

STATE OF MICHIGAN  
DEPARTMENT OF INSURANCE AND FINANCIAL SERVICES  
Before the Director of Insurance and Financial Services

In the matter of:

██████████  
Petitioner

v

Blue Cross Blue Shield of Michigan  
Respondent

File No. 149374-001

Issued and entered  
this 14<sup>th</sup> day of September 2015  
by Randall S. Gregg  
Special Deputy Director

**ORDER**

**I. PROCEDURAL BACKGROUND**

On August 14, 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 August 21, 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 HSA Group Benefits Certificate with Prescription Drugs*.

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

**II. FACTUAL BACKGROUND**

The Petitioner is ██████ years old and has uveal melanoma (a rare form of cancer) in his right eye. His physician ordered a medical test, the DecisionDx-UM gene expression profile assay, to determine his risk of metastases. The DecisionDx-UM test was performed by the test's developer, Castle Biosciences, Inc. The amount charged for this test was \$7,990.00.

BCBSM denied coverage for the test, ruling that it was experimental in the treatment of Petitioner's condition. The Petitioner appealed the denial through BCBSM's internal grievance process. BCBSM issued a final adverse determination dated June 23, 2015. The Petitioner now seeks review of that determination from the Director.

### III. ISSUE

Is the Decision Dx-UM test experimental or investigational for treatment of the Petitioner's condition?

### IV. ANALYSIS

#### BCBSM's Argument

In its final adverse determination, BCBSM wrote to the Petitioner's representative:

[A] board certified D.O. in Internal Medicine reviewed this claim, your appeal, and [Petitioner's] health care plan benefits for BCBSM. The physician determined that:

...According to Blue Cross and Blue Shield Association medical policy titled "Gene Expression Profiling for Uveal Melanoma" gene expression profiling for uveal melanoma is considered investigational as the clinical utility of the test (that using the test will change treatment decisions and improve subsequent outcomes that matter to the patient such as mortality, morbidity or quality of life) has not been established.

#### Petitioner's Argument

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

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) [American Joint Committee on Cancer] 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.

\* \* \*

As a rare cancer, treatment of primary uveal melanoma is generally referred to the top 50 centers across the U.S. that specialize in or have a focus in treating eye cancer. Today, the DecisionDx-UM uveal melanoma gene expression assay is

standard of care in the majority of these eye cancer centers....Additionally, it is recommended for use by the American Joint Committee on Cancer...as the results are “clinically significant” for patient care.

\* \* \*

The clinical need that the DecisionDx-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 DecisionDx-UM assay was developed and clinically validated through a 694 patient, NCI- supported prospective, multicenter, blinded 5-year study. To 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 DecisionDx-UM has been directly compared to the clinicopathologic factors noted above and is statistically superior to all of them....

### Director’s Review

The *Simply Blue* certificate of coverage (page 134) excludes coverage for experimental and investigational medical services. Page 151 of the certificate defines experimental treatment 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 DecisionDx-UM test is experimental or 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 in active practice who is certified by the American Board of Ophthalmology, is an associate professor of ophthalmology at a major metropolitan university medical center, and is published in peer reviewed literature. The reviewer’s report included the following analysis and recommendation:

Uveal melanoma is the most common primary cancer of the eye and remains one of the most deadly diseases encountered in ophthalmology, with many patients dying of metastatic disease. Despite improvements in diagnosis and treatment of the primary tumor, there has not been a corresponding improvement in survival. This

inability to prevent metastatic disease appears to be due to clinically undetectable micrometastasis occurring before the primary tumor is treated and becoming clinically manifest only months to years later. Concurrently, there are no existing therapies, or new ones on the horizon, with a reasonable prospect of improving survival in patients with advanced metastatic melanoma, so waiting for overt metastatic disease to manifest before initiating systemic therapy will continue to be of limited value. If metastasis is detected earlier, when it is confined to the liver, survival undoubtedly can be extended in some patients using hepatic chemoembolization and other regional techniques. Further, if high-risk patients could be identified accurately when the micrometastases are still small and undetectable, targeted molecular agents and immunotherapies could be instituted in a prophylactic setting, where they would probably be more effective. The key to such a preemptive treatment strategy is an accurate predictive test for identifying high-risk patients without unnecessarily treating low-risk patients.

\* \* \*

The medical/scientific evidence has demonstrated the validity of the DecisionDx-UM assay testing. The expected benefits of the requested health care service are likely to be beneficial to the enrollee. No other standard testing is identified as being available. The DecisionDx-UM assay testing identified the enrollee as having a Class I molecular signature associated with a low risk of near term (within five years) clinical metastasis. Sub-analysis indicates a class 1A tumor which carries the lowest metastatic risk. The provider states that, as a result of this testing, he has modified his recommendations for follow-up surveillance and believes it is likely sufficient to perform liver function enzyme assays and chest x-rays on an annual basis. The DecisionDx-UM assay was standard of care for management of the enrollee's condition at the time services were rendered. Therefore, for the reasons noted above, the DecisionDx-UM assay was not considered experimental/investigational for the treatment of the enrollee's condition.

**Recommendation:**

It is the recommendation of this reviewer that the denial by Blue Cross and Blue Shield of Michigan for the DecisionDx-UM Assay on July 14, 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 and, for that reason, is a covered benefit.

**V. ORDER**

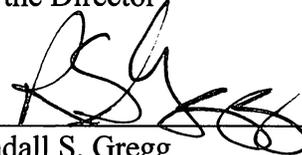
BCBSM's final adverse determination of June 23, 2015 is reversed. BCBSM shall immediately provide coverage for the Petitioner's July 14, 2014 Decision Dx-UM test, and shall, within seven days of providing coverage, furnish the Director with proof it has implemented this order.

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

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

Randall S. Gregg  
Special Deputy Director