STATE OF IOWA DEPARTMENT OF
Health AND Human
SERVICES

Genetic Testing for Hereditary Breast and Ovarian Cancer Syndrome (BRCA1/BRCA2)
LAB-004

Iowa Medicaid Program:	Prior Authorization	**Effective Date:**	5/14/2008
Revision Number:	11	**Last Rev Date:**	1/19/2024
Reviewed By:	Medicaid Medical Director	**Next Rev Date:**	1/17/2025
Approved By:	Medicaid Clinical Advisory Committee	**Approved Date:**	4/22/2020

Descriptive Narrative

Potentially harmful mutations of the breast cancer susceptibility 1 and 2 genes (BRCA1/2) are associated with increased risk for breast, ovarian, fallopian tube, pancreatic, prostate, and peritoneal cancer. For women in the United States, breast cancer is the most common cancer after non-melanoma skin cancer and the second leading cause of cancer death. In the general population, BRCA1/2 mutations occur in an estimated 1 in 300 to 500 women and account for 6 percent of breast cancer cases and 20 percent of ovarian cancer cases.

This policy discusses the genetic testing that can identify individuals at high risk for what has been called hereditary breast and ovarian cancer syndrome (HBOC). However, with the recognition that pathogenic variants in the most implicated genes (BRCA1/2) also predispose to cancers affecting men, namely prostate and pancreatic cancer, the acronym HBOC is less inclusive.

For individuals whose family or personal history is associated with an increased risk for harmful mutations in the BRCA1/2 genes, or who have an ancestry associated with BRCA1/2 gene mutations, there is adequate evidence that the benefits of risk assessment, genetic counseling, genetic testing, and interventions are moderate. For individuals whose personal or family history or ancestry is not associated with an increased risk for harmful mutations in the BRCA1/2 genes, there is adequate evidence that the benefits of risk assessment, genetic counseling, genetic testing, and interventions are small to none.

Criteria

Testing for BRCA 1 and BRCA 2 mutations may be medically necessary when **ONE** of the following is met:

1. Member from a family with a known BRCA 1 or 2 mutation; **OR**
2. Personal history of breast cancer and **ONE** or more of the following:
   a. Diagnosed at or younger than 45 years of age; **OR**
   b. Diagnosed between 46-50 years of age with:
      1) An additional breast cancer primary at any age; **AND**
      2) More than one close blood relative with breast cancer at any age; **AND**
      3) More than one close blood relative with high-grade prostate cancer (Gleason score >7); **AND**
      4) An unknown or limited family history; **OR**
   c. Diagnosed younger than 60 years of age with triple negative breast cancer, **OR**
   d. Diagnosed at any age **AND** more than one close blood relative with:
      1) Breast cancer diagnosed younger than 50 years of age, **OR**
      2) Ovarian carcinoma, **OR**
      3) Male breast cancer, **OR**
      4) Metastatic prostate cancer, **OR**
      5) Pancreatic cancer; **OR**
   e. Two or more additional diagnoses of breast cancer at any age in member and/or close blood relatives; **OR**
   f. Ashkenazi Jewish ancestry; **OR**
3. Personal history of ovarian, fallopian tube, and primary peritoneal cancer; **OR**
4. Personal history of male breast cancer; **OR**
5. Personal history of pancreatic cancer; **OR**
6. Personal history of metastatic prostate cancer; **OR**
7. Personal history of high-grade prostate cancer (Gleason score >7) at any age with **ONE** of the following:
   a. More than one close blood relatives with ovarian carcinoma, pancreatic cancer or metastatic prostate cancer at any age OR breast cancer younger than 50 years of age, **OR**
   b. More than two close blood relatives with breast OR prostate cancer (any grade) at any age, **OR**
   c. Ashkenazi Jewish ancestry; **OR**
8. BRCA1/2 pathogenic/likely pathogenic variant detected by tumor profiling on any tumor type in the absence of germline pathogenic/likely pathogenic variant analysis; **OR**
9. Regardless of family history, some members with a BRCA-related cancer may benefit from genetic testing to determine eligibility for targeted treatment; **OR**
10. A member who does not meet the other criteria but with more than one first- or second-degree blood relative meeting any of the above criterial; **AND**
11. All requests for testing must be accompanied by genetic counseling performed by a qualified professional. This includes components of taking a personal and family history to assess risk of disease, education about inheritance and resources, and counseling to promote informed choices and psychological implications of undergoing testing.

Definitions

- Close blood relative - first-, second-, and third-degree relatives on same side of family.
- First degree relative - parent, sibling, children.
- Second degree relative - grandparent, aunt, uncle, niece, nephew, grandchild, half-sibling.
- Third degree relative – great grandparent, great aunt, great uncle, great grandchild, first cousin, half aunt, half uncle.
- Refer to pedigree chart.
- Ashkenazi Jewish ancestry refers to those individuals of Jewish descent whose family emigrated from Northern Europe.
- Qualified professional such as certified genetic counselor or oncologist.

Coding

The following list of codes is provided for reference purposes only and may not be all inclusive. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment, nor does the exclusion of a code imply that its association to the HCPCS/CPT code is inappropriate.

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

Compliance

1. Should conflict exist between this policy and applicable statute, the applicable statute shall supersede.
2. Federal and State law, as well as contract language, including definitions and specific contract provisions or exclusions, take precedence over medical policy and must be considered first in determining eligibility for coverage.
3. Medical technology is constantly evolving, and Iowa Medicaid reserves the right to review and update medical policy on an annual and as-needed basis.

Medical necessity guidelines have been developed for determining coverage for member benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Criteria are revised and updated annually, or more frequently if new evidence becomes available that suggests needed revisions.

References

The American Society of Breast Surgeons: Consensus Guideline on Genetic Testing for Hereditary Breast Cancer 2019 Official Statement.

Optum360 EncoderPro.

Risk Assessment, Genetic Counseling and Genetic Testing for BRCA-Relate Cancer in Women: Updated Evidence Report and Systematic Review for the US Preventive Services Task Force. JAMA. 2019; 322(7):666-685, doi:10:1001/jama.2019.8430.

Risk Assessment, Genetic Counseling, and Genetic Testing for BRCA-Related Cancer. US Preventive Services Task Force Recommendation Statement. JAMA.2019; 322 (7): 652-655. Doi10.1001/jama.2019.10987.

Clinical Guideline. Familial Breast Cancer: classification and care of people at risk of familial breast cancer and management of breast cancer and related risks in people with a family history of breast cancer. Developed for NICE by the National Collaborating Centre for Cancer. June 2013.

American Society of Clinical Oncology Policy Statement Update: Genetic and Genomic Testing for Cancer Susceptibility, Mark E. Robson, Angela R. Bradbury, Banu Arun, Susan M. Domchek, James M. Ford, Heather L. Hampel, Stephen M. Lipkin, Sapna Syngal, Dana S. Wollins, and Noralane M. Lindor. Journal of Clinical Oncology, Special Article, Volume 33, Number 31, November 1 2015, pp 3660-3667.

National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Breast and Ovarian. Version 1.2023-September 7, 2022.

Breast or Ovarian Cancer, Hereditary – BRCA1 and BRCA2 Genes. ACG: A-0499 (AC) Milliman Clinical Guidelines. Ambulatory Care 25th Edition. Last update: June 7, 2021.

Peshkin BN. Isaacs C. Genetic testing and management of individuals at risk of hereditary breast and ovarian cancer syndromes. UpToDate. Last updated: August 18, 2022.

Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

Criteria Change History

Change Date	Changed By	Description of Change	Version
Signature			

Change Date	Changed By	Description of Change	Version
Signature			

Change Date	Changed By	Description of Change	Version
1/19/2024	CAC	Annual review.	11
Signature William (Bill) Jagiello, DO			

Change Date	Changed By	Description of Change	Version
1/20/2023	CAC	Annual review. Descriptive Narrative and References updated.	10
Signature William (Bill) Jagiello, DO			

Change Date	Changed By	Description of Change	Version
1/21/2022	CAC	Annual review.	9
Signature William (Bill) Jagiello, DO			

Criteria Change History (continued)

Change Date	Changed By	Description of Change	Version
1/10/2020	Medical Director	Title changed from Genetic Testing for Cancer to Genetic Testing for Hereditary Breast and Ovarian Cancer Syndrome (BRCA1/BRCA2). Formatting changes. Reworded criteria. New investigational indications. New code updates consistent with CPT changes October 2019. New references added. Content reviewed by external Certified Genetic Counselor. Added references to BRCA testing in male patients.	8
Signature William (Bill) Jagiello, DO			

Change Date	Changed By	Description of Change	Version
8/17/2018	CAC	Changed criterion #5 to read "Personal history of pancreatic or aggressive prostate cancer (Gleason score of 7 or more) at any age".	7
Signature C. David Smith, MD			

Change Date	Changed By	Description of Change	Version
7/10/2017	Medical Director	Updated to include genetic testing for other cancer syndromes.	6
Signature			

Change Date	Changed By	Description of Change	Version
7/15/2016	CAC	Added "must meet one of the following numbered criteria."	5
Signature			

Change Date	Changed By	Description of Change	Version
7/17/2015	CAC	Added last paragraph under References.	4
Signature			

Change Date	Changed By	Description of Change	Version
7/19/2013	CAC	Added "BART testing (for rearrangement) will be covered as a reflex test when BRCA 1 & 2 testing is negative".	3
Signature			

Change Date	Changed By	Description of Change	Version
4/19/2013	CAC	Removed criterion #7.	2
Signature			

Change Date	Changed By	Description of Change	Version
3/27/2013	Medical Director	Reflection of new guidelines issued by NCCN.	1
Signature			