

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. 148686-001

Blue Cross Blue Shield of Michigan
Respondent

Issued and entered
this 5th day of August 2015
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

The Patient's Right to Independent Review Act (MCL 550.1901 *et seq.*) authorizes the Director of Insurance and Financial Services to review denials of coverage for health care services. These external reviews are initiated by policyholders or an authorized representative once a coverage denial has been reviewed by the insurer in its internal grievance process.

On July 6, 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. The request concerned a denial of coverage for a medical test ordered by the Petitioner's doctor. (██████████ is an employee of the company which performed the test.)

The Petitioner receives health care benefits through a group plan underwritten by Blue Cross Blue Shield of Michigan (BCBSM). The Petitioner's health care benefits are described in BCBSM's *Nongroup Comprehensive Health Care Benefits Certificate*.

On July 13, 2015, 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 27, 2015.

II. FACTUAL BACKGROUND

The Petitioner was diagnosed with cancer in his right eye. The eye was removed on September 18, 2013. On October 22, 2013, he underwent a genetic test, the Decision DX-UM uveal melanoma gene expression profile assay, to determine the risk of metastization. The test was provided by [REDACTED] company that is not a member of BCBSM's provider network. The amount charged for this test was \$7,990.00.

BCBSM denied coverage for the test, ruling that it was experimental/investigational for the Petitioner's condition. The Petitioner appealed the denial through BCBSM's internal grievance process. BCBSM issued a final adverse determination on May 7, 2015. The Petitioner now seeks review of that determination from the Director.

III. ISSUE

Is the Decision DX-UM test the Petitioner received experimental or investigational for treatment of his condition?

IV. ANALYSIS

BCBSM's Argument

In its May 7, 2015 final adverse determination, BCBSM stated that it denied coverage because the Decision DX-UM test is investigational/experimental, stating:

A board-certified M.D. in Family Practice reviewed the claim, the appeal and [Petitioner's] health care plan benefits for BCBSM. It was determined that based on the Blue Cross Blue Shield Association medical policy *Gene Expression Profiling for Uveal Melanoma*, gene expression profiling for uveal melanoma is considered investigational because the use of this test has not been shown to improve patient outcomes.

Petitioner's Argument

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

I am appealing on behalf of [the Petitioner] who was diagnosed with uveal melanoma, a rare cancer of the eye....Coverage was denied for the DecisionDX-UM uveal melanoma gene expression profile assay as being Experimental/ Investigational. This appeal describes why this is an incorrect assessment. Specifically, 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, and c) is recommended for use by the only national guidelines (AJCC) developed for uveal melanoma....

The DecisionDX-UM gene expression profile assay...identifies patients with a low risk of developing metastatic disease from the patient at high risk....

As a rare cancer, treatment of primary uveal melanoma is generally referred to the top 50 (fifty) 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.

Director's Review

The BCBSM *Nongroup Comprehensive Health Care Benefit Certificate* excludes coverage for experimental and investigational medical services (page 5.3). Section 6 of the certificate (page 6.11) 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 for the treatment of 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. This test allows physician to intensively screen the higher risk patients, thereby avoiding unnecessary testing and expense to many patients.

* * *

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 I patients do not need this option.

* * *

The DecisionDX-UM test is not considered investigational. Although there are only 2,300 uveal melanomas a year in the US, 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 violation of the standard of care for ocular melanoma in that it greatly influences decision-making in the care of patients with this disease. Without the use of this test, 50% of patients will be exposed to unnecessary frequent metastatic screening by abdominal CT or PET scanning. [Citations omitted.]

The enrollee has a Class 2 tumor and will require higher intensity metastatic surveillance. The benefit to this enrollee cannot be achieved by any other standard health care service. In this specific situation, the DecisionDX-UM test is a one-time event. 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 is a highly beneficial test that saves many patients unnecessary risk and cost for metastatic surveillance. The DecisionDX-UM test is not experimental and is the standard of care among the ocular oncology centers in the United States.

Recommendation:

It is the recommendation of this reviewer that the denial by [BCBSM] for DecisionDX-UM testing performed on October 22, 2013 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's condition and, for that reason, is a covered benefit.

V. ORDER

BCBSM's final adverse determination of July 10, 2015 is reversed. BCBSM shall immediately provide coverage for the Petitioner's October 22, 2013 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



Randall S. Gregg
Special Deputy Director