

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. 150068-001-SF

████████████████████
and
Blue Cross Blue Shield of Michigan
Respondents

Issued and entered
this 28th day of October 2015
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On September 28, 2015, ██████████, authorized representative of ██████████ (Petitioner), filed a request for external review with the Department of Insurance and Financial Services, appealing a claim denial issued by Blue Cross Blue Shield of Michigan (BCBSM), the administrator of the Petitioner's health benefit plan which is sponsored by ██████████ ██████████

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 benefit plan is such a governmental self-funded plan. The plan's benefits are described in BCBSM's *Community Blue Group Benefits Certificate ASC*.

On October 5, 2015, after a preliminary review of the information submitted, the Director accepted the Petitioner's request. The Director notified BCBSM of the appeal and asked BCBSM to provide the information used to make its final adverse determination. BCBSM furnished its response on October 9, 2015.

This case involves medical issues so the Director assigned it to an independent review organization which provided its recommendation to the Director on October 16, 2015.

II. FACTUAL BACKGROUND

The Petitioner has uveal melanoma, a rare form of cancer, in her right eye. Her physician ordered the Decision DX-UM assay, a test used to determine the risk of her cancer metastasizing.

The test was performed on February 14, 2014, by Castle Biosciences, Inc. which charged \$7,972.00. BCBSM denied coverage for the test, ruling it was investigational for the treatment of the Petitioner's condition and was therefore not a covered benefit.

The Petitioner appealed the denial through BCBSM's internal grievance process. At the conclusion of that process BCBSM issued a final adverse determination dated July 30, 2015, affirming its denial. The Petitioner now seeks review of that final adverse determination from the Director.

III. ISSUE

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

IV. ANALYSIS

BCBSM's Argument

In its final adverse determination BCBSM stated that it does not provide coverage for experimental treatment. BCBSM wrote:

A board-certified M.D. in Family Practice reviewed your claim, your appeal and your health care plan benefits....Based on that review, and current BCBSM Medical Policy, procedure code 84999 (unlisted chemistry procedure) and 99000 (Specimen handling, office to lab) are considered experimental/ investigational. Decision DX-UM testing was ordered because the member was diagnosed with choroidal melanoma in her left [sic] eye. According to the Blue Cross Blue Shield Association medical policy "Gene Expression Profiling for Uveal Melanoma," this test is considered investigational/experimental. There is insufficient evidence that this test improves patient outcomes. Therefore, the services are considered experimental/investigational and we are unable to approve payment.

Petitioner's Argument

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

[T]he Decision Dx-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 [the 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 Decision Dx-UM assay is not Experimental/Investigational.

The Decision Dx-UM gene expression profile assay... identifies patients with a low risk of developing metastatic disease from those patients at high risk.... The results are necessary for determining [Petitioner's] surveillance and treatment plans.

Director's Review

BCBSM's denial was based on this exclusion in Section 6 the *Community Blue* certificate:

Experimental Treatment

Services That Are Not Payable

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

"Experimental treatment" is defined in the certificate 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."

The question of whether the Decision DX-UM test was investigational for treating 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 who is certified by the American Board of Ophthalmology and is a clinical associate professor of ophthalmology at a university based school of medicine. The reviewer is a member of the American Academy of Ophthalmology and is published in peer reviewed medical literature. The IRO 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 Decision DX-UM test to classify ocular melanoma patients as to risk of future metastatic disease. 50% of ocular melanoma patients develop metastasis within five years, but most of these have Class 2 tumors. The Decision DX-UM test allows physicians to intensively screen the higher risk patients, thereby avoiding unnecessary testing in many patients and unnecessary expense to the insurance carrier. It is a violation of the standard of care to not provide this testing to facilitate decision making in ocular melanoma.

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. Class 2 tumors patients may choose to have adjuvant chemotherapy because of their high risk of metastasis whereas Class 1 patients do not need this option.

* * *

In this specific situation, the enrollee has a Class 1A tumor and can be spared high intensity metastatic surveillance. Rather than having frequently repeated PET and CT scans, she is being followed with yearly liver ultrasounds, indicating a great benefit to the enrollee with decreased risks and cost savings. The enrollee is at low risk of metastasis, but the outcomes of the test could not have been known before it was performed. Had the enrollee had a Class 2 tumor, there would have been a significant increase in cost and risk for metastatic screening. Not covering this testing is not within the standard of care for ocular melanoma as practiced by virtually every ocular oncology center in the United States. Therefore, for the reasons noted above the Decision DX-Um test is not experimental/investigational for the enrollee's condition.

Recommendation:

It is the recommendation of this reviewer that the denial issued by Blue Cross Blue Shield of Michigan for the Decision DX-UM test provided on February 14, 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 review 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 the present case, finds that the Decision DX-UM test is not experimental/investigational in the treatment of the Petitioner's condition, and is therefore is a covered benefit.

V. ORDER

The Director reverses BCBSM's final adverse determination dated July 30, 2015. BCBSM shall immediately provide coverage for the Petitioner's Decision DX-UM test performed on February 14, 2014, subject to any applicable cost sharing provisions of the *Community Blue* certificate. Within seven days of providing coverage, BCBSM shall furnish the Director with 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, 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



Randall S. Gregg
Special Deputy Director