

II. FACTUAL BACKGROUND

The Petitioner has a personal history of melanoma in 2021 and a family history of breast cancer. The Petitioner's physician recommended the CancerNext test panel to assess their risk for other cancers. On March 28, 2024, the Petitioner's blood sample was processed by Ambry Genetics Corporation for the CancerNext test panel. The amount charged was \$2,000.00. BCBSM denied coverage on the basis that the test is experimental or investigational and therefore excluded from the terms of the Petitioner's coverage.

The Petitioner appealed the denial through BCBSM's internal grievance process. At the conclusion of that process, BCBSM issued a final adverse determination dated January 7, 2025, affirming its coverage

III. ANALYSIS

Respondent's Argument

In its final adverse determination, BCBSM wrote:

You are appealing the denial of payment for genetic testing performed on March 28, 2024. The documentation submitted for review indicates your provider ordered the CancerNext panel genetic (hereditary risk factors) blood test because you have a personal history of melanoma (skin cancer) and family history of breast cancer. This test is a panel of 34 genes that uses next generation sequencing (NGS, a method to assess multiple genes at one time) which proposes to identify inherited (passed down from family) risks for multiple types of cancers.

According to our medical policy, "Genetic, Molecular and Other Tests - Experimental/Investigational Status", the CancerNext test is considered experimental and investigational. There is not enough clinical data to support the clinical usefulness of this testing or that it contributes to better health outcomes. Therefore, the denial is maintained.

You are covered by the [REDACTED] group health care plan. A summary of your benefit coverage can be found in the *Member Handbook for Active Employees/COBRA* of [REDACTED]. Benefit exclusions are listed on pages 62 and 63 of the *Handbook*.

"Services, care, devices or supplies considered experimental or investigative" is included in the list of exclusions on page 63 of the *Handbook*.

Because the genetic laboratory testing you received is considered experimental and investigational, as explained above by the Medical Director, payment cannot be approved.

Petitioner's Argument

In the request for review, the Petitioner wrote:

I am writing to appeal the denial of my claim for lab 'tests performed on March 28, 2024, by Ambry Genetics. My medical records clearly demonstrate the need for such tests.

Dr. [REDACTED] ordered the BRCA testing done due to patient history of melanoma and abnormal paps, as well as family history of breast cancer. BRCA is able to help identify people with a higher risk of developing certain cancers and help physicians to take steps to reduce that risk or detect cancer early.

I am attaching a copy of the Office Clinic Notes in which Dr. [REDACTED] has specified her reasons for ordering said test.

I respectfully request a review of my claim and a reconsideration of the denial decision.

In office clinic notes accompanying the request for external review, the Petitioner's physician wrote:

She has a family history of cancer. She had melanoma in 2021 and her sister BCA in 40s ... – BRCA testing done today.

Director's Review

The Director assigned an independent review organization (IRO) to evaluate BCBSM's medical policy criteria and help determine whether the CancerNext test panel was experimental or investigational for treating the Petitioner's condition. This review is required by section 11(7) of the Patient's Right to Independent Review Act, MCL 550.1911(7).

The IRO reviewer is a physician who is board certified in obstetrics & gynecology, with a subspecialty of reproductive endocrinology and infertility, and has been in active practice for 42 years. The IRO reviewer's report included the following analysis and recommendation:

- 1. Are the plan's criteria titled "Genetic, Molecular and Other Tests – Experimental/Investigational Status" that denied coverage for the CancerNext test as experimental/investigational consistent with the standard of care?**

Yes. The health plan's criteria that denied coverage for the CancerNext test are consistent with the standard of care.

- 2. If they are consistent, does the member meet these criteria?**

No. The patient does not meet the plan's coverage criteria for the CancerNext test.

Reviewer's Clinical Rationale for the Decision:

The National Comprehensive Cancer Network (NCCN), in its guidelines, states:

Overview of multi-gene testing: The recent introduction of multi-gene testing for hereditary forms of cancer has rapidly altered the clinical approach to testing at-risk patients and their families.

Based on next-generation sequencing technology, these tests simultaneously analyze a set of genes that are associated with a specific family cancer phenotype or multiple phenotypes.

Patients who have a personal or family history suggestive of a single inherited cancer syndrome are most appropriately managed by genetic testing for that specific syndrome. When more than one gene can explain an inherited cancer syndrome, then multi-gene testing may be more efficient and/or cost effective.

There may be a role for multi-gene testing in individuals who have tested negative (indeterminate) for a single syndrome, but whose personal or family history remains suggestive of an inherited susceptibility.

As commercially available tests differ in the specific genes analyzed (as well as classification of variants and many other factors), choosing the specific laboratory and test panel is important.

Multi-gene testing can include “intermediate” penetrant (moderate-risk) genes. For many of these genes, there are limited data on the degree of cancer risk and there are no clear guidelines on risk management for carriers of mutations. Not all genes included on available multi-gene tests are necessarily clinically actionable. As is the case with high-risk genes, it is possible that the risks associated with moderate-risk genes may not be entirely due to that gene alone, but may be influenced by gene/gene or gene/environment interactions. In addition, certain mutations in a gene may pose higher or lower risk than other mutations in that same gene.

Therefore, it may be difficult to use a known mutation alone to assign risk for relatives. In many cases, the information from testing for moderate penetrance genes does not change risk management compared to that based on family history alone. Mutations in many breast cancer susceptibility genes involved in DNA repair may be associated with rare autosomal recessive conditions. There is an increased likelihood of finding variants of unknown significance when testing for mutations in multiple genes. It is for these and other reasons that multigene testing is ideally offered in the context of professional genetic expertise for pre- and post-test counseling”.

This patient has a family history of breast cancer. Multigene testing is not indicated per NCCN guidelines as there is no evidence that the patient has a family history or personal medical history of documented BRCA gene positivity. Therefore, the testing is not medically necessary by the standard of care.

The health plan considers the CancerNext test experimental/investigational, stating that there is not enough clinical data to support the clinical usefulness of the test and to contribute to better health outcomes. This is consistent with current standards of care.

The IRO reviewer recommended that the Director uphold BCBSM's denial of coverage.

The Director is not required to accept the IRO's recommendation. *Ross v Blue Care Network of Michigan*, 480 Mich 153 (2008). However, the recommendation is afforded deference by the Director. In a decision to uphold or reverse an adverse determination, the Director must cite "the principal reason or reasons why the director did not follow the assigned independent review organization's recommendation." MCL 550.1911(18)(b). The IRO's review is based on extensive experience, expertise, and professional judgment. In addition, the IRO's recommendation is not contrary to any provision of the Petitioner's certificate of coverage. MCL 550.1911(17).

The Director, discerning no reason why the IRO's recommendation should be rejected, finds that the CancerNext test is experimental or investigational, therefore, it is not a covered benefit under the Petitioner's benefit plan.

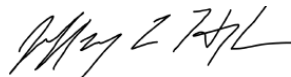
IV. ORDER

The Director upholds Blue Cross Blue Shield of Michigan's January 7, 2025, final adverse determination.

This is a final decision of an administrative agency. Under MCL 550.1915, any person aggrieved by this order may seek judicial review no later than 60 days from the date of this order in the circuit court for the county where the covered person resides or in the circuit court of Ingham County. A copy of the petition for judicial review should be sent to the Department of Insurance and Financial Services, Office of Appeals, Legal Research, and Market Regulation, P.O. Box 30220, Lansing, MI 48909-7720.

Anita G. Fox
Director

For the Director:



Jeffrey Hayden
Special Deputy Director