BlueCross BlueShield Minnesota

Blue Cross Blue Shield of Minnesota Medical Policy

Medical Policy:	VI-56-013
Topic:	Genetic Cancer Susceptibility Panels
Section:	Laboratory
Effective Date:	January 27, 2025
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Genetic testing for cancer susceptibility involves identifying well-characterized genetic variants based on clinical evidence that has identified genes associated with a high risk of heritable cancer. Genes included in a panel must be relevant to the personal and family history of the individual being tested, clinically actionable, and provide necessary information for clinical decision making.

The majority of commercially available genetic test panels use next-generation sequencing (NGS) or technologies that allow for the analysis of multiple genes at one time. Some of these panels address types of cancer that have a well-defined hereditary component, including breast, ovarian, endometrial, colon, pancreatic and renal cancers. Comprehensive panels are also available that include genetic variants associated with moderate, low, or unknown levels of risk of developing cancer. A limited number of variants are associated with higher risk of well-defined cancer syndromes for which clinical management guidelines are available. Clinical management recommendations for the genetic variants associated with low-to-intermediate or unknown risk of cancer are generally not standardized and could potentially lead to harm, as high rates of variants of uncertain significance have been reported with the use of these panels.

Definitions

Genetic Testing: Genetic testing involves the analysis of chromosomes, DNA, RNA, genes, or gene products to detect inherited (germline) or noninherited (somatic) genetic variants related to disease or health.

Pedigree: Genetic counseling often includes development of a pedigree, which is a diagram of genetic relationships and medical history of a family to determine inheritance patterns of genetic conditions. A pedigree used for purposes of risk assessment for a condition generally include a minimum of 3 generations.

- **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.

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: Testing for hereditary breast and ovarian cancer syndrome (*BRCA1* and *BRCA2* genes) including related panel testing is not addressed in this policy. Please refer to policy VI-16: Genetic Testing for Hereditary Breast and/or Ovarian Cancer.

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

Multigene cancer susceptibility panel testing may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria for genetic counseling are met along with criteria in section II:

- 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*;

    - **OR**
    - An American Board of Medical Genetics or American Board of Genetic Counseling certified or certification eligible Genetic Counselor who has no financial relationship with the testing laboratory*; **OR**
    - 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*; **OR**
    - Board certified or board eligible medical specialist who is trained in the treatment of the genetic condition that is being tested, 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 or parent/guardian of individual:
        - When clinically appropriate, options for surveillance and risk reduction (e.g., reproductive decision-making, lifestyle, preventive measures) 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 the laboratory test itself.

II. Multigene Cancer Susceptibility Panels

Multigene cancer susceptibility panels may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when criteria in Section I and **ALL** of the following are met:

- The genetic disorder is associated with one or more cancers; **AND**
- The risk of cancer from the genetic disorder cannot be identified through biochemical or other testing; **AND**
- The panel is limited to genes that have proven utility for clinical management of the specific cancer or cancer syndrome in question; **AND**
- Results of testing will impact the medical management of the individual (e.g., increased screening or surveillance, initiation of treatment); **AND**
- No previous germline cancer susceptibility testing or results of previous testing were incomplete.

III. Experimental/Investigative Testing

Multigene cancer susceptibility panels are considered **EXPERIMENTAL/INVESTIGATIVE** for all other indications, including but not limited to the following, due to a lack of clinical evidence demonstrating an impact on improved health outcomes:

- Panel includes genes for which there is no proven utility for clinical management of a specific cancer or cancer syndrome. These include but are not limited to:
    - CancerNext®/CancerNext® Expanded
    - ColoNext®
    - Color Extended
    - Color Hereditary Cancer Test
    - Counsyl Reliant™ Cancer Screen
    - CustomNext-*Cancer*®
    - CustomNext + RNA: Lynch (MLH1, MSH2, MSH6, PMS2)
    - GeneDx Comprehensive Common Cancer Panel
    - genTrue™ Hereditary Cancer Test
    - iGene Cancer Panel
    - Invitae Multi-Cancer Panel
    - mRNA CancerDetect™
    - MyVantage Hereditary Comprehensive Cancer Panel
    - NxGen MDx Hereditary Cancer Panel
    - OncoGeneDx Comprehensive Cancer Panel
    - OncoGeneDx High/Moderate Risk Panel
    - Oseq Hereditary Cancer Panel
    - University of Washington ColoSeq™ Lynch and Polyposis Gene Panel
    - RenalNext™
    - +RNAinsight for BRCA1/2
    - +RNAinsight for BreastNext
    - +RNAinsight for CancerNext
    - +RNAinsight for ColoNext
    - +RNAinsight for GYNPlus
    - +RNAinsight for OvaNext
    - +RNAinsight for PALB2
    - +RNAinsight for ProstateNext
    - Sema4 Signal Hereditary Cancer Panel
    - VistaSeq Hereditary Cancer Panel

- Testing performed in the absence of pretest genetic counseling by a cancer genetics professional independent of the laboratory performing the test
- Panel is offered as a direct access (also known as direct to consumer) test
- Panel testing in the general population as a screening tool
- All other uses of genetic cancer susceptibility panel testing which do not meet criteria as stated above

Procedure Codes

0048U 0101U 0129U 0238U 0296U 0297U 0298U 0299U 0300U 0342U 81432 81435 81437 81445 81449 81450 81451 81479 81599 Multiple codes apply

Denial Statements

No additional statements

Links

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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).

请注意：如果您说中文，可向您提供免费语言协助服务。

请拨打您的身份证背面的号码（TTY：711）。

CHÚ Ý: Nếu quý vị nói tiếng Việt, chúng tôi cung cấp dịch vụ hỗ trợ ngôn ngữ miễn phí cho quý vị. Xin gọi số điện thoại ở mặt sau thẻ ID của quý vị (TTY: 711).

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).

ВНИМАНИЕ: Если вы говорите по-русски, вы можете воспользоваться бесплатными услугами языковой поддержки. Позвоните по номеру, указанному на обороте вашей идентификационной карты (номер для текст-телефонных устройств (TTY): 711).

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).

ATTENTION: Si c'est créole que vous connaissez, il y a un certain service de langues qui est gratis et disponible pour vous-même. Composez le numéro qui est au dos de votre carte d'identité. (TTY: 711).

ATTENTION: Si vous parlez français, les services d'assistance linguistique, gratuitement, sont à votre disposition. Appelez le numéro au dos de votre carte d'identité (TTY: 711).

UWAGA: Dla osób mówiących po polsku dostępna jest bezpłatna pomoc językowa. Zadzwoń pod numer podany na odwrocie karty ubezpieczenia zdrowotnego (TTY: 711).

ATENÇÃO: Se a sua língua é o português, temos atendimento gratuito para você no seu idioma. Ligue para o número no verso da sua identidade (TTY: 711).

ATTENZIONE: se parla italiano, per lei sono disponibili servizi di assistenza linguistica a titolo gratuito. Contatti il numero riportato sul retro della sua carta d'identità (TTY: 711).

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.