

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. 147930-001

Blue Cross Blue Shield of Michigan,
Respondent.

Issued and entered
this 18th day of June 2015
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On May 18, 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 26, 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 2, 2015.

The case was assigned to an independent review organization (IRO) for review. The IRO provided its analysis and recommendation to the Director on June 9, 2015.¹

II. FACTUAL BACKGROUND

The Petitioner's health care benefits are described in BCBSM's *Community Blue Group Benefits Certificate LG²* (the certificate).

The Petitioner has choroidal melanoma, a type of eye cancer, in his left eye. His physician ordered the DecisionDx-Melanoma assay, a test used to determine the risk of metastasization.

¹ The IRO submitted a corrected version of its report on June 12, 2015. The initial report incorrectly identified the credentials of the physician who conducted the review. The initial report's recommendation was unchanged in the corrected version.

² BCBSM form no. 679E, approved 3/14.

The test was performed on March 24, 2014, by ██████ Biosciences, Inc. ██████, a nonparticipating provider. ██████ charge for the test was \$7,972.00.³ 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 appealed the denial through BCBSM's internal grievance process. At the conclusion of that process BCBSM issued a final adverse determination dated April 16, 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:

The laboratory services were denied because the procedure codes billed were determined to be investigational. . . . [The Petitioner's] health care Plan does not cover investigational or experimental services. Therefore, we cannot honor [the] request to cover these laboratory services, and [the Petitioner] remains responsible for the billed charges.

* * *

To ensure all consideration was given, a board-certified D.O., in Internal Medicine reviewed the claim, the appeal, and [the Petitioner's] health care plan benefits for [BCBSM]. Our medical consultant determined:

All documentation was reviewed. This is an appeal for the denial of the DecisionDx-Melanoma Assay on March 24, 2014. The doctor ordered the DecisionDx-Melanoma Assay for prognostic information (to help the doctor detect the spread of cancer and a treatment plan) for a member diagnosed with a rare cancer of the eye. According to the BCBSA [*Blue Cross Blue Shield Association*] policy "General Approach to Genetic Testing" the DecisionDx-Melanoma Assay is considered investigational. Deny procedure codes 84999 for the DecisionDx-Melanoma Assay and procedure code 99000, for the specimen handling associated with this test.

Petitioner's Argument

On the request for external review form the Petitioner wrote:

³ Castle also billed \$18.00 for handling the transfer of the specimen from the physician's office to the laboratory (CPT code 99000). BCBSM says CPT code 99000 is "not separately reimbursable" from the test itself.

This research was requested by my eye surgeon and I was not aware that it was experimental and investigatory. I was asked to do this [test] to confirm the type of cancer I had.

In a “letter of medical necessity” dated March 10, 2014, Petitioner’s physician wrote:

. . . The American Joint Committee on Cancer (2010) identifies this assay as “clinically significant” and therefore recommends it for collection. The DecisionDx-UM⁴ assay is only available through Castle Biosciences.

CLINICAL NEED: The treatment approach for the primary melanoma for [the Petitioner] is highly effective for the primary (eye) tumor. However, at the time of the diagnosis, approximately 50% of patients have already experienced a micro (undetectable) metastatic event. These patients with micro-metastatic events will typically develop clinical metastatic disease of the liver within 5 years. Unfortunately, today’s imaging techniques can only detect 1-4% of these metastases at the time of primary tumor diagnosis.

CLINICAL USE: The DecisionDx-UM assay was developed and clinically validated through a 694 patient, NCI-supported prospective study to identify those patients at high risk from those at low risk for metastatic disease. The need to identify which patients are at high risk (Class 2) from those patients at low risk (Class 1) is clear. In conjunction with other clinical assessments, results from the DecisionDx-UM assay will assist with formulating surveillance and treatment plans.

A representative of Castle said in a letter to BCBSM dated March 6, 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. This letter and the accompanying articles and summaries provide additional proof that the DecisionDx-UM assay is not Experimental/Investigational.

The DecisionDx-UM gene expression profile assay is a robust, high-complexity, multivariate assay, is a proprietary assay that can only be performed through ██████ Biosciences. 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

4 The test the Petitioner received is called both DecisionDx-Melanoma and DecisionDx-UM in the record.

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

BCBSM's denial was based on this exclusion in the certificate (p. 133):

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. . . .

"Experimental treatment" is defined in the certificate (p. 148) 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."

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, has been in active practice for more than 12 years, and is familiar with the medical management of patients with the Petitioner's condition. The IRO report included the following analysis and recommendation:

The DecisionDx Melanoma assay is a gene profiling test for patients diagnosed with choroidal melanoma of the eye. Choroidal melanomas are extremely rare tumors and therefore, studies involving large numbers of patients are unlikely. However, the MAXIMUS physician consultant explained that the DecisionDx Melanoma assay is considered state of the art and standard of care in the treatment of any individual with the diagnosis. The physician consultant indicated that this test is routinely ordered in such circumstances to allow the treating physician and patient a better idea of the probability of metastasis from the melanoma. The consultant also indicated that the treatment and surveillance frequency depend on the type of gene expression noted in the tumor. The consultant also explained that this test should not be considered experimental/investigational since it is not only the accepted standard of care in the ophthalmic oncology community, but it has also been clinically validated to be highly accurate.

Pursuant to the information set forth above and available documentation, the MAXIMUS physician consultant determined that the DecisionDx Melanoma assay performed on 3/24/14 was not experimental/ investigational for diagnosis and treatment of the member's condition.

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, is the standard of care for the Petitioner's condition, and is therefore is a covered benefit.

V. ORDER

The Director reverses BCBSM's final adverse determination dated April 16, 2015.

BCBSM shall, within 60 days of the date of this Order, cover the Petitioner's DecisionDx-Melanoma assay performed on March 24, 2014, subject to all applicable terms and conditions of the certificate.⁵ 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

⁵ According to the certificate (p. 19), BCBSM pays its "approved amount" for covered treatment and services. The record does not indicate what BCBSM's approved amount is for the DecisionDx-Melanoma assay; 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.

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

Randall S. Gregg
Special Deputy Director