BlueCross BlueShield Minnesota

Blue Cross Blue Shield of Minnesota Medical Policy

Medical Policy:	VI-16-014
Topic:	Genetic Testing for Hereditary Breast and/or Ovarian Cancer
Section:	Laboratory
Effective Date:	January 27, 2025
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Several genetic cancer syndromes with an autosomal dominant pattern of inheritance associated with an increased risk of breast or ovarian cancer have been identified. Genes included in this policy are those associated with hereditary breast and/or ovarian cancer syndromes that have been shown to have high penetrance, meaning that a large proportion of individuals with certain mutations in the gene will develop the disorder.

Genetic testing for cancer susceptibility may be approached by a focused method that involves testing for well-characterized mutations based on a clinical suspicion of which gene(s) may be the cause of the familial cancer. Panel testing involves testing for multiple mutations in multiple genes at one time.

Several companies offer genetic testing panels for assessing risk of hereditary cancers that use next generation sequencing methods. Next generation sequencing refers to one of several methods that use massively parallel platforms to allow the sequencing of large numbers of DNA segments. Panel testing is potentially associated with greater efficiencies in evaluating genetic diseases; however, it may provide information on genetic variants of unclear clinical significance, or which would not lead to changes in patient management.

FDA approval is not currently required for these genetic tests. Clinical laboratories may develop and validate tests in-house ("home-brew") and market them as a laboratory service. The laboratory offering the service must be licensed by Clinical Laboratory Improvement Amendments (CLIA) for high-complexity testing.

Genetic Counseling

Determining the appropriateness of genetic testing for a particular individual can be complex due to the many personal and family history factors that must be taken into consideration to determine which, if any, test is appropriate. Interpretation of test results and discussion of the possible health implications for the patient and family members are also important considerations.

Definitions

Close Blood Relative: for the purposes of this policy, a relative is someone who is related by blood; a first-, second-, or third-degree relative from the same side of the family.

- **First degree relative:** A family member who shares about 50 percent of their genes with a particular individual in a family. First degree relatives include parents, offspring, and siblings.
- **Second degree relative:** A family member who shares about 25 percent of their genes with a particular individual in a family. Second degree relatives include grandparents, grandchildren, uncles, aunts, nephews, nieces, and half-siblings.
- **Third degree relative**: A family member who shares about one-eighth of their genes, such as first cousins, great-grandparents, great-aunts, great-uncles.

Unaffected Member

The purpose of this genetic testing is to help inform a person's likelihood of developing a specific condition. Increased risk of developing a condition, or of passing on a genetic condition to their children. Testing should be considered in appropriate individuals where it is likely to impact the risk management and/or treatment of the tested individuals and/or their family members who also have increased risk. For the purpose of this policy, an unaffected member is one that has no personal history of breast and/or ovarian cancer and has not had testing to determine if genetic variants increase their risk of developing breast and/or ovarian cancer.

Affected Family Member

For the purpose of this policy, an affected family member is one that has a history of breast and/or ovarian cancer or has a history of another cancer that thereby increases the risk of the development of breast and/or ovarian cancer (i.e. fallopian tube cancer, primary peritoneal cancer, pancreatic cancer, or prostate cancer)

Gleason score is the preferred system for histopathological grading of prostate cancer. The score reflects the differentiation of cells in primary and secondary patterns. The combined scores from each pattern may range from 2-10. A Gleason score of 7 indicates a moderately aggressive tumor with intermediate differentiation. A score of 8 or greater indicates poorly differentiated or undifferentiated cells and a more aggressive tumor.

Lynch Syndrome-related cancers include colorectal, endometrial, gastric, ovarian, exocrine pancreatic, upper tract urothelial, glioblastoma, biliary tract, and small intestinal cancers.

Germline: Hereditary variant identified through a blood or saliva sample.

This policy is designed to address medical guidelines that are appropriate for the majority of individuals with a particular disease, illness, or condition. Each person's unique clinical circumstances may warrant individual consideration, based on review of applicable medical records.

Policy Position *Coverage is subject to the specific terms of the member's benefit plan.*

NOTES:

- This policy only addresses genetic testing for breast and/or ovarian cancer.
- Please refer to policy VI-49: Expanded Molecular Panel Testing of Cancers to Identify Targeted Therapies, for pharmacogenetic testing to aid in identifying targeted therapies for breast or ovarian cancers.
- Please refer to policy VI-56: Genetic Cancer Susceptibility Panels, for multi-gene panel testing for other cancers.
- Coverage may be subject to legislative mandates, including but not limited to the following, which applies prior to the policy statements:
  - Minnesota Statute 62Q.473 Biomarker Testing.

I. Genetic Counseling

Genetic testing for hereditary breast and/or ovarian cancer may be considered **MEDICALLY NECESSARY and APPROPRIATE** when **ALL** of the following criteria for genetic counseling are met along with criteria in sections II, IV, or V below:

- A recommendation for testing is confirmed by **ONE** of the following:
  - A physician who is certified by the American Board of Medical Genetics and Genomics or has active candidate status for certification who has no financial relationship with the testing laboratory*;
  - An American Board of Medical Genetics and Genomics or American Board of Genetic Counseling certified or certification eligible Genetic Counselor who has no financial relationship with the testing laboratory*;
  - A nurse credentialed as either a Genetic Clinical Nurse (GCN) or an Advanced Practice Nurse in Genetics (APNG) by either the Genetic Nursing Credentialing Commission (GNCC) or the American Nurses Credentialing Center (ANCC) who has no financial relationship with the testing laboratory*;
  - An oncologist or a surgical oncologist who has no financial relationship with the testing laboratory*;
- **AND**
- Content of counseling includes BOTH of the following:
  - Evaluation of a 3-generation pedigree; and
  - Discussion of ALL of the following with the individual who is considering testing:
    - When clinically appropriate, options for surveillance and risk reduction (e.g., lifestyle, chemoprevention, risk-reducing surgery) for individuals with positive results, individuals with negative results, and key differences between the two; and
    - Potential for uninformative or uncertain test results; and
    - Potential that test results may provide health information regarding the risk of disease for other family members.

*Genetics professionals are not excluded if they are employed by or contracted with a laboratory that is part of an Integrated Health System which routinely delivers health care services beyond just the laboratory test itself.

II. Known Familial Mutation

Single-site (known familial variant) analysis of *BRCA1* and/or *BRCA2* may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for an individual who meets **ALL** of the following:

- Genetic counseling criteria in section I have been met; **AND**
- Known familial mutation in BRCA1 and or BRCA2 identified in 1st, 2nd, or 3rd degree relative(s); **AND**
- No previous germline *BRCA1* and/or *BRCA2* testing or results of previous testing were incomplete.

III. Personal History of Cancer

Genetic testing of *BRCA1* and/or *BRCA2* may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for an individual who meets **ALL** of the following:

- Testing recommended by the treating surgeon, oncologist, or genetic counselor; **AND**
- Personal history of one or more of the following at any age:
  - Breast cancer
  - Ovarian cancer
  - Fallopian tube cancer
  - Primary peritoneal cancer
  - Pancreatic cancer

    - Prostate cancer that meets at least one of the following:
        - Metastatic; or
        - Intraductal/cribriform histology; or
        - High or very-high risk group defined as any of the following:
            - Gleason score ≥ 8; or
            - T stage of T3a, T3b, or T4; or
            - PSA > 20 ng/mL; or
            - Gleason pattern 5 histology; or:
        - Ashkenazi Jewish ancestry; or
        - One or more close blood relative(s) with:
            - breast cancer age ≤ 50 years; or
            - colorectal cancer age ≤ 50 years; or
            - endometrial cancer age ≤ 50 years; or
            - ovarian cancer at any age; or
            - pancreatic cancer at any age; or
            - metastatic, regional, very-high risk, high risk prostate cancer at any age; or
        - Two or more close blood relatives, on the same side of the family, with breast or prostate cancer at any age; or
- **AND**
- No previous germline *BRCA1* and/or *BRCA2* testing; or results of previous testing were incomplete.

IV. **Predisposition Testing in Individuals with No Personal History of Cancers in Section III**

Genetic testing of *BRCA1* and/or *BRCA2* may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for an individual with no personal history of cancers listed in section III of this policy who meets **ALL** of the following:

- Genetic counseling criteria in section I have been met; **AND**
- A first-or second-degree blood relative meets any of the criteria in section III of this policy; **AND**
- Has a reasonable likelihood of a mutation based on pre-test genetic counseling; **AND**
- Unaffected member is the most informative person to test. All affected family members are deceased, or all affected family members have been contacted and are unwilling to be tested; **AND**
- No previous germline *BRCA1* and/or *BRCA2* testing; or results of previous testing were incomplete.

V. Multi-Gene Panel Sequencing

Genetic testing for hereditary breast and/or ovarian cancer using a multi-gene sequencing panel that includes *BRCA1/BRCA2* genes is considered **MEDICALLY NECESSARY AND APPROPRIATE** when an individual meets ALL of the following:

- Genetic counseling meeting criteria in section I documents a family history/pedigree demonstrating a reasonable likelihood for one of the following cancer syndromes (associated genes in parentheses):
    - Bannayan-Riley-Ruvalcaba syndromes, Cowden syndrome, PTEN hamartoma syndrome (*PTEN*)
    - Hereditary diffuse gastric cancer syndrome (*CDH1*)
    - Li Fraumeni syndrome (*TP53*)
    - Lynch syndrome/hereditary non-polyposis colorectal cancer (*MSH2, MLH1, MSH6, MUYH, PMS2, PMS1, EPCAM*)
    - PALB2 genetic mutation associated with increased risk of breast cancer (*PALB2*)
    - Peutz-Jeghers syndrome (*STK11*)
- **AND**
- Unaffected member is the most informative person to test. All affected family members are deceased, or all affected family members have been contacted and are unwilling to be tested; **AND**
- The majority of genes in the panel have a proven association with breast and/or ovarian cancer (e.g. ATM, BRCA1, BRCA2, BRIP1, CDH1, CHEK2, MLH1, MSH2, MSH6, PALB2, PTEN, STK11, TP53); **AND**
- Results of testing will impact the medical management of the individual (e.g., increased screening or surveillance).

VI. Experimental/Investigative

Genetic testing for hereditary breast and/or ovarian cancer as either a single-gene or multi-gene panel test is considered **EXPERIMENTAL/INVESTIGATIVE** for all other indications including but not limited to the following due to a lack of clinical evidence demonstrating an effect on health outcomes:

- Testing will not affect treatment or surveillance decisions
- Testing offered as a direct access (also known as direct to consumer)
- Testing in the general population as a screening tool
- All other testing for risk of hereditary breast and/or ovarian cancer that do not meet criteria as stated above.

Procedure Codes

0102U 0103U 0129U 81162 81163 81164 81165 81166 81167 81212 81215 81216 81217 81307 81308 81432 81479

Documentation Submission

Documentation from the ordering clinician supporting the medical necessity criteria in the policy must be included in the prior authorization. In addition, the following documentation must be submitted:

- The request states the specific test(s) name and included genes, AND
- Documentation from the clinical notes that criteria for genetic counseling (if required) have been met, AND
- Documentation of one of the following:
  - Known deleterious mutation in genes addressed in this policy in a close blood relative; OR
  - Diagnosis of individual with personal history of cancers addressed in this policy; OR
  - Results of pedigree indicating need for testing in individual with family history only; OR
  - Results of pedigree and genes for which multigene panel testing is indicated

Link to Pre-Authorization Form: https://www.bluecrossmn.com/sites/default/files/DAM/2021-12/BCBSMN-Pre-Auth-Request-fillable-X18509R07.pdf

Denial Statements

No additional statements.

Links

Summary of Evidence

Hereditary breast and ovarian cancer (HBOC) is an inherited form of cancer. About 1 in 400-500 people in the general population has a BRCA1 or BRCA2 mutation. The prevalence of mutations is higher in people of Norwegian, Dutch, Greenland, or Icelandic ethnicity. The prevalence of BRCA mutations varies among African Americans, Hispanics, Asian Americans, and non-Hispanic whites. About 1 in 40 people of Ashkenazi Jewish ancestry has a BRCA1 or BRCA2 mutation. Most of the risk in the Ashkenazi Jewish population is associated with three common founder mutations, two of which are in the BRCA1 gene and one in the BRCA2 gene. People with a BRCA mutation have an increased risk of various types of cancer. Up to 10% of all breast cancer and 15% of all ovarian cancer is associated with an inherited gene mutation, with BRCA1 and BRCA2 accounting for about 20-25% of all hereditary cases. As additional genes and cancers are linked to the risk of developing breast and/or ovarian cancer, multigene panel testing has increased.

Rationale

Individuals and/or families with HBOC may have the following histories of cancer or other characteristics:

- breast cancer ata young age, typically under 50
- multiple breast primaries in one individual and/or family memebers (on the same side of the family)
- triple negative breast cancer (ER-, PR-, HER2-)
- ovarian, fallopian tube, or primary peritoneal can cer
- metastatic (radiographic evidence of or biopsy-proven disease)
- intraductal/cribriform histology, high-risk, or very-high-risk group prostate cancer as defined by NCCN
- male breast cancer
- exocrine pancreatic cancer
- multiple cases of breast and/or ovarian cancer in a family or one individual with breast and ovarian cancer
- a confirmed diagnosis of prostate cancer and a family history of ovarian, breast, prostate, or pancreatic cancer
- previously identified germline BRCA1 or BRCA2 mutation in the family, or
- any of the above with Ashkenazi Jewish ancestry.

HBOC due to a mutation in BRCA1 or BRCA2 is an autosomal dominant disorder. In autosomal dominant inheritance, individuals have 2 copies of the gene and only one mutation is required to cause disease. When a parent has a mutation, each offspring has a 50% risk of inheriting the mutation. Males and females are equally likely to be affected.. The diagnosis is established by the identification of a pathogenic mutation in a gene associated with HBOC. Screening and prevention options are available to specifically address the increased risk of these cancers in a person with a BRCA mutation. BRCA testing may include known familial mutation anslysis. Ashkenazi Jewish founder mutation analysis, next generation sequencing, and/or deletion/duplication analysis.

The American College of Medical Genetics and Genomics (2019) issued a statement regarding BRCA1/2 testing in all individuals with breast cancer: “With the advances in sequencing technologies and increasing access to and expanding indications for genetic testing, it remains critical to ensure that implementation of testing is based on evidence. Currently, there is insufficient evidence to recommend genetic testing for BRCA1/2 alone or in combination with multi-gene panels for all breast cancer patients.”

The American Society of Breast Surgeons (2019) published a consensus guideline on genetic testing for hereditary breast cancer. They stated the following: "Breast surgeons, genetic counselors, and other medical professionals knowledgeable in genetic testing can provide patient education and counseling and make recommendations to their patients regarding genetic testing and arrange testing. When the patient’s history and/or test results are complex, referral to a certified genetic counselor or genetics professional may be useful. Genetic testing is increasingly provided through multi-gene panels. There are a wide variety of panels available, with different genes on different panels. There is a lack of consensus among experts regarding which genes should be tested in different clinical scenarios. There is also variation in the degree of consensus regarding the understanding of risk and appropriate clinical management of mutations in some genes. Genetic testing should be made available to all patients with a personal history of breast cancer. Recent data supports the idea that genetic testing should be offered to each patient with breast cancer (newly diagnosed or with a personal history). If genetic testing is performed, such testing should include BRCA1/BRCA2 and PALB2, with other genes as appropriate for the clinical scenario and family history. For patients with newly diagnosed breast cancer, identification of a mutation may impact local treatment recommendations (surgery and potentially radiation) and systemic therapy. Additionally, family members may subsequently be offered testing and tailored risk reduction strategies. Patients who had genetic testing previously may benefit from updated testing. Every patient being seen by a breast surgeon, who had genetic testing in the past and no pathogenic variant was identified, should be re-evaluated and updated testing considered. In particular, a patient who had negative germline BRCA1 and 2 testing, who is from a family with no pathogenic variants, should be considered for additional testing. Genetic testing performed prior to 2014 most likely would not have had PALB2 or other potentially relevant genes included and may not have included testing for large genomic rearrangements in BRCA1 or BRCA2. Genetic testing should be made available to patients without a history of breast cancer who meet NCCN guidelines. Unaffected patients should be informed that testing an affected relative first, whenever possible, is more informative than undergoing testing themselves. When it is not feasible to test the affected relative first, then the unaffected family member should be considered for testing if they are interested, with careful pre-test counseling to explain the limited value of “uninformative negative” results. It is also reasonable to order a multi-gene panel if the family history is incomplete (i.e., a case of adoption, patient is uncertain of exact type of cancer affecting family members, among others) or other cancers are found in the family history, as described above."

The National Comprehensive Cancer Network (2023) evidence and consensus-based guidelines addressed test indications for BRCA testing. These guidelines included recommendations related to unaffected individuals with a family history of cancer, those with a known mutation in the family, those with a personal history of breast cancer, exocrine pancreatic cancer, ovarian cancer, a confirmed diagnosis of prostate cancer, and men with breast cancer. They take into consideration age of diagnosis, tumor pathology, degree of relationship, and Ashkenazi Jewish ancestry.

The U.S. Preventive Services Task Force (2019) recommendations addressed women with a personal and/or family history of breast cancer and/or ovarian, tubal, or primary peritoneal cancer. The USPSTF guideline recommended: “When a woman's personal or family history of cancer is consistent with a BRCA1/2 mutation: “that primary care clinicians assess women with a personal or family history of breast, ovarian, tubal, or peritoneal cancer or who have an ancestry associated with breast cancer susceptibility 1 and 2 (BRCA1/2) gene mutations with an appropriate brief familial risk assessment tool. Women with a positive result on the risk assessment tool should receive genetic counseling and, if indicated after counseling, genetic testing. When a woman's personal or family history is not consistent with a BRCA1/2 mutation: “recommends against routine risk assessment, genetic counseling, or genetic testing for women whose personal or family history or ancestry is not associated with potentially harmful BRCA1/2 gene mutations. Genetic risk assessment and BRCA1/2 mutation testing is a multistep process that begins with identifying patients with family or personal histories of breast, ovarian, tubal, or peritoneal cancer; family members with known harmful BRCA1/2 mutations; or ancestry associated with harmful BRCA1/2 mutations. Risk for clinically significant BRCA1/2 mutations can be further evaluated with genetic counseling by suitably trained health care clinicians, followed by genetic testing of selected high-risk individuals and posttest counseling about results. The type of mutation analysis required depends on family history. Individuals from families with known mutations or from ancestry groups in which certain mutations are more common (eg, Ashkenazi Jewish founder mutations) can be tested for these specific mutations."

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Blue Cross and Blue Shield of Minnesota medical policies apply generally to all Blue Cross and Blue Plus plans and products. Benefit plans vary in coverage and some plans may not provide coverage for certain services addressed in the medical policies. When determining coverage, reference the member's specific benefit plan, including exclusions and limitations.

Medicaid products may provide different coverage for certain services, which may be addressed in different policies. For Minnesota Health Care Program (MHCP) policies, please consult the MHCP Provider Manual website.

Medicare products may provide different coverage for certain services, which may be addressed in different policies. For Medicare National Coverage Determinations (NCD), Local Coverage Determinations (LCD), and/or Local Coverage Articles, please consult CMS, National Government Services, or CGS websites.

Note that services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial of claims may result if criteria are not met.

Blue Cross and Blue Shield of Minnesota reserves the right to revise, update and/or add to its medical policies at any time without notice. Codes listed on this policy are included for informational purposes only and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

Acknowledgements:

ATTENTION: If you speak English, language assistance services, free of charge, are available to you. Call the number on the back of your ID card (TTY: 711).

ATENCIÓN: Si usted habla español, servicios de asistencia lingüística, de forma gratuita, están disponibles para usted. Llame al número en la parte posterior de su tarjeta de identificación (TTY: 711).

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알림: 한국어를 사용하시는 분들을 위해 무료 통역이 제공됩니다. ID 카드 뒷면에 있는 번호로 전화하십시오 (TTY: 711).

ATENSYON: Kung nagsasalita ka ng Tagalog, may makukuha kang mga libreng serbisyong tulong sa wika. Tawagan ang numero sa likod ng iyong ID card (TTY: 711).

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تنبيه: إذا كنت تتحدث اللغة العربية، فهناك خدمات المعاونة في اللغة المجانية متاحة لك. اتصل بالرقم الموجود خلف بطاقة هويتك (جهاز الاتصال لذوي صعوبات السمع والنطق: 711).

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ACHTUNG: Wenn Sie Deutsch sprechen, steht Ihnen unsere fremdsprachliche Unterstützung kostenlos zur Verfügung. Rufen Sie dazu die auf der Rückseite Ihres Versicherungsausweises (TTY: 711) aufgeführte Nummer an.

注：日本語が母国語の方は言語アシスタンス・サービスを無料でご利用いただけます。ID カードの裏に明記されている番号に電話をおかけください (TTY: 711)。

توجه : اگر شما به زبان **فارسی** صحبت می کنید، خدمات کمک زبان، به صورت رایگان، در دسترس شماست. با شماره واقع در پشت کارت شناسایی خود (TTY: 711) تماس بگیرید.