

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. 148573-001

Blue Cross Blue Shield of Michigan

Respondent

Issued and entered
this 3rd day of August 2015
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On June 29, 2015, ██████████ (Petitioner) filed with the Department of Insurance and Financial Services a request for an external review under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.* On July 7, 2015, after a preliminary review of the information submitted, the Director accepted the request.

The Petitioner receives health care benefits through an individual plan underwritten by Blue Cross Blue Shield of Michigan (BCBSM). The Petitioner's health care benefits are described in BCBSM's *Blue Cross Premier Gold Benefits Certificate*. The Director notified BCBSM of the request and asked BCBSM to provide the information used to make its final adverse determination. BCBSM provided its response on July 10, 2015.

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, 2015.

II. FACTUAL BACKGROUND

The Petitioner, who is ██████ years old, has a history of recurrent breast cancer. Her physician recommended a test – CYP2D6 gene analysis – to help determine the best course of treatment. The test was provided on January 22, 2015, at a cost of \$928.70.

BCBSM denied coverage for the test. The Petitioner appealed the denial through BCBSM's internal grievance process. BCBSM issued a final adverse determination on June 12, 2015, affirming its denial. The Petitioner now seeks review of that determination from the Director.

III. ISSUE

Was the CYP2D6 gene analysis test the Petitioner received on January 22, 2015, investigational for the medical management of her condition?

IV. ANALYSIS

BCBSM's Argument

In its June 12, 2015 final adverse determination, BCBSM stated that it denied coverage because the CYP2D6 test is investigational:

[A] board-certified M.D. in Family Practice reviewed your claim, your appeal, and health care plan benefits for [BCBSM]. Our consultant determined:

We have received your appeal regarding the denial of coverage for CYP2D6 genetic testing which was ordered to see how your body breaks down (metabolizes) Tamoxifen. According to the Blue Cross Blue Shield Association medical policy "Genetic Testing for Tamoxifen Treatment," this testing is considered investigational for the purpose of managing women with breast cancer. The impact of testing on the health outcomes is unknown. Therefore, we are not able to approve this request.

Petitioner's Argument

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

In October 2011 I was diagnosed with a recurrence of breast cancer following a bilateral mastectomy ten years earlier (2001 which, according to the statistics available at the time of surgical decision, was thought to offer a 98-99% cure rate).

As a medical practitioner, when I was diagnosed with a recurrence, I sought the best possible traditional treatment, and found that to be at [REDACTED] and since October 2011 I have been provided treatment at the [REDACTED] facility, of the highest and most conservative approach. I have participated in no clinical studies or experimental trials.

Following my most recent visit to [REDACTED] I have learned that [BCBSM] rejected payment of a routine lab charge, and indicated the reason for rejection as the care provided was “experimental” and not “standard of care”. The professional practitioners at [REDACTED] Clinic clearly understand that I would not agree to anything experimental, and that all of my treatment must be a result of extensive research, study and clinical trials.

So few woman have fallen victim to a recurrence of breast cancer following a bilateral mastectomy that there is no follow (sic), and little, if any, supporting science in the treatment of the recurrence. Therefore, there is no “standard of care” for this specific situation, and this does not mean that the lab procedure billed was invalid or “experimental” in nature. [REDACTED] Clinic supports their decision and recommendations with conservative, published research findings.

In support of the request for coverage, the Petitioner’s nurse practitioner wrote:

The patient has undergone a course of chemotherapy, radiation and has now been on tamoxifen for three years. She recently was recommended switching from tamoxifen to an aromatase inhibitor based on the Intergroup Exemestane Study showing benefit of switching to an aromatase inhibitor after two to three years of tamoxifen therapy. Before finalizing the decision to switch to an aromatase inhibitor, we advised CYP2D6 testing to see how readily she metabolizes tamoxifen....

There is secondary data from a prospective clinical trial demonstrating the importance of CYP2D6 genotyping. [Citation omitted.] These data demonstrate that CYP2D6 genotyping is associated with the risk of recurrence in tamoxifen-treated patients, but not aromatase inhibitor patients. Additionally, a meta-analysis supported the importance of CYP2D6 genotyping in tamoxifen-treated patients. [Citation omitted.]

Based on this information, we would ask that you reimburse [the Petitioner] for the cost of the CYP2D6 genotype testing. Her genotype did show that she is an intermediate tamoxifen metabolizer, based on the result [her doctor] did recommend that she switch from tamoxifen to an aromatase inhibitor.

Director’s Review

The Petitioner’s certificate excludes coverage for experimental or investigational medical services which it defines as:

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 CYP2D6 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 internal medicine, medical oncology and hematology 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 member underwent a bilateral mastectomy in 2001 and was diagnosed with recurrent breast cancer in 2011. She was treated with chemotherapy and radiation followed by tamoxifen. A letter from a nurse practitioner submitted in support of the appeal stated that CYP2D6 testing was performed to help decide whether the member's treatment should be switched from tamoxifen to an aromatase inhibitor and that based on the results of this test this change of treatment was recommended.

Two references were submitted in support of the test...[O]ne of these studies stated that prospective studies are needed to see if changing therapy based on CYP2D6 is needed. [Citation omitted.] The other study stated that although CYP2D6 is a strong predictor of invasive disease free survival using strict inclusive criteria, prospective studies are needed to establish the value of CYP2D6 genotyping in tamoxifen therapy. [Citation omitted.] The National Comprehensive Cancer Network guidelines do not support the use of this testing at this time....[T]he American Society of Clinical Oncology in 2013 stated that the National Surgical Adjuvant Breast and Bowel Project (NSABP) and Study of Tamoxifen and Raloxifene (STAR) did not support the use of CYP2D6 testing.

Pursuant to the information set forth and available documentation...procedure code 81126 (CYP2D6 gene analysis, common variants) performed on 1/22/15 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 CYP2D6 test is investigational for the treatment of the Petitioner's condition and, for that reason, is not a covered benefit.

V. ORDER

BCBSM's final adverse determination of June 12, 2015 is upheld. BCBSM is not required to provide coverage for the Petitioner's CYP2D6 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



Randall S. Gregg
Special Deputy Director