

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. 150915-001

Blue Cross Blue Shield of Michigan  
Respondent

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Issued and entered  
this 16<sup>th</sup> day of December 2015  
by Randall S. Gregg  
Special Deputy Director

**ORDER**

**I. PROCEDURAL BACKGROUND**

On November 16, 2015, ██████████, authorized representative of ██████████ (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 November 23, 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 *Simply Blue Group Benefits Certificate SG*. The Director notified BCBSM of the appeal and asked it to provide the information used to make its final adverse determination. BCBSM provided its response on November 24, 2015.

The medical issues in this case were evaluated by an independent review organization which provided its analysis and recommendation to the Director on December 4, 2015.

**II. FACTUAL BACKGROUND**

The Petitioner is █████ years old. In March 2014, he was found to have a malignant melanoma in his left eye. His physician recommended a medical test, the DecisionDX-UM, to aid in planning his treatment by determining the risk of his cancer metastasizing. The test was

performed on April 16, 2014. The amount charged for the test was \$7,990.00.

BCBSM denied coverage for the test, ruling that it was investigational/experimental. The Petitioner appealed the denial through BCBSM's internal grievance process. BCBSM issued a final adverse determination on September 15, 2015. The Petitioner now seeks the Director's review of that determination.

### III. ISSUE

Is the DecisionDX-UM test experimental or investigational in the treatment of the Petitioner's condition?

### IV. ANALYSIS

#### BCBSM's Argument

In its final adverse determination, BCBSM stated that it denied coverage because the DecisionDX-UM test is investigational/experimental. According to BCBSM's medical policy "Gene Expression Profiling for Uveal Melanoma," the test is considered investigational because the usefulness of the test in improving patient outcomes has not been established.

#### Petitioner's Argument

In the request for external review, the Petitioner's representative wrote:

[T]he 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 assay identifies patients with a low risk of developing metastatic disease from the patient at high risk....

The results are necessary for determining [Petitioner's] surveillance and treatment plans....

The Petitioner's representative submitted an extensive collection of medical studies and other material in support of the argument that the DecisionDX-UM test is not experimental or investigational.

Director's Review

The Petitioner's health benefit plan excludes coverage for experimental and investigational medical services. Section 6 (page 137) of the *Simply Blue* certificate of coverage provides:

Services That Are Not Payable

We do not pay for experimental treatment (including experimental drugs or devices) or services related to experimental treatment...

The *Simply Blue* certificate, on page 154, defines experimental treatment:

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 determine whether the DecisionDX-UM test is investigational or experimental in the treatment of the Petitioner's condition, 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 in active practice who is certified by the American Board of Ophthalmology. The reviewer is a clinical associate professor of ophthalmology at a university based school of medicine and is published in peer reviewed literature. The reviewer's report included the following analysis and recommendation:

The standard of care at virtually all ocular oncology centers in the United States is to use the DecisionDX-UM test to classify ocular melanoma patients as to the risk of future metastatic disease. 50% of ocular melanoma patients develop metastasis within five (5) years, but most of these have Class 2 tumors. This test allows physicians to intensively screen the higher risk patients, thereby avoiding unnecessary testing in many patients. It is a violation of the standard of care to not provide this testing to facilitate decision making in ocular melanoma.

There is significant medical literature to show that this test is not experimental or investigational for uveal melanoma. Because Class 2 uveal melanoma has a high risk of metastasis, frequent metastatic screening is warranted. On the other hand, Class 1A tumors have a very low risk of metastasis, so significantly less ongoing monitoring is needed. In addition, Class 2 tumor patients may choose to have adjuvant chemotherapy because of their high risk of metastasis, whereas Class 1 patients do not need this option. The American Joint Commission on Cancer recommended the use of this testing in 2010 because it significantly affects clinical decision making, metastatic screening and prognosis in uveal melanoma.

\* \* \*

This test has not been approved by the Food and Drug Administration (FDA) nor is FDA approval relevant for this diagnostic testing. However, it is the standard of care in virtually every ocular oncology service for the classification and

prediction of necessary future metastatic screening for uveal melanoma. This test is performed in a Clinical Laboratory Improvement Amendments (CLIA) certified laboratory and does not require FDA approval. This test should definitely not be considered investigational. There is clearly sufficient data that this test is superior to the previous clinical options and reduces unnecessary testing in half the patients with this condition. At this point in time, not using this test would be a significant violation of the standard of care for ocular melanoma in that it greatly influences decision-making in the care of patients with this disease.

The benefit of the DecisionDX-UM test to this enrollee cannot be achieved by any other standard health care service. In this specific situation, this test is a one-time event and the enrollee has already had the benefit of this test which is to know that the frequent metastatic screening scans are the proper choice of clinical management, even though there is both a risk of radiation exposure and reaction to contrast. This test has shown that this enrollee has a high likelihood of developing metastatic melanoma, but if he had a Class 1A tumor, significant screening risks would have been avoided. Hence the use of this test significantly alters care in half of ocular melanoma patients by decreasing costs and screening risks; therefore it meets the criteria of not being experimental or investigational.

In this specific situation, the enrollee has a Class 2 tumor and requires higher intensity metastatic surveillance. The results of the DecisionDX-UM tests were not known at the time of the gene expression profiling for the tumor, which must be done at the time of initial diagnosis, and hence it was absolutely correct to obtain this test in this enrollee. Therefore, for the reasons noted above, the DecisionDX-UM test was not experimental/investigational for the enrollee's condition.

Recommendation:

It is the recommendation of this reviewer that the denial issued by Blue Cross Blue Shield of Michigan for the DecisionDX-UM genetic test performed on April 16, 2014 be overturned.

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 DecisionDX-UM test is not experimental or investigational for the Petitioner.

**V. ORDER**

BCBSM's final adverse determination of September 15, 2015 is reversed. BCBSM shall immediately provide coverage for the Petitioner's April 16, 2014 DecisionDX-UM test, and 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 telephone 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 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



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Randall S. Gregg  
Special Deputy Director