

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. 153862-001

Blue Care Network of Michigan
Respondent

Issued and entered
this 27th day of June 2016
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On May 25, 2016, ██████████, authorized representative of ██████████ (Petitioner), filed a request with the Director of Insurance and Financial Services for an external review under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.*

The Petitioner receives health care benefits through a group plan that is underwritten by Blue Care Network of Michigan (BCN). The benefits are described in BCN's *Certificate of Coverage BCN1 for Large Groups*. The Director notified BCN of the external review request and asked for the information used to make its final adverse determination. The Director received BCN's response on May 31, 2016 and, after a preliminary review of the material submitted, accepted the request for an external review.

The medical issue in this case was evaluated by an independent review organization, which provided its analysis and recommendation to the Director on June 14, 2016.

II. FACTUAL BACKGROUND

The Petitioner is 16 years old and has uveal ocular melanoma, a rare eye cancer, in her left eye. As part of her ongoing treatment, her doctor ordered a test, the

DecisionDx-UM, to determine the likelihood of subsequent metastasis. The test was performed on July 14, 2015, by Castle Biosciences, the company that developed the test. The cost of the test was \$7,990.00.

BCN denied coverage for the test, saying it was experimental or investigational and therefore not a covered benefit. The Petitioner appealed the denial through the plan's internal grievance process. At the conclusion of that process, on April 8, 2016, BCN issued a final adverse determination upholding the decision. The Petitioner now seeks the Director's review of that final adverse determination.

III. ISSUE

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

IV. ANALYSIS

BCN's Argument

In its final adverse determination, BCN stated that its appeal panel "has maintained the denial for Gene Expressing Profiling, as this service is considered experimental and not a benefit per the member's certificate of coverage. Additionally, the provider is out-of-network."

BCN also cited its medical policy titled, "Gene Expression Profiling for Uveal Melanoma" which states:

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

Petitioner's Argument

In a letter dated May 16, 2016, submitted with the external review request, the Petitioner's representative wrote:

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 ... 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 ...

[Description of published studies 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. DecisionDx-UM offers the ability to individualize patient care and leads to more efficient utilization of healthcare resources. Therefore, this test is medically necessary ... and should not be considered experimental or investigational.

Director's Review

BCN's *Certificate of Coverage BCN1 for Large Groups* (page 31) provides coverage for medically necessary outpatient diagnostic and therapeutic services, tests, and treatments. The certificate defines medically necessary services as:

health care services provided to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are ... [n]ot regarded as experimental by BCN.

To determine whether the DecisionDx-UM test is experimental or investigational in the medical management of the 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 with a subspecialty certification by the American Society of Ophthalmic Plastic and Reconstructive Surgery. The reviewer is an instructor at two schools of medicine and is published in peer reviewed medical literature. The IRO report included the following analysis and recommendation:

It is the determination of this reviewer that the Decision Dx-UM laboratory test provided on July 14, 2015 was not experimental/investigational for the treatment of the enrollee's condition.

Clinical Rationale for the Decision:

It has become increasingly apparent, with the advent of genetic testing, that genetic analysis of tumor origin and genetic makeup often play a crucial and significant role in prognosis of clinical outcome and treatment.

Over the past five years, standard of care has shifted towards studying genetic implications of rare uveal melanoma tumors (about 2000 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 prognosis of uveal melanoma is extraordinarily difficult to predict. There is no simple way to tell whether micrometastases are present at the time of initial diagnosis. Genetic testing of the cell type of tumor, 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, the Decision Dx-UM gene expression assay should be considered standard of care for management of this rare eye cancer. As of 2015, the time of the enrollee's diagnosis, this diagnostic test was not considered experimental/investigational.

There is a gray zone regarding Food and Drug Administration (FDA) approval in that the DecisionDx-UM represents a diagnostic test, utilizing a patient's deoxyribonucleic acid (DNA) from either enucleation tissue or tissue from a fine needle aspiration inside the eye, not a treatment per se.

There are only perhaps sixty five ocular centers within the entire United States which specialize in treatment of this particular rare cancer. Between 65-80% of these centers currently recognize the DecisionDx-UM gene expression assay as an important and effective tool in management of this cancer.

The expected benefits of the DecisionDx-UM test are more likely to be beneficial than available standard health care service in that appropriate emphasis can be placed on focused follow-up when focused follow-up is necessary. This particular case has a very guarded prognosis, and very close clinical monitoring of the enrollee will likely be required for years if not decades into the future. Therefore, for the reasons noted above, the Decision Ox-LIM laboratory test was not experimental/investigational for this enrollee.

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 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. MCL 550.1911(15). The Director, discerning no reason why the IRO's recommendation should be rejected in this case, accepts the IRO's recommendation and 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

The Director reverses BCN's final adverse determination of April 8, 2016. BCN shall immediately provide coverage for the Petitioner's July 14, 2015, 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 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