

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. 151490-001

Blue Cross Blue Shield of Michigan

Respondent

Issued and entered
this 2nd day of February 2016
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On December 28, 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 January 7, 2016, 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 *Community Blue Group Benefits Certificate with Prescription Drugs LG*.

The medical issues in this case were evaluated by an independent review organization which provided its analysis and recommendation to the Director on January 26, 2016.

II. FACTUAL BACKGROUND

The Petitioner is ██████ years old and has a history of uveal melanoma, a rare cancer of the eye. As part of her ongoing treatment, her doctor prescribed a DecisionDx-UM test to determine the likelihood of subsequent metastasis. The test was processed on October 20, 2014 by Castle Biosciences, a Dallas, Texas company that developed the test. The cost of the test is \$7,990.00.

BCBSM denied coverage for the test, ruling that it was investigational/experimental, not a proven test for the Petitioner's condition. The Petitioner appealed the denial through BCBSM's internal grievance process. BCBSM issued a final adverse determination on November 4, 2015. The Petitioner now seeks review of that determination from the Director.

III. ISSUE

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

IV. ANALYSIS

BCBSM's Argument

In its November 4, 2015 final adverse determination, BCBSM stated that it denied coverage because the DecisionDx-UM test is investigational/experimental:

[A] board-certified M.D. in Internal Medicine reviewed [Petitioner's] claim, the appeal, and her health care plan benefits for BCBSM. Our medical consultant determined:

Your provider ordered DecisionDx-UM assay testing to determine management of your condition. Per Blue Cross Blue Shield of Michigan Policy "Gene Expression Profiling for Uveal Melanoma," this test is considered experimental/investigational. The impact of this test in improving the patient outcome has not been established....

Petitioner's Argument

In a letter dated December 15, 2015 accompanying the request for an external review, the Petitioner's representative 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....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

The *Community Blue Group Benefits Certificate LG* (page 135) excludes coverage for experimental and investigational medical services:

Services That Are Not Payable

We do not pay for experimental treatment (including experimental drugs or devices) or services related to experimental treatment....

The *Community Blue* certificate, on page 150, 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 investigational/experimental, 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 and is an instructor at two schools of medicine. The reviewer's report included the following analysis and recommendation:

The DecisionDx-Um gene expression profile assay is not investigational/experimental for the treatment of this enrollee's condition. It has become increasingly apparent, with the advent of genetic testing, that genetic analysis origin and genetic makeup is often crucial and significant role in the prognosis of clinical outcome and treatment. Over the past five years the standard of care has shifted toward studying genetic implications of these rare tumors (about 2,000 cases per year are diagnosed in the United States). Evidence is now compelling concerning genetic footprints of these tumors with significant management implications, based upon the genetic basis of the tumors.

The DecisionDx-UM gene expression profile assay represents a diagnostic test, utilizing the patient's deoxyribonucleic acid (DNA) from either enucleation tissue or fine needle aspiration tissue from the eye, not a treatment per se. For this reason, this test has not been approved by the United States Food and Drug Administration (FDA) nor is FDA approval relevant for this diagnostic testing. There are only perhaps sixty five (65) ocular oncology centers within the entire United States which specialize in treatment of this particular rare cancer, and between 65% and 80% of these centers currently recognize the DecisionDx-UM gene expression assay as an important and effective tool in the management of this cancer.

The expected benefits of this test are more likely to be beneficial than available standard health care services in that appropriate emphasis can be placed on focused follow-up when focused follow-up is necessary. The prognosis of uveal melanoma is extraordinarily difficult to predict. There is no simple way to tell whether micro metastases are present at the time of the initial diagnosis. Genetic testing of the cell type of the tumor, via methods mentioned above, developed from an assay involving over 600 patients over the past two 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 five to ten years, this particular assay should be considered standard of care from management of this rare eye cancer. Therefore, for the reasons noted above, the DecisionDx-UM gene expression profile assay was not experimental/investigational for this enrollee.

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

V. ORDER

BCBSM's final adverse determination of November 4, 2015 is reversed. BCBSM shall immediately provide coverage for the Petitioner's October 20, 2014 DecisionDx-UM test, and shall, within seven days of providing coverage, furnish the Director with proof it has implemented this order. See 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 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