

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. 153358-001

Blue Cross Blue Shield of Michigan,

Respondent.

Issued and entered
this 24th day of May 2016
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On April 22, 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 April 29, 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 Director immediately notified BCBSM of the external review request and asked for the information it used to make its final adverse determination. BCBSM responded on May 5, 2016.

The medical issues in this case were evaluated by an independent review organization which provided its analysis and recommendation to the Director on May 13, 2016.

II. FACTUAL BACKGROUND

The Petitioner's health care benefits are described in BCBSM's *Community Blue Group Benefits Certificate LG* (the certificate).

On May 5, 2015, the Petitioner had nine genetic tests performed in advance of aortic valve replacement surgery. The charge for these tests was \$4,250.00. BCBSM denied coverage,

saying the tests were experimental or investigational for 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 March 8, 2016, upholding its decision. The Petitioner now seeks review of that final adverse determination from the Director.

III. ISSUE

Were the genetic tests experimental or investigational for the treatment of the Petitioner's condition?

IV. Analysis

Petitioner's Argument

On the external review request form the Petitioner wrote:

[My doctor] requested a test to determine my ability to tolerate warfarin before making the decision to choose the type of replacement valve. This test needed to be performed to determine the best long term care. BCBSM sees this as experimental, I am requesting a discussion of requirement of this test.

BCBSM's Argument

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

To ensure that all consideration has been extended to your appeal, an Associate Medical Director, who is a board-certified D.O. in Internal Medicine, has reviewed the claim, the appeal, your health care plan benefits, and your medical records that relate to the laboratory services at issue. The medical consultant stated:

All documentation was reviewed. Your doctor ordered a panel of genetic tests to assess how your body breaks down and uses medication. According to the [BCBSM] medical policies: "Genetic Testing for Cytochrome P450 Polymorphisms," "Genetic Testing for Inherited Thrombophilia," and "Genetic Testing for Warfarin Dosing" - CYP450 genotyping for the purpose of aiding in the choice of drug or dose in increase efficacy and/or avoid toxicity is excluded from coverage, therefore we are unable to approve [procedure codes] 81225, 81226, 81227, 81400, 81401, 81479. Testing for mutations in the MTHFR gene is considered investigational as there is lack of

evidence for the utility of this testing. Testing for the F5 gene requires documentation of risk that was not included within this paperwork, therefore we are unable to approve 81291, 81241. Genetic testing for warfarin dosing is experimental / investigational. The clinical utility of genetic testing to determine cytochrome p450 2C9 (CYP2C9) and vitamin K epoxide reductase subunit C1 (VKORC1) genetic polymorphisms for the purpose of determining warfarin dosing has not been demonstrated. The peer-reviewed medical literature has not yet shown that this testing has sufficient diagnostic accuracy to provide clinically relevant information for patient management, therefore we are unable to approve 81355.

I realize that your physician recommended this genetic testing as part of your presurgical treatment plan, and I understand that you may be concerned about the out-of-pocket cost of these services. However, BCBSM must administer benefits in accordance with the provisions of your group coverage, and I am unable to make an exception on your behalf.

Director's Review

The certificate (p. 133) has this exclusion:

Services That Are Not Payable

We do not pay for experimental treatment (including experimental drugs or devices) or services related to experimental treatment. . . . In addition, we do not pay for administrative costs related to experimental treatment or for research management.

“Experimental treatment” is defined in the certificate (p. 150) 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.”

To help the Director answer the question of whether the genetic tests the Petitioner received are experimental or investigational in the medical management of her condition, the issue was presented 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 physician reviewer is board certified in clinical genetics, clinical biochemical genetics and pediatrics, has been in active practice for more than 15 years, and is familiar with the medical management of patients with the Petitioner's condition. The IRO report included the following recommendation and analysis:

Recommended Decision:

The MAXIMUS physician consultant determined that the genetic testing (CPT codes 81226, 81225, 81401, 81227, 81241, 81291, 81355, 81400 and 81479) performed on 5/5/15 was experimental / investigational for diagnosis and treatment of the member's condition.

Rationale:

* * *

The member's aortic valve was replaced with a mechanical valve. The member requires lifelong Coumadin therapy for the mechanical valve. Testing was done for determination of CYP2D6, CYP2C19 and CYP2C9 status, as well as for F5, MTHFR and VKORC1 analysis. The ordering provider indicated that this testing was done to determine if the member could tolerate life-long Coumadin therapy.

The MAXIMUS physician consultant explained that while both CYP2C9 and VKORC1 have a known role in warfarin metabolism, there is no evidence of clinical utility for these tests at present. The physician consultant also explained that in fact, warfarin is administered as a racemic mixture of (S) and (R) warfarin, each with different metabolic pathways. As such, many pathways are involved in the metabolism. The consultant indicated that CYP2C9 is the principle enzyme involved in metabolizing S-warfarin, but CYP12A and CYP3A4 are the main enzymes used in metabolizing R-warfarin. Warfarin works by interfering with the synthesis of vitamin K by inhibiting VKORC1.

The physician consultant indicated that many authors note that while ongoing research efforts may lead to utility in the future, routine use testing of CYP2C9 and VKORC1 is not currently supported by available evidence. The consultant explained that there is no evidence for the other tests sent for the member. The consultant noted that guidelines have been published to suggest starting Coumadin doses in patients based on CYP2C9 and VKORC1 genotypes. However, the physician consultant explained that it is unclear if this is better than standard practices of titrating dose based on INR level.

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 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 this case, finds that the genetic testing the

Petitioner received on May 5, 2015, is experimental or investigational and is therefore not a covered benefit.

V. ORDER

The Director upholds BCBSM's final adverse determination dated March 8, 2016.

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

A handwritten signature in black ink, appearing to read 'R. S. Gregg', is written over a horizontal line.

Randall S. Gregg
Special Deputy Director