

**STATE OF MICHIGAN**  
**DEPARTMENT OF INSURANCE AND FINANCIAL SERVICES**  
**Before the Director of Insurance and Financial Services**

**In the matter of:**

████████████████████

**Petitioner**

v

**File No. 148635-001**

**Blue Cross Blue Shield of Michigan**

**Respondent**

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**Issued and entered**  
**this 4<sup>th</sup> day of August 2015**  
**by Randall S. Gregg**  
**Special Deputy Director**

**ORDER**

**I. PROCEDURAL BACKGROUND**

The Patient's Right to Independent Review Act (MCL 550.1901 *et seq.*) authorizes the Director of Insurance and Financial Services to review denials of coverage for health care services. These external reviews are initiated by policyholders or an authorized representative once a coverage denial has been reviewed by the insurer in its internal grievance process.

On July 1, 2015, ██████████ authorized representative of ██████████ (Petitioner), filed a request with the Department of Insurance and Financial Services for an external review under the Patient's Right to Independent Review Act. ██████████ is an employee of the company which performed the test. The request concerned a denial of coverage for a medical test ordered by the Petitioner's doctor.

The Petitioner receives health care benefits through a group plan underwritten by Blue Cross Blue Shield of Michigan (BCBSM). The Petitioner's health care benefits are described in BCBSM's *Community Blue Group Benefits Certificate and Rider GLE-1 General Limitations and Exclusions*.

On July 10, 2015, after a preliminary review of the information submitted, the Director accepted the request. The medical issues in this case were evaluated by an independent review organization which provided its analysis and recommendation to the Director on July 24, 2015.

## II. FACTUAL BACKGROUND

The Petitioner has a history of colon cancer. Her physician recommended Oncotype DX Colon Cancer Assay test to help determine the best course of treatment post-surgically. The test was performed by [REDACTED] company which is the sole provider of this test. [REDACTED] is not a member of the BCBSM provider network. The cost of the test was \$4,030.00.

In denying coverage, BCBSM ruled that the test was experimental/investigational for the Petitioner's condition. The Petitioner appealed the denial through BCBSM's internal grievance process. BCBSM issued its final adverse determination on July 10, 2015. The Petitioner now seeks review of that determination from the Director.

## III. ISSUE

Is the Oncotype Dx colon cancer test experimental or investigational for treatment of the Petitioner's condition?

## IV. ANALYSIS

### BCBSM's Argument

In its July 10, 2015 final adverse determination, BCBSM wrote:

At the time that the services were rendered, [Petitioner] was covered under the *Community Blue Group Benefits Certificate*. Page 7.10, **Section 7: The Language of Health Care**, explains that experimental treatment is considered treatment that has not been scientifically proven to be as safe and effective for treatment of the patient's conditions as conventional treatment. Also, it explains that sometimes experimental treatment is referred to as investigational.

Further, *Rider GLE-1 General Limitations and Exclusions*, which amends the *Certificate*, clearly indicates that we do not pay for experimental treatment or services related with experimental treatment.

To ensure all consideration was given to you, a board-certified M.D. in Internal Practice reviewed your claim, your appeal, and [Petitioner's] health care plan benefits for [BCBSM]. Our medical consultant determined:

All the provided information was reviewed. You had stage II colon cancer with some poor prognostic features, like high grade and lack of greater than 10 [notes] identified. Your provider ordered Oncotype Dx test for determining the management. This testing is considered experimental as the utility of this test in improving the long term outcome

has not been established, particularly comparing with current clinical approach to decision making (histologic features of aggressiveness, lack of greater than 10 [notes] identified etc.). We used [BCBSM] medical policy, *Genetic Testing – Multigene Expression Assays for Predicting Recurrence in Colon Cancer* for this decision.

### Petitioner's Argument

In a June 19, 2015 communication to her authorized representative, the Petitioner wrote:

Thank you for helping with the appeal for payment of the Oncotype Dx colon test. I can tell you that the results of the test changed the recommended follow up chemotherapy treatment for me. I was slated for the five days in a row, once a month treatment over six months, which would have been harder than the once, every other week (12 treatments over six months) that I had.

My oncologist told me that they used this type of tissue testing regularly for breast cancer so I doubt it can be called "experimental."

In a letter of appeal to BCBSM dated February 5, 2015, the Petitioner's authorized representative offered reasons why the test should be covered:

[Petitioner] was diagnosed with early stage colon cancer for which she underwent surgery. Knowing important medical decisions needed to be made subsequent to this diagnosis, [her doctor] ordered the Oncotype DX colon cancer assay for the clinically-validated information it would yield and to help guide and ensure that the most appropriate overall treatment decision would be rendered for [Petitioner].

\* \* \*

One of the most crucial and irrevocable decisions that must be made following surgery is how aggressively to treat the patient with systemic, adjuvant therapy. Presently, those patients most likely to benefit from chemotherapy are difficult to identify by standard clinical and pathological risk factors and the selection of patients is often subjectively based. In the absence of an accurate assessment of disease recurrence, stage two colon cancer patients are being both over treated and under treated beyond surgery because it is difficult to identify those with a high risk of disease recurrence.

██████████ believes the Oncotype DX colon cancer test will allow physicians, for the first time, to go beyond the limited set of traditional clinical and pathological markers currently in use and informative for the majority of patients. The Oncotype DX colon cancer assay represents the second successful application of ██████████ unique technology, building on the widely adopted and Medicare coverage approved, Oncotype DX breast cancer assay. For

the colon cancer program, [REDACTED] and its collaborators at the National Surgical Adjuvant Breast and Bowel Project (NSABP), the Cleveland Clinic and the QUASAR study group used the same rigorous clinical development strategy and standardized quantitative technology designed for the company's Oncotype DX breast cancer test.

\* \* \*

The patient should not be penalized by denying her coverage of the Oncotype DX colon cancer assay, particularly when her physician feels Oncotype DX is medically indicated and would assist in determining important, life-altering, adjuvant, treatment decisions. In denying coverage [BCBSM] is essentially disallowing the patient additional medical information regarding her colon cancer.

### Director's Review

As noted in the final adverse determination, the *Community Blue* certificate and related rider exclude coverage for experimental and investigational medical services. To evaluate the question of whether the Oncotype DX test is experimental or investigational in the treatment of Petitioner's condition, the Director presented the issue to an independent review organization (IRO) for analysis as required by section 11(6) of the Patient's Right to Independent Review Act, MCL 550.1911(6). The IRO reviewer is a physician who is board certified in medical oncology and has been in active practice for more than 12 years. The reviewer is familiar with the medical management of patients with the Petitioner's condition. The IRO reviewer's report included the following analysis and recommendation:

The National Comprehensive Cancer Network Guidelines state that the Oncotype DX colon cancer test gives information about risk of occurrence...[T]he panel questions the value of the added information this test gives compared with that given by known prognostic parameters like microsatellite instability and grade...[T]here is no evidence that the Oncotype DX colon cancer test adds to the predictive value of ascertaining the benefit from chemotherapy...[A]s this member was deemed to be at high risk, chemotherapy should have been, and was given and the use of Oncotype DX test was not necessary.

Pursuant to the information set forth and available documentation...the Oncotype DX cancer test performed on 1/16/14 was experimental/investigational for diagnosis and treatment of the member's condition.

While the Director is not required in all instances to accept the IRO's recommendation, the recommendation is afforded deference by the Director. *Ross v Blue Care Network of Michigan*, 480 Mich 153 (2008). 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(16)(b). The IRO's

analysis 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. See MCL 550.1911(15).

The Director can discern no reason why the IRO's recommendation should be rejected in the present case. The Director finds that the Oncotype Dx test is experimental/investigational in the treatment of the Petitioner's condition. BCBSM's denial of coverage is consistent with terms of the *Community Blue* certificate.

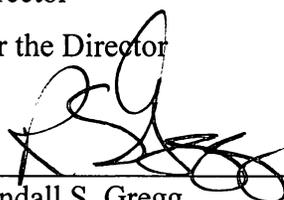
#### V. ORDER

BCBSM's final adverse determination of July 10, 2015 is upheld. BCBSM is not required to provide coverage for the Petitioner's January 16, 2014 Oncotype DX test.

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 General Counsel, Post Office Box 30220, Lansing, MI 48909-7720.

Patrick M. McPharlin  
Director

For the Director



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Randall S. Gregg  
Special Deputy Director