. Ashkenazi Jewish ancestry
- B. Personal history of any of the following:
  - a. Epithelial ovarian, fallopian tube, or primary peritoneal cancer
  - b. Pancreatic cancer
  - c. Prostate cancer with Gleason score of 7
- C. Prior to treatment with PARP inhibitors for metastatic breast cancer
- D. Prior to treatment with olaparib for HER2 negative breast cancer
- E. Unaffected individual with an affected close blood relative who meets criteria  $\underline{A}$  or  $\underline{B}$  above
- F. Affected or unaffected individual who does not meet criteria above but has a probability of 5% or greater of carrying a BRCA1/2 pathogenic variant based on a USPSTF approved risk stratification tool

Close blood relatives are first or second degree relatives on the same side of the family.

First degree relatives: Parents, siblings, and children

Second degree relatives: Grandparents, aunts, uncles, nieces, nephews, grandchildren, and half-siblings

**USPSTF** recognized risk stratification tools include:

- 7 Question Family History Screening Test
- BRCAPRO
- International Breast Cancer Intervention Study Instrument (Tyrer-Cuzick)
- Manchester Scoring System
- Ontario Family History Assessment Tool
- Pedigree Assessment Tool
- Referral Screening Tool

#### TRICARE Operations Manual (TOM) Ch. 18, Sec 2

## 3.10 BRCA1 or BRCA2 Genetic Counseling and Testing

- 3.10.1 The contractor shall not charge a copayment or cost-share for genetic counseling rendered by a TRICARE-authorized provider that precedes BRCA1 or BRCA2 gene testing performed as a preventive service for women who are identified as high risk for breast cancer by their primary care clinician.
- 3.10.2 The contractor shall not charge a copayment or cost-share for BRCA1 or BRCA2 gene testing performed as a preventive service for women who meet the coverage guidelines outlined in Figure 18.2-1 on the approved LDT list.

Note: For men, the contractor shall apply copayments or cost-shares to medically necessary and appropriate BRCA1 or BRCA2 genetic counseling and testing.





GENE:	BRCA1/BRCA2
Effective Date:	January 1, 2013
	BRCA1/BRCA2 gene testing is covered in accordance with the most current National Comprehensive Cancer Network (NCCN) Guidelines for Breast Cancer.

### **Coding information**

81162	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (eg,
	hereditary breast and ovarian cancer) gene analysis; full sequence analysis and full
	duplication/deletion analysis (ie, detection of large gene rearrangements)
81163	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (eg,
	hereditary breast and ovarian cancer) gene analysis; full sequence analysis
81164	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (eg,
	hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis
	(ie, detection of large gene rearrangements)
81165	BRCA1 (BRCA1, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene
	analysis; full sequence analysis
81166	BRCA1 (BRCA1, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene
	analysis; full duplication/deletion analysis (ie, detection of large gene rearrangements)
81167	BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene
	analysis; full duplication/deletion analysis (ie, detection of large gene rearrangements)
81212	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (eg,
	hereditary breast and ovarian cancer) gene analysis; 185delAG, 5385insC, 6174delT
	variants
81215	BRCA1 (BRCA1, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene
	analysis; known familial variant
81216	BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene
	analysis; full sequence analysis
81217	BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene
	analysis; known familial variant

#### References

- 1. TRICARE Operations Manual Chapter 18, Section 2 TRICARE Manuals Display Chap 18 Sect 2 (Change 50, Sep 17, 2025)
- Centers for Medicare and Medicaid Services. Local Coverage Determination L36499 BRCA1 and BRCA2 Genetic Testing. Effective Date 12/10/2020
- 3. Centers for Medicare and Medicaid Services. Local Coverage Article A57449: Billing and Coding: BRCA1 and BRCA2 Genetic Testing. Effective Date 10/01/2021
- **4.** MCG Health. Ambulatory Care. Breast or Ovarian Cancer, Hereditary BRCA1 and BRCA2 Genes. 29<sup>th</sup> edition. ACG: A-0499 (AC). Last reviewed: 06/13/2025
- MCG Health. Ambulatory Care. Prostate Cancer BRCA1 and BRCA2 Genes. 29<sup>th</sup> edition. ACG: A-0612 (AC). Last reviewed: 06/13/2025





**6.** NCCN Clinical Practice Guidelines in Oncology. Genetic/Familial High-Risk Assessment: Breast, Ovarian, and Pancreatic. Version 2.2026 – October 10, 2025

**Revision History:** 

October 2025: Updated criteria and references

October 2023:

Updated references

November 2023:

Updated criteria based on latest NCCN guidelines

**Updated References** 

Approved by:

Joseph F. McKeon, MD, MPH

**Chief Medical Officer** 

Date of approval: 10/20/2025

