

**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. 154268-001-SF

University of Michigan, Plan Sponsor  
and  
BCN Service Company, Plan Administrator  
Respondents

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Issued and entered  
this 22<sup>ND</sup> day of July 2016  
by Joseph A. Garcia  
Special Deputy Director

**ORDER**

**I. PROCEDURAL BACKGROUND**

On June 22, 2016, ██████████, authorized representative of ██████████ (Petitioner), filed a request for external review with the Department of Insurance and Financial Services. The request for review concerns a denial of coverage for a medical test. The denial was issued by BCN Service Company (BCNSC), the administrator of the Petitioner's health benefit plan.

The request for external review was filed under Public Act No. 495 of 2006 (Act 495), MCL 550.1951 *et seq.* Act 495 requires the Director to provide external reviews to a person covered by a self-funded health plan that is established or maintained by a state or local unit of government. The Director's review is performed "as though that person were a covered person under the Patient's Right to Independent Review Act." MCL 550.1952. The Petitioner's health benefit plan, sponsored by the University of Michigan, is such a governmental self-funded plan. The benefits are described in the *U-M Premier Care Benefit Document*.

The Director notified BCNSC of the external review request and asked for the information used to make its final adverse determination. BCNSC furnished the requested information on June 24, 2016. On June 29, 2016 after a preliminary review of the information submitted, the Director accepted the request.

The medical issues in this case were evaluated by an independent review organization which provided its analysis and recommendation to the Director on July 13, 2016.

## II. FACTUAL BACKGROUND

The Petitioner is 55 years old and has uveal melanoma of the right eye. As part of his ongoing treatment, his doctor ordered a DecisionDx-UM test to determine the likelihood of subsequent metastasis. The test was performed on September 30, 2015 by Castle Biosciences, a Dallas, Texas company that developed the test and is the only laboratory which can perform the test. The cost of the test was \$7,990.00.

BCNSC denied coverage for the test, ruling that it was experimental or investigational and therefore not a covered benefit. The Petitioner appealed the denial through BCNSC's internal grievance process requesting that it provide retro-authorization and payment. BCNSC issued a final adverse determination dated April 28, 2016 maintaining its decision. The Petitioner now seeks the Director's review of that determination.

## III. ISSUE

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

## IV. ANALYSIS

### Respondent's Argument

In its final adverse determination, a BCNSC representative wrote that the Petitioner's appeal had been reviewed by its grievance panel:

The Panel, which consisted of our senior medical director, and MD, who is Board Certified in Psychiatry and the manager of Special Inquiries and Social Media, reviewed the information your company submitted and provided during the Panel meeting, along with the medical documentation submitted by Ophthalmologist Dr. [REDACTED] as well as the BCBSM/BCN medical policy "Gene Expression Profiling for Uveal Melanoma" and the member's *UM Premier Care Benefit Document*. 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 *UM Premier Care Benefit Document*.

As outlined in section 9 Exclusions and Limitations: 9.16 Unauthorized and Out-of-Plan Services-Except for emergency and urgent care as specified in Section 8 of this booklet, health, medical and hospital services listed in this Benefit Document are covered only if they are: Provided by a UM Premier Care Network 1 or Network 2 affiliated provider or Preauthorized by BCN. Any other services will not be paid for by BCN either to the provider or the Member. Per section 9.3 Noncovered Services-Coverage does not include the following services: Services that do not meet the terms and guidelines of this Benefit Document. All facility, ancillary and physician services, including diagnostic tests, related to experimental or investigational procedures.

### Petitioner's Argument

In a letter dated June 16, 2016 accompanying the request for an external review, the Petitioner's representative wrote:

The DecisionDx-UM test was ordered by Dr. [REDACTED] who, as an in-network provider with your health plan, cited medical necessity for your member based on intent to use test results in the management of the member. The DecisionDx-UM test is exclusively available through Castle Biosciences, Inc. as a validated prognostic test for the prediction of metastatic recurrence in early stage uveal melanoma.

#### **Test Background**

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 (Ehlers, J.P. and J.W. Harbour, *Molecular pathobiology of uveal melanoma*. Int Ophthalmol Clin, 2006.) 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.

[List of cited publications omitted.]

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. Decision Ox-UM offers the ability to individualize patient care and leads to more efficient utilization of healthcare resources. Therefore, this test is medically necessary for management of your member and should not be considered experimental or investigational.

#### Director's Review

The *U-M Premier Care Benefit Document* excludes coverage for any experimental or investigational medical service, defined in the *Benefit Document* as "a service that has not been scientifically proven to be as safe and effective for treatment of the Member's condition as conventional or standard treatment in the United States."

BCNSC stated in its final adverse determination, "the test is experimental/ investigational and not a covered benefit per the [BCBSM/BCN "Gene Expression Profiling for Uveal Melanoma"] medical policy and the member's *UM Premier Care Benefit Document*." BCNSC then cited the *Benefit Document* provisions relating to provider network status and preauthorization. The questions of network status and preauthorization, mentioned but not elucidated in the final adverse determination, seem to be based on BCNSC's conclusion that the test is experimental/investigational. BCNSC did not offer any additional reason why it would deny preauthorization. It is also noted that the DecisionDx-UM test is not available from any in-network provider.

In short, BCNSC's final adverse determination is based on its position that the DecisionDx-UM test is experimental/investigational. To evaluate the question of

whether the DecisionDx-Melanoma test is experimental or investigational in the medical management of the Petitioner's condition, the Director presented the question 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 for more than ten years who is board certified in ophthalmology and is familiar with the medical management of patients with the Petitioner's condition. The reviewer's report included the following analysis and recommendation:

[T]his case involves a 55 year-old male who has been diagnosed with choroidal melanoma ... The member also has a history of renal carcinoma and osteogenic sarcoma. There is a strong suspicion that he is carrying a genetic mutation. The DecisionDx-UM assay was ordered by the member's treating providers to help determine his risk of metastasis from the melanoma.

[T]he DecisionDx-Um assay is an integral part of a patient's work-up in the majority of practices in the United States where patients with uveal and choroidal melanoma are treated. These types of melanoma are rare and are treated by relatively few physicians ...

[T]he majority of the physicians who treat these patients use this genetic test ... [T]his test differentiates between those patients with a low risk of metastasis and those with a higher risk of metastasis and determines how aggressive their surveillance and treatment should be.

Pursuant to the information set forth above and available documentation...the DecisionDx-Melanoma test performed on 9/30/15 was not experimental/ investigational for diagnosis and treatment of the member's condition.

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. 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 as a part of the Petitioner's treatment and, for that reason, is a covered benefit.

**V. ORDER**

BCN Service Company's final adverse determination of April 28, 2016 is reversed. BCN Service Company shall immediately provide coverage for the Petitioner's September 30, 2015 DecisionDx-UM test. See MCL 550.1911(17). In addition, BCN Service Company 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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Joseph A. Garcia  
Special Deputy Director