

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. 150541-001-SF

Blue Cross Blue Shield of Michigan
Respondent

Issued and entered
this 2nd day of December 2015
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On October 26, 2015, ██████████, authorized representative of ██████████ (Petitioner), filed a request with the Director of Insurance and Financial Services for an external review under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.* On November 2, 2015, 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 benefits are described in BCBSM's *Community Blue Group Benefits Certificate LG*. The Director notified BCBSM of the external review request and asked for the information it used to make its final adverse determination. BCBSM provided its response on November 9, 2015.

Because the case involves medical issues, it was assigned to an independent medical review organization which provided its analysis and recommendation to the Director on November 16, 2015.

II. FACTUAL BACKGROUND

The Petitioner has a history of malignant neoplasm of the left eye. Her physician ordered the Decision DX-UM assay, a laboratory test used to determine the risk of her cancer metastasizing.

The test was performed on November 26, 2014, by ██████████, a laboratory in ██████████ that developed the test. ██████████ does not participate with BCBSM.

██████████' charge for the test was \$7,990.00. BCBSM denied coverage, ruling that the test was an experimental/ investigational treatment.

The Petitioner appealed the denial through BCBSM's internal grievance process. At the conclusion of that process, on September 1, 2015, BCBSM issued a final adverse determination affirming its denial. The Petitioner now seeks review of that final adverse determination from the Director.

III. ISSUE

Was the Decision DX-UM assay experimental or investigational for the treatment of the Petitioner's condition?

IV. ANALYSIS

BCBSM's Argument

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

[The Petitioner] is covered under the *Community Blue Group Benefits Certificate LG*. On page 135 of **Section 6: General Conditions of Your Contract**, the certificate states that experimental treatment (including experimental drugs or devices), and services related to experimental treatment, are excluded from coverage under the member's plan. To ensure that all possible consideration has been extended to this appeal, a board-certified D.O. in Internal Medicine has reviewed the claim, your appeal, and the member's health care plan benefits for BCBSM. The reviewer determined:

According to the Blue Cross Blue Shield Association medical policy – "Gene Expression Profiling for Uveal Melanoma" – this test is considered investigational/experimental as there is insufficient evidence that this test improves patient outcomes, therefore, we are unable to approve this test.

Petitioner's Argument

The Petitioner's representative, an employee of ██████████, wrote in a letter dated October 20, 2015, filed with the request for external review:

[T]he Decision Dx-UM assay a) has completed technical and clinical validation (the majority of the data has been published in numerous peer-reviewed journals dating back to 2004), b) has been adopted for routine clinical use by the majority of specialists treating this condition, c) is recommended for use by the only

national guidelines [the American Joint Committee on Cancer] developed for uveal melanoma and as the results are 'clinically significant' for patient care.

The clinical need that the Decision Dx-UM assay addresses is identifying patients who may be at a low risk of developing metastasis from those patients who are at a high risk and therefore enabling development of a patient specific surveillance and treatment plan. Various clinicopathologic prognostic factors, including tumor size, mitotic activity, metabolic activity and chromosomal deletion, have been evaluated to predict the risk of metastasis. However, their low sensitivity and specificity make these factors unreliable for individual patient care. The Decision Dx-UM assay was developed and clinically validated through a 694 patient, NCI- supported prospective, multicenter, blinded 5-year study. To date (Nov '09 censor date), the patients identified as having a low risk of metastatic disease have not experienced a metastatic event while 75% of the patients in the high risk group developed metastatic disease by the 51st month. The Decision Dx-UM has been directly compared to the clinicopathologic factors noted above and is statistically superior to all of them.

Director's Review

The question of whether the Decision DX-UM test is experimental or investigational as a part of the Petitioner's medical care was presented to an independent review organization (IRO) for analysis and a recommendation. See section 11(6) of the Patient's Right to Independent Review Act, MCL 550.1911(6).

The IRO reviewer is a physician in active practice who is board certified in ophthalmology and is familiar with the medical management of patients with the Petitioner's condition. The IRO reviewer's report included the following analysis and recommendation:

[T]he Decision DX-UM assay is the standard of care in all patients diagnosed with uveal melanoma....[D]epending on the results of this assay, the treating doctor can determine how aggressively to follow the patient and how often to order follow-up tests after the diagnosis has been made and the treatment plan has been established....[C]horoidal melanoma is a very rare type of cancer and can be lethal if not treated and managed appropriately.

Pursuant to the information set forth above and available documentation...
Decision DX-UM assay performed on 11/26/14 was not experimental/
investigational for diagnosis and treatment of the member's condition.

The Director is not obligated 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 Decision DX-UM test is not experimental/investigational and is therefore a covered benefit.

V. ORDER

The Director reverses BCBSM's final adverse determination of September 1, 2015. In accordance with section 1911(17) of the Patient's Right to Independent Review Act, MCL 550.1911(17), BCBSM shall immediately provide coverage for the Petitioner's Decision DX-UM test subject to any applicable deductibles or copayments required by the Petitioner's benefit plan.¹

BCBSM shall, within seven days of providing coverage, furnish the Director with proof it has implemented this order.

To enforce this order, the Petitioner may report any complaint regarding its implementation to the Department of Insurance and Financial Services, Health Care Appeals Section, at this toll free number: (877) 999-6442.

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



Randall S. Gregg
Special Deputy Director

1. According to the certificate (p. 121), BCBSM pays its "approved amount" for covered treatment and services. The record does not indicate what BCBSM's approved amount is for the Decision DX-UM test; it may be less than Castle's charge. Because Castle does not participate in BCBSM's provider network, it has not agreed to accept BCBSM's approved amount as payment in full for the test.