

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. 152631-001-SF

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

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Issued and entered  
this 13<sup>th</sup> day of April 2016  
by Randall S. Gregg  
Special Deputy Director

**ORDER**

**I. PROCEDURAL BACKGROUND**

On March 11, 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 issued by BCN Service Company (BCNSC), the administrator of the Petitioner's health benefit plan which is sponsored by the University of Michigan.

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 is such a governmental self-funded plan. The benefits are described in BCNSC's *U-M Premier Care Benefit Document*.

The Director notified BCNSC of the appeal and asked it to provide the information used to make its final adverse determination. BCNSC furnished its response on March 15, 2016. On March 18, 2016, after a preliminary review of the information submitted, the Director accepted the request for review. BCNSC submitted additional material on March 22, 2016.

This case involves medical issues so the Director assigned it to an independent review organization which provided its analysis and recommendation to the Director on April 4, 2016.

## II. FACTUAL BACKGROUND

The Petitioner is [REDACTED] years old and has uveal melanoma, a rare cancer of the eye. His physician ordered a medical test, the Decision Dx-UM, used to determine the risk of metastasization. The test was performed on March 23, 2015, by Castle Biosciences, Inc., a Dallas, Texas company that developed the test. The charge for the test was \$7,990.00. BCNSC denied coverage, ruling that the test was experimental for the treatment of the Petitioner's condition.

The Petitioner appealed the denial through BCNSC's internal grievance process. At the conclusion of that process, BCNSC issued a final adverse determination dated January 19, 2016, affirming its denial. The Petitioner now seeks the Director's review of that final adverse determination.

## III. ISSUE

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

## IV. ANALYSIS

### BCNSC's Argument

In its final adverse determination, BCNSC stated that coverage was denied because Castle Biosciences is not a network provider, their medical test was not preauthorized, and the test is considered experimental.

Because BCNSC concluded that the DecisionDx-UM test was experimental, Castle Biosciences is not eligible to be a BCNSC network provider for the test and the test itself would not be preauthorized.

### Petitioner's Argument

In the request for external review, a representative of Castle Biosciences 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 [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.

\* \* \*

Uveal melanoma is a rare cancer and is generally treated by tertiary care surgeons who specialize in eye cancers....It is estimated that patients diagnosed with uveal melanoma are treated at one of the 60-65 centers in the U.S. The majority of these ocular oncology services (over 45 centers through February 2011) have incorporated the DecisionDx-UM gene expression profile assay into their standard order set.

**Recommended for Clinical Use by American Joint Committee on Cancer:**

The AJCC is the only national guideline association that specifically reviews uveal melanoma. The AJCC reviewed the clinical validation and clinical use of this assay (identified as the gene expression profile assay) during the last revision (version 7, 2010). The AJCC concluded that the results are 'clinically significant' and therefore recommended for patient care....

The DecisionDx-UM uveal melanoma gene expression assay is considered standard of care by the specialists treating eye cancer and is not considered experimental or investigational because:

- It was clinically validated in a 5-year, prospective, multi-center, blinded study of 694 U.S. patients diagnosed with uveal melanoma;
- The results are therapy directing in that they are necessary for the development of individual surveillance plans and treatment plans, resulting in a decrease in MRI, CT and other advanced imaging orders for the patient at low risk of metastatic disease and an increase in MRI, CT and other advanced imaging orders for the patient at high risk of metastatic disease;
- Is being ordered in routine clinical care at the majority of the eye cancer centers in the U.S....
- Has been recommended for collection as the results are clinically significant for patient care by the AJCC....
- It has been technically validated in a CAP accredited/CLIA certified laboratory.

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....

[Citations omitted.]

Director’s Review

BCNSC’s *U-M Premier Care Benefit Document* provides coverage for medically necessary health services but excludes coverage for services that are experimental or investigational.

Under Section 9: Exclusions and Limitations the *Benefit Document* (page 55) states:

**9.3 Noncovered Services**

Coverage does not include the following services:

\* \* \*

- All facility, ancillary and physician services, including diagnostic tests, related to experimental or investigational procedures.

BCNSC also has a medical policy entitled, *Gene Expression Profiling for Uveal Melanoma* effective September 1, 2015, wherein BCNSC has determined the DecisionDx-UM test provided by Castle Biosciences is experimental/investigational:

**Medical Policy Statement**

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

The question of whether the Decision Dx-UM test is experimental in the treatment of the Petitioner's condition was presented 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 12 years who is board certified in ophthalmology. The reviewer is published in peer reviewed literature and is familiar with the medical management of patients with the Petitioner's condition. The IRO report included the following analysis:

[T]he DecisionDx Melanoma assay is used by virtually all experts in the field of ocular oncology for patients with choroidal melanoma....[T]he DecisionDx-UM assay is a genetic test that differentiates between patients at a high risk of metastasis versus those with a low risk of metastasis. This differentiation determines how aggressively a patient should be treated and how frequently the patient should undergo tumor surveillance....[T]his test is considered the standard of care in the community of experts who treat this rare condition....[T]his test is very safe, appropriate and cost effective as it can greatly reduce the need for frequent surveillance in a low risk patient.

Pursuant to the information set forth above and available documentation...the DecisionDx Melanoma assay performed on 3/25/15 was not experimental/ investigational for diagnosis and treatment of the member's condition. (Cassoux N, et al. Genome-wide profiling is a clinically relevant and affordable prognostic test in posterior uveal melanoma. *Br J Ophthalmol*. 2014 Jun;98(6):769-74. Werdich XQ, et al. A review of advanced genetic testing for clinical prognostication in uveal melanoma. *Semin Ophthalmol*. 2013 Sep-Nov;28(5-6): 361-71.)

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 the terms of coverage of the Petitioner’s health benefit plan. See MCL 550.1911(15).

The Director can discern no reason why the IRO’s recommendation should be rejected in the present case. Therefore, the Director finds that the Decision Dx-UM test is not experimental/investigational in the treatment of the Petitioner’s condition.

#### V. ORDER

The Director reverses BCNSC’s final adverse determination of January 19, 2016.

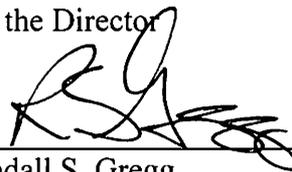
BCNSC shall immediately provide coverage for the Petitioner’s Decision Dx-UM test performed on March 23, 2015. See MCL 550.1911(17). Within seven days of providing coverage, BCNSC shall provide to the Director proof it has complied with this order.

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(1), 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



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Randall S. Gregg  
Special Deputy Director