

**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. 151468-001-SF**

**City of Troy, Plan Sponsor**

**and**

**Blue Cross Blue Shield of Michigan, Plan Administrator**

**Respondents.**

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**Issued and entered**  
this 25<sup>th</sup> day of January 2016  
**by Randall S. Gregg**  
**Special Deputy Director**

**ORDER**

**I. PROCEDURAL BACKGROUND**

██████████ (Petitioner) was denied coverage for genomic testing by his health plan. On December 23, 2015, he filed a request with the Director of Insurance and Financial Services for an external review of that denial under Public Act No. 495 of 2006 (Act 495), MCL 550.1951 *et seq.* On January 5, 2016, after a preliminary review of the information submitted, the Director accepted the request.

The Petitioner receives health care benefits through a group plan sponsored by the City of Troy, a self-funded government health plan as defined in Act 495. Blue Cross Blue Shield of Michigan (BCBSM) administers the plan. The Director immediately notified BCBSM of the external review request and asked for the information it used to make the plan's final adverse determination. BCBSM's response was received on January 12, 2016.

Section 2(2) of Act 495, MCL 550.1952(2), authorizes the Director to conduct this external review as though the Petitioner were a covered person under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.*

The case was assigned to an independent review organization (IRO) to address the medical issues. The IRO provided its analysis and recommendation to the Director on January 19, 2016.

## II. FACTUAL BACKGROUND

The Petitioner's health care benefits are described in BCBSM's *Community Blue Group Benefits Certificate ASC*<sup>1</sup> (the certificate).

The Petitioner has a history of renal carcinoma with metastasis to the liver. As part of his care he received FoundationOne genomic testing on December 23, 2014. The purpose of the testing is to help physicians make treatment decisions for cancer patients. The charge for the test was \$5,800.00.

BCBSM, acting for the plan, denied coverage for the testing, saying it was investigational or experimental for the treatment of the Petitioner's condition and therefore not a covered benefit. The Petitioner appealed the denial through BCBSM's internal grievance process. At the conclusion of that process BCBSM issued a final adverse determination dated November 11, 2015, affirming its denial. The Petitioner now seeks review of that final adverse determination from the Director.

## III. ISSUE

Was the FoundationOne genomic testing investigational for the treatment of the Petitioner's condition?

## IV. ANALYSIS

### Petitioner's Argument

On the external review request form the Petitioner said:

Because of the rarity of my cancer there are few treatments available. I have exhausted the treatments that have been known to have limited success. Because of genetic testing from Foundation Medical I am receiving a treatment that we did not know about. I have a "Pecoma" or EAML cancer. If you check the rarity of the cancer it is clear that genetic testing was necessary.

### BCBSM's Argument

In its final adverse determination, BCBSM explained the reasons for its denial to the Petitioner's representative:

... After review, I am unable to approve further payment. The BCBSM/BCN Joint Uniform Medical Policy Committee (JUMP) has determined that FoundationOne testing . . . is considered an investigational and / or experimental treatment. Because experimental and investigational treatments are not covered under [the Petitioner's] plan, we are unable to approve payment for these laboratory services.

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<sup>1</sup> BCBSM form no. 457F, effective 07/14.

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A board-certified D.O. in Internal Medicine has also reviewed the claims, your appeal, and [the Petitioner's] health care plan benefits for BCBSM. The reviewer stated:

According to the [BCBSM] medical policy "Genetic Testing-Molecular Panel Testing of Cancers to Identify Targeted Therapies," the peer-reviewed medical literature has not demonstrated the clinical utility of molecular panel testing of cancers to identify targeted therapies. Therefore, this service is experimental / investigational. Therefore, we are unable to approve this testing.

I do understand that genetic testing was recommended as a part of [the Petitioner's] treatment. However, BCBSM must administer benefits in accordance with the terms of [his] group coverage. I am unable to make an exception on his behalf, and payment cannot be approved. Additionally, it appears that the related services on these claims have been paid in error. While no recall of payment will be initiated at this time, please note that any charges that have been paid in error may be subject to recall in the future.

#### Director's Review

The plan's denial was based on this exclusion in the certificate (p. 132):

##### ***Experimental Treatment***

##### **Services That Are Not Payable**

We do not pay for experimental treatment (including experimental drugs or devices) or services related to experimental treatment. . . .

"Experimental treatment" is defined in the certificate (p. 147) as

[t]reatment that has not been scientifically proven to be as safe and effective for treatment of the patient's conditions as conventional treatment. Sometimes it is referred to as "investigational" or "experimental services."

The question of whether the FoundationOne testing was investigational or experimental in the treatment of the Petitioner's condition was presented to an independent review organization (IRO) for analysis and a recommendation as required by section 11(6) of the Patient's Right to Independent Review Act, MCL 550.1911(6).

The IRO physician reviewer is board certified in oncology, has been in active practice for more than ten years, and is familiar with the medical management of patients with the Petitioner's condition. The IRO report included the following analysis and recommendation:

The results of the consultant's review indicates that this case involves a [REDACTED] year-old male who has a history of a metastatic epithelial angiomyioma or a malignant Pecoma. At issue in this appeal is whether the FoundationOne testing performed on 12/23/14 was experimental/investigational for diagnosis and treatment of the member's condition.

The member has a rare disease. However, the MAXIMUS physician consultant explained that there is no support in the literature that the results of FoundationOne genetic testing and sequencing will translate into clinical efficacy in treatment. The physician consultant indicated that a literature search shows that mTor inhibition with DSmirolimus has activity for malignant perivascular epitheloid cell tumors (Pecomas). The consultant indicated that it is not the standard of care to use FoundationOne testing results in making clinical decisions at this time. [Citation omitted]

Pursuant to the information set forth above and available documentation, the MAXIMUS physician consultant determined that the FoundationOne testing performed on 12/23/14 was experimental/investigational for diagnosis and treatment of the member's condition.

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(16)(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(15).

The Director, discerning no reason why the IRO's recommendation should be rejected in the present case, finds that the FoundationOne testing is experimental or investigational and therefore is not a covered benefit.

#### V. ORDER

The Director upholds the plan's final adverse determination dated November 11, 2015.

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 Michigan 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