

**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. 147762-001**

**Blue Cross Blue Shield of Michigan**

**Respondent**

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**Issued and entered**  
this 5<sup>th</sup> day of June 2015  
by **Randall S. Gregg**  
**Special Deputy Director**

**ORDER**

**I. PROCEDURAL BACKGROUND**

On May 6, 2015, ██████████ (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 May 13, 2015, after a preliminary review of the information submitted, the Director accepted the request.

The Petitioner receives group 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 LG*.

The medical issues in this case were evaluated by an independent review organization which provided its analysis and recommendation to the Director on May 28, 2015.

**II. FACTUAL BACKGROUND**

The Petitioner, 44 years old, had two miscarriages in 2014 (she had nine successful pregnancies in the previous 22 years). Her physician recommended a test – MTHFR genetic analysis – to help determine the cause of her miscarriages. The test detects a genetic abnormality that can cause thrombophilia, a blood clotting disorder. The Petitioner's physician suspected that such a disorder could be the cause of her miscarriages. The test cost \$390.00.

BCBSM denied coverage for the test, ruling that it was investigational, not a proven test for the Petitioner's condition. The Petitioner appealed the denial through BCBSM's internal grievance process. BCBSM issued a final adverse determination on April 24, 2015, affirming its denial. The Petitioner now seeks review of that determination from the Director.

### III. ISSUE

Is the MTHFR genetic test the Petitioner received experimental or investigational for treatment of her condition?

### IV. ANALYSIS

#### BCBSM's Argument

In its April 24, 2015 final adverse determination, BCBSM stated that it denied coverage because the MTHFR test is investigational:

To ensure all consideration, our medical consultants reviewed your claim and its supporting medical records. Our consultant found the following:

All documentation was reviewed. You are appealing the denial of payment for a genetic test that evaluates mutations in the MTHFR gene.... This test was ordered because you experienced 2 miscarriages that could not be explained. According to the BCBSM Medical Policy: "Genetic Testing for Inherited Thrombophilias," testing for mutations in the MTHFR gene is considered investigational as there is limited published evidence on the utility of the testing. There is a lot of controversy over this genetic testing and what to do with the results of the testing. There are several different treatment options (Folate or methyl-folate, usually) but none have been proven to be effective for all patients. In your case, the single mutation for MYHFR C677T is reported as "not associated with an increased risk of elevated homocysteine (which is the real culprit in this setting), venous thrombosis (blood clot), coronary artery disease or recurrent pregnancy loss." Because of this controversy this test is not approved.

#### Petitioner's Argument

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

I am seeking payment by BCBSM for the MTHFR gene test that was ordered by my doctor. Although it determined that I have one mutation that is not associated with the problem I was having, multiple pregnancy loss. It still was valuable for me to know and rule this out [and] to search for other causes. Also, it benefitted me to be urged to take extra folic acid & 81 mg aspirin daily. I already have diagnosis of peripheral; vascular disease so this test was of interest to me. Also, it has benefitted me to be urged to take extra folic acid and... aspirin daily. I already have a diagnosis of Peripheral Vascular Disease so this test was of interest to me. This leading me to better health ultimately saves BCBSM money.

In support of BCBSM covering the test, the Petitioner's physician wrote:

[Petitioner] is currently under my care for obstetrics and gynecology. In 2014 she experienced a spontaneous miscarriage in April, 2014 and October 2014. To determine the reason for recurrent pregnancy loss...blood work was drawn including MTHFR. The lab result was positive and [Petitioner] is a genetic carrier of a blood clotting mutation that may lead to multiple spontaneous miscarriages.

### Director's Review

The Petitioner's health benefit plan excludes coverage for experimental and investigational medical services. Section 6 of the *Community Blue* certificate of coverage provides:

#### **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....

The *Community Blue* certificate, on page 150, defines experimental treatment:

Treatment 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."

To evaluate the question of whether the MTHFR gene analysis is investigational, 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 obstetrics and gynecology and has been in active practice for more than 15 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:

[T]his case involves a 44-year old female who has a history of 9 prior successful pregnancies. The member presented with 2 first trimester spontaneous abortions in a 6 month period. A thrombophilia evaluation was performed including MTHFR testing. At issue is whether the MTHFR gene analysis performed on 10/30/14 was investigational for diagnosis and treatment of the member's condition.

The member has no prior history of thrombophilia. The MTHFR testing found a single mutation...[T]he member has proven fertility in the past and therefore, there is nothing to suggest a thrombophilia as a cause of her spontaneous abortions....[A] link between a MTHFR mutation and spontaneous abortion has

not been found....[T]he miscarriage rate at the age of 44 is over 50%, so the member's situation was in the expected range for her age....MTHFR testing is not indicated in the evaluation of recurrent miscarriage.

Pursuant to the information set forth above and available documentation...the MTHFR gene analysis performed on 10/30/14 was 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 MTHFR test is, in this instance, investigational and, for that reason, is not a covered benefit.

#### V. ORDER

BCBSM's final adverse determination of April 24, 2015 is upheld. BCBSM is not required to provide coverage for the Petitioner's October 30, 2014 MTHFR 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