

**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. 154080-001

Blue Care Network of Michigan,

Respondent.

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Issued and entered  
this 10<sup>th</sup> day of July 2016  
by Randall S. Gregg  
Special Deputy Director

**ORDER**

**I. PROCEDURAL BACKGROUND**

██████████ski (Petitioner) was denied coverage for a genetic test by his health plan, Blue Care Network of Michigan (BCN), a health maintenance organization.

On June 10, 2016, ██████████, the Petitioner's authorized representative, filed a request with the Director of Insurance and Financial Services for an external review of that denial under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.*

The Petitioner receives group health care benefits through BCN. The Director immediately notified BCN of the external review request and asked for the information it used to make its final adverse determination. BCN responded on June 14, 2016. After a preliminary review of the material submitted, the Director accepted the request on June 17, 2016. BCN provided additional information for the review on June 22, 2016.

The medical issues in this case were evaluated by an independent review organization, which provided its recommendation to the Director on July 5, 2016.

## II. FACTUAL BACKGROUND

The Petitioner's health care benefits are described in BCN's *Classic for Large Groups* certificate of coverage (the certificate).

The Petitioner was diagnosed with a large ocular tumor in one eye in 2014 that required removal of the eye. Pathology testing confirmed that the tumor was choroidal melanoma. As part of his ongoing treatment following the surgery, his doctor prescribed a genetic test called DecisionDx-UM to determine the likelihood of subsequent metastasis.

The test was performed on November 11, 2014, by Castle Biosciences, the Texas company that developed the test. The charge was \$7,990.00.

BCN denied coverage for the test, saying it was experimental or investigational and therefore not a covered benefit. The Petitioner appealed the denial through BCN's internal grievance process, requesting retro-authorization for the test. At the conclusion of that process, BCN issued a final adverse determination on April 15, 2016, upholding the decision. The Petitioner now seeks the Director's review of that final adverse determination.

## III. ISSUE

Is the DecisionDx-UM test experimental or investigational when used in the medical management of the Petitioner's condition?

## IV. ANALYSIS

### BCN's Argument

In its final adverse determination to the Petitioner's representative, a BCN representative stated:

The [*grievance*] Panel ... reviewed the information your company submitted and provided during the Panel meeting, along with the medical documentation submitted by [the Petitioner's ophthalmologist] as well as the BCBSM / BCN medical policy Gene Expression Profiling for Uveal Melanoma and the member's BCN Classic for Large Groups Certificate of Coverage (COC). The Panel maintained the denial stating that the test is experimental / investigational and not a covered benefit per the above referenced medical policy and the member's BCN COC.

As outlined in section 9 Exclusions and Limitations: 9.1

Unauthorized and Out of Network Services - Except for emergency care as specified in Section 8 of this Certificate, health, medical and Hospital services listed in this Certificate are covered only when: Provided by a Participating Provider; and Preauthorized by BCN for select services. Section 9.4 Non-Covered Services states: Coverage does not include the following services: Services that do not meet the terms and guidelines of this Certificate.

### Petitioner's Argument

In a letter dated June 8, 2016, submitted with the external review request, the Petitioner's authorized representative wrote:

Uveal melanoma (UM) is a rare intra-ocular cancer with an annual U.S. incidence of 1600-1700 cases. Ninety-six percent of patients present without known or detectable metastatic disease, and there is a 93% to 98% successful primary tumor control rate. Given this high success in local control, the major clinical concern and challenge for physicians and patients is determining whether distant metastatic disease will develop, as up to 50% of patients can develop metastases within 5 years ... This risk determination is critical for subsequent management planning, including surveillance intensity and frequency, as well as treatment options, and cannot be obtained by clinicopathologic factors alone.

The DecisionDx-UM test is a gene expression profile test that identifies metastatic risk in patients diagnosed with uveal melanoma. The test classifies patients into categories based on risk of metastasis.

Clinical validation of the test was performed in multi-center and single-center prospective studies, including the first report of the Collaborative Ocular Oncology Group (COOG) that showed that gene expression profiling using the DecisionDx-UM platform was the most accurate predictor of metastatic risk compared to all other prognostic factors: low (Class 1 A), intermediate (Class 1 B), or high risk (Class 2); based on the gene expression levels (mRNA) of 15 genes, as evaluated by quantitative reverse transcriptase polymerase chain reaction (qRT-PCR).

\* \* \*

In summary, the DecisionDx-UM test is an analytically and clinically validated test that provides accurate stratification of a uveal melanoma patient's risk of metastasis and has established clinical utility. As documented in the publications above, this information is

used by physicians to develop a patient-specific surveillance and treatment plan, based on that individual's metastatic risk. The benefits of this individualized risk profile are that intensive clinical surveillance efforts can be focused in the patients who need it most, those with a high risk for metastasis, while patients with a low risk can be spared frequent visits, imaging and laboratory tests. DecisionDx-UM offers the ability to individualize patient care and leads to more efficient utilization of healthcare resources. Therefore, this test is medically necessary ... and should not be considered experimental or investigational. [References omitted.]

### Director's Review

The certificate (p. 32) covers outpatient diagnostic laboratory, pathology, and radiology services. Those services must be medically necessary (p. 57); the term "medically necessary services" does not include experimental services (p. iv).

BCN denied coverage for the DecisionDx-UM test, saying it was experimental or investigational (certificate, p. iv). BCN based its denial on its medical policy titled, "Gene Expression Profiling for Uveal Melanoma," which says:

The peer reviewed medical literature has not demonstrated the clinical utility of gene expression profiling for uveal melanoma. Therefore, this service is experimental / investigational.

To determine whether the DecisionDx-UM test is experimental or investigational in the medical management 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 physician reviewer is certified by the American Board of Ophthalmology with a subspecialty certification by the American Society of Ophthalmic Plastic and Reconstructive Surgery; a member of the American Academy of Ophthalmology, the American Medical Association, and the American Society of Ophthalmology Plastic and Reconstructive Surgery; and is published in the peer review medical literature. The IRO report included the following analysis and recommendation:

#### **Reviewer's Decision and Principal Reasons for the Decision:**

**Is the DecisionDx-UM gene expression profile test performed on November 11, 2014 experimental / investigational for the treatment of the enrollee's condition?**

No. It is the determination of this reviewer that the Decision DX-UM gene expression profile test on November 11, 2014 was not

experimental / investigational for the treatment of the enrollee's condition.

**Clinical Rationale for the Decision:**

It has become increasingly apparent with the advent of genetic testing, that genetic analysis of tumor origin and genetic makeup play an important and often crucial role in the prognosis of clinical outcome and treatment. Over the past five (5) to ten (10) years, standard of care has shifted toward studying genetic implications of these rare tumors (about 2500 cases per year are diagnosed in United States). Evidence is now quite compelling concerning genetic footprints of these tumors, affecting management of the patients after initial diagnosis. Genetic testing of the cell type of tumor, developed from an assay involving over 600 patients over the past two (2) decades, has provided an algorithm which makes predictability for potential metastatic disease much more accurate. Given the profound shift in the understanding of the genetic origins of these tumors in the past decade, this particular assay is now considered standard of care for management of this rare eye tumor.

Food and Drug Administration (FDA) approval is a gray zone, in that the Decision DX-UM gene expression profile test represents a diagnostic test, utilizing a patient's tissue from an enucleation specimen, not a treatment per se. There are only about sixty five (65) centers across the United States which specialize in management of these types of rare tumors. Between 65-80% of these centers currently recognize the DecisionDX-UM gene expression assay as an effective and important tool in management of this cancer. As of 2014, the time the DecisionDx-UM gene expression profile test was performed, it was no longer considered experimental / investigational.

The scientific or medical evidence demonstrates the expected benefits from the test are more likely to be beneficial to the enrollee than any available standard health care service in that appropriate emphasis can be placed on focused follow-up, especially when focused follow-up is necessary. This particular case is unusual in that, although the prognosis for the enrollee, per the test results, is quite good, the enrollee does have a suspicious choroidal pigmented lesion in his only remaining eye. The prognosis of uveal melanoma is notoriously difficult to predict and there is no simple way to predict whether micrometastases are present at the time of initial diagnosis. Therefore, for the reasons noted above, the

DecisionDx-UM gene expression profile test was not experimental / investigational for the treatment of the enrollee's condition.

**Recommendation:**

It is the recommendation of this reviewer that the denial issued by Blue Care Network of Michigan for DecisionDx-UM gene expression profile test on November 11, 2014 be overturned.

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 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. MCL 550.1911(15). The Director, discerning no reason why the IRO's recommendation should be rejected in this case, accepts the IRO's recommendation and finds that the DecisionDx-UM test is not experimental or investigational as a part of the Petitioner's treatment and, for that reason, is a covered benefit.

BCN also denied coverage because the test was performed by a nonparticipating provider. In section 9.1 (p. 57), the certificate says:

Except for Emergency care ... health, medical and hospital services listed in this Certificate are covered only when:

- Provided by a Participating Provider .

However, BCN must also comply with the requirements of the Michigan Insurance Code which pertain to health maintenance organizations. Section 3519(3) of the Code, MCL 500.3519(3), provides: "All health maintenance organization contracts shall include, at a minimum, basic health services." Basic health services includes diagnostic laboratory and diagnostic and therapeutic radiological services. See MCL 500.3501(b)(vii).

The DecisionDx-UM test has been determined by the IRO to be medically necessary in the treatment of the Petitioner's condition. The provider is the creator of the test and appears to be the only provider offering the test. In this circumstance, the mandate of the Insurance Code must take precedence over BCN's policy provision limiting coverage to services obtained from participating providers. BCN must provide coverage for the Petitioner's November 19, 2014 DecisionDx-UM test.

**V. ORDER**

The Director reverses BCN's final adverse determination of April 15, 2016.

BCN shall immediately cover the Petitioner's November 11, 2014 DecisionDx-UM test and shall, within seven days of providing coverage, furnish the Director with proof it has implemented this order. MCL 550.1911(17).

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 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:

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

Randall S. Gregg  
Special Deputy Director