

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. 148136-001

Blue Cross Blue Shield of Michigan,

Respondent.

Issued and entered
this 1st day of July 2015
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On June 2, 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 June 9, 2015, after a preliminary review of the information submitted, the Director accepted the request.

The Petitioner receives health care benefits through a group plan that is 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's response was received on June 12, 2015.

Because it involved a medical question, the case was assigned to an independent review organization (IRO) for review. The IRO provided its analysis and recommendation to the Director on June 23, 2015.

II. FACTUAL BACKGROUND

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

The Petitioner has uveal melanoma, a rare form of eye cancer, in her right eye. Her phy-

¹ BCBSM form no. 6225, approved 10/12.

sician ordered the DecisionDx-Melanoma assay, a test used to determine the risk of metastasization.

The test was performed on February 6, 2014, by [REDACTED] a non-participating provider. [REDACTED] charge for the test was \$7,990.00. BCBSM denied coverage for the test, saying it was investigational for the treatment of the Petitioner's condition and was therefore not a covered benefit.

The Petitioner's authorized representative appealed the denial through BCBSM's internal grievance process. At the conclusion of that process BCBSM issued a final adverse determination dated April 15, 2015, affirming its denial. The Petitioner now seeks review of that final adverse determination from the Director.

III. ISSUE

Was the DecisionDx-Melanoma assay experimental or investigational for the treatment of the Petitioner's condition?

IV. ANALYSIS

BCBSM's Argument

In its final adverse determination, BCBSM explained the reasons for its denial:

This letter will inform you of the outcome of the appeal . . . regarding denial of payment for the laboratory service (procedure code 84999 unlisted chemistry procedure; DecisionDx-UM uveal melanoma gene expression profile assay test) provided on February 6, 2014. . . . After review, our denial of payment is maintained because the service is deemed experimental/investigational. Investigational services are not a benefit and payment cannot be approved.

* * *

A board-certified D.O. in Internal Medicine reviewed the claim, your appeal, and [the Petitioner's] health care plan benefits for Blue Cross Blue Shield of Michigan (BCBSM) and determined according to BCBSM medical policy "Gene Expression Profiling for Uveal Melanoma" gene expression profiling for uveal melanoma is considered investigational. The test is considered investigational because the clinical utility of the test has not been established; using the test will not change the treatment plan or improve patient outcome.

Petitioner's Argument

The Petitioner's authorized representative wrote to BCBSM on May 21, 2015:

I am appealing on behalf of [the Petitioner] who was diagnosed with uveal melanoma, a rare cancer of the eye. . . . Coverage was denied for the DecisionDx-UM uveal melanoma gene expression profile assay as being Experimental / Investigational. This appeal letter describes why this is an incorrect assessment. Specifically, the DecisionDx-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 (AJCC) developed for uveal melanoma and as the results are 'clinically significant' for patient care. . . .

The DecisionDx-UM gene expression profile assay is a robust, high-complexity, multivariate assay, is a proprietary assay that can only be performed through [REDACTED]. This assay identifies patients with a low risk of developing metastatic disease from those patients at high risk. A core component of the DecisionDx-UM gene expression profile assay is the proprietary algorithm. There is no CPT code for this algorithm. In accordance with standard practice, the algorithm was submitted under an 84999 code to enable reimbursement for the performance of the proprietary algorithm while the existing procedures were submitted under existing CPT codes.

The results are necessary for determining [the Petitioner's] surveillance and treatment plans. This appeal letter describes why your assessment is incorrect and requests prompt payment for the services ordered under the care of your in-network specialist provider . . . for [the Petitioner].

Director's Review

The certificate (p. 6.3) 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, except as explained under "Services That Are Payable" below.² 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. 7.10) 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."

² None of the exceptions apply to the Petitioner.

The question of whether the DecisionDx Melanoma assay was investigational for treating 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 ophthalmology and has been in active practice for more than 12 years. The IRO report included the following analysis and recommendation:

Recommended Decision:

The MAXIMUS physician consultant determined that the DecisionDx Melanoma assay performed on 2/6/14 was not experimental/investigational for diagnosis and treatment of the member's condition.

Rationale:

The MAXIMUS independent physician consultant, who is familiar with the medical management of patients with the member's condition, has examined the medical record and the arguments presented by the parties.

The results of the consultant's review indicate that this case involves a 38 year-old female who has a history of uveal melanoma of the right eye. At issue in this appeal is whether the DecisionDx Melanoma assay performed on 2/6/14 was experimental/investigational for diagnosis and treatment of the member's condition.

The MAXIMUS physician consultant explained that the DecisionDx Melanoma assay is used at almost every medical center that treats patients with uveal melanoma in the United States. The physician consultant indicated that this test is safe and is highly useful in distinguish[ing] between two groups of patients with this diagnosis. One group of patients with uveal melanoma has a very low chance of metastasis and the other has a very high chance of metastasis from this rare cancer. The consultant explained that the ability to distinguish between these two groups is critical in determining their prognosis as well as management, since cancer surveillance depends on prognosis of metastasis.

Pursuant to the information set forth above and available documentation, the MAXIMUS physician consultant determined that the DecisionDx Melanoma assay performed on 2/6/14 was not experimental/ investigational for diagnosis and treatment of the member's condition. [Citation omitted]

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 DecisionDx-Melanoma assay is not investigational and is therefore is a covered benefit.

V. ORDER

The Director reverses BCBSM's final adverse determination dated April 15, 2015.

BCBSM shall, within 60 days of the date of this Order, cover the Petitioner's DecisionDx-Melanoma assay performed on February 6, 2014, subject to all applicable terms and conditions of the certificate.³ Within seven days of providing coverage, BCBSM shall furnish the Director with proof it has complied with 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

³ According to the certificate (p. 4.2), BCBSM pays its "approved amount" for covered diagnostic services. The record does not indicate what BCBSM's approved amount is for the DecisionDx-Melanoma assay; it may be less than ██████ charge. Because ██████ 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.