

**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. 154399-001

Blue Cross Blue Shield of Michigan  
Respondent

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Issued and entered  
this 4<sup>th</sup> day of August 2016  
by Randall S. Gregg  
Special Deputy Director

**ORDER**

**I. PROCEDURAL BACKGROUND**

On June 30, 2016, ██████████ (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, MCL 550.1901 *et seq.* On July 8, 2016, after a preliminary review of the information submitted, the Director accepted the request.

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 *Simply Blue Group Benefits Certificate LG*.

The medical issues in this case were evaluated by an independent review organization which provided its analysis and recommendation to the Director on July 21, 2016.

**II. FACTUAL BACKGROUND**

The Petitioner is 45 years old and has cancer. In October 2015, her physician ordered a panel of tests known as "FoundationOne" performed by Foundation Medicine, a Massachusetts company. The charges for the testing totaled \$5,800.00.

BCBSM denied coverage for the testing, ruling that it was experimental/investigational. The Petitioner appealed the denial through BCBSM's internal grievance process. BCBSM issued a final adverse determination on May 25, 2016 affirming its denial. The Petitioner now seeks review of that determination from the Director.

### III. ISSUE

Is the FoundationOne test experimental or investigational in the Petitioner's treatment?

### IV. ANALYSIS

#### BCBSM's Argument

In its final adverse determination, BCBSM stated that the Petitioner's appeal had been reviewed by a medical consultant, board-certified in internal medicine, who consulted BCBSM's medical policy "Molecular Panel Testing of Cancers to Identify Targeted Therapies" and concluded that the testing is experimental/investigational because "[t]he evidence is insufficient to draw conclusions regarding the clinical utility of this testing."

#### Petitioner's Argument

In the request for an external review, the Petitioner wrote:

My doctor wanted this test done because there are limited treatment options for me and he wanted to provide me with the best and more options. I'm requesting an external review to see if any of the claims can be paid. The testing that was done was to test for genetic mutations of my cancer in the hopes for a targeted therapy. The FoundationOne test proved ultimately helpful since I was able to find a clinical trial and am now enrolled in that treatment.

#### Director's Review

The question of whether the FoundationOne testing, as provided to the Petitioner, is investigational or experimental was presented by the Director 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 oncology and has been in active practice for more

than 10 years. The reviewer is familiar with the medical management of patients with the Petitioner's condition. The reviewer's report included the following analysis and recommendation:

The results of the consultant's review indicate that this case involves a 45 year-old female who has a history of stage IV metastatic vulvar carcinoma. At issue in this appeal is whether the FoundationOne testing performed on 10/18/15 was experimental/investigational for diagnosis and treatment of the member's condition.

The member has been treated with chemotherapy involving Carboplatin and Taxol. The member has also receive radiation therapy in combination with 5FU. FoundationOne testing was obtained to look for an actionable mutation to help direct further treatment.

[A]ccording to National Comprehensive Cancer Network (NCCN) Guidelines, regimens that can be used for vulvar cancer include cisplatin and navelbine. (NCCN Guidelines: Vulvar Cancer. v.1. 2016.)...[N]avelbine as a single agent can be considered....[A]ctionable mutations in vulvar cancer are deemed experimental, for example a HER-2/neu mutation or overexpression would not warrant Herceptin outside of a clinical trial. Therefore...the information provided by FoundationOne testing would be considered experimental in nature for this member's diagnosis.

Pursuant to the information set forth above and available documentation...the FoundationOne testing performed on 10/18/15 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, discerning no reason why the IRO's recommendation should be rejected in the present case, finds that the FoundationOne testing provided the Petitioner on October 18, 2015, is experimental/investigational and, for that reason, is not a covered benefit.

**V. ORDER**

BCBSM's final adverse determination is upheld. BCBSM is not required to provide coverage for the Petitioner's October 18, 2015 FoundationOne 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