Medical Coverage Policy
Policy Number – MP22-019E
Original review date – 02/25/2022
Effective date – 10/23/2024

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 TRICARE 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. Lobular breast cancer with personal or family history of diffuse gastric cancer
v. Male breast cancer
vi. One or more blood relatives with male breast cancer
vii. 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 A or 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, second, and third 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

Third degree relatives: Great-grandparents, great-aunts, great-uncles, great-grandchildren, first cousins, half-aunts, half-uncles

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 3

3.11 BRCA1 or BRCA2 Genetic Counseling and Testing

3.11.1 Genetic counseling rendered by a TRICARE-authorized provider that precedes BRCA1 or BRCA2 gene testing is covered with no copayment or cost-share as a preventive service for women who are identified as high risk for breast cancer by their primary care clinician.

3.11.2 BRCA1 or BRCA2 gene testing is covered with no copayment or cost-share as a preventive service for women who meet the coverage guidelines outlined in Figure 18.3-1 .

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

GENE:	**BRCA1/BRCA2**
Effective Date:	January 1, 2013
Coverage Guidelines:	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 3 TRICARE Manuals - Manual Information (health.mil)
2. 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. 28th edition. ACG: A-0499 (AC). Last reviewed: 03/14/2024
5. MCG Health. Ambulatory Care. Prostate Cancer – BRCA1 and BRCA2 Genes. 28th edition. ACG: A-0612 (AC). Last reviewed: 03/14/2024

6. NCCN Clinical Practice Guidelines in Oncology. Genetic/Familial High-Risk Assessment: Breast, Ovarian, and Pancreatic. Version 1.2025 – September 25, 2024 Guidelines Detail (nccn.org)

Revision History:

October 2023:

Updated references

November 2023:

Updated criteria based on latest NCCN guidelines

Updated References

Approved by:

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Chief Medical Officer

Date of approval: 10/23/2024