

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. 153737-001-SF

University of Michigan, Plan Sponsor,

and

BCN Service Company, Plan Administrator,

Respondents.

Issued and entered
this 14th day of June 2016
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

██████████ (Petitioner) was denied coverage for a diagnostic test by her health plan.

On May 18, 2016, ██████████, the Petitioner's authorized representative, filed a request with the Director of Insurance and Financial Services for an external review of that denial under Public Act No. 495 of 2006 (Act 495), MCL 550.1951 *et seq.* On May 25, 2016, after a preliminary review of the information submitted, the Director accepted the request.

The Petitioner receives health care benefits through a group plan that is sponsored by the University of Michigan (the plan), a self-funded governmental health plan subject to Act 495. BCN Service Company (BCNSC) administers the plan. The Director immediately notified BCNSC of the external review request and asked for the information it used to make the plan's final adverse determination. The Director received BCNSC's response on May 26, 2016.

Section 2(2) of Act 495, MCL 550.1952(2), authorizes the Director to conduct this external review as though the Petitioner were a covered person under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.*

The medical issue in this case was evaluated by an independent review organization, which provided its analysis and recommendation to the Director on June 6, 2016.

II. FACTUAL BACKGROUND

The Petitioner's health care benefits are described in BCNSC's *U-M Premier Care Benefit Document* (the benefit document).

The Petitioner has uveal melanoma, a rare eye cancer, in her left eye. As part of her ongoing treatment, her doctor ordered a test called DecisionDx-UM to determine the likelihood of subsequent metastasis. The test was performed on November 18, 2014, by Castle Biosciences, the company that developed the test. The cost was \$7,990.00.

The plan 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, BCNSC issued a final adverse determination dated March 31, 2016, upholding the decision. The Petitioner now seeks a review of that final adverse determination from the Director.

III. ISSUE

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

IV. ANALYSIS

Petitioner's Argument

In a letter dated May 7, 2016, accompanying the external review request, the Petitioner's representative wrote in part:

The DecisionDx-UM test was ordered by [the Petitioner's physician] who, as an in-network provider with your health plan, cited medical necessity for your member based on intent to use test results in the management of the member. The DecisionDx-UM test is exclusively available through Castle Biosciences, Inc. as a validated prognostic test for the prediction of metastatic recurrence in early stage uveal melanoma.

Test Background

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 as follows: low (Class 1A), intermediate (Class 1B), or high risk (Class 2); based on the gene expression levels (mRNA) of 15 genes, as evaluated by quantitative reverse transcriptase polymerase chain reaction (qRT-PCR).

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. . . .

* * *

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 for management of your member and should not be considered experimental or investigational.

BCNSC's Argument

In its final adverse determination, BCNSC, acting for the plan, explained its decision:

Our step two grievance panel . . . reviewed all of the medical documentation submitted and has upheld the previous denial. We based our decision on per the BCBSM/BCN Medical Policy titled "Gene Expression Profiling for Uveal Melanoma," the procedure is considered investigational / experimental.

The medical policy relied on by the plan, “Gene Expression Profiling for Uveal Melanoma,” says:

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

Director’s Review

The plan covers medically necessary outpatient diagnostic and therapeutic services, tests, and treatments (benefit document, p. 25). The benefit document also has this definition of “medically necessary services” (pp. iv):

Medical Necessity or Medically Necessary services are 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:

* * *

- Not regarded as experimental by BCN. . .

To answer the question of 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 physician reviewer is certified by the American Board of Ophthalmology, is in active clinical practice, and is familiar with the medical management of patients with the Petitioner’s condition. The IRO report included the following analysis and recommendation:

Reviewer's Decision and Principal Reasons for the Decision:

Is the Decision DX-UM lab test provided the enrollee experimental / investigational for treatment of her condition?

No. It is the determination of this reviewer that the Decision DX-UM laboratory test 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. Genetic testing of the cell type of the 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 DecisionDx-UM gene expression assay should be considered standard of care for management of this rare eye cancer. As of 2014, at the time of the enrollee's diagnosis, the DecisionDx-UM laboratory 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 prognosis of uveal melanoma is extraordinarily difficult to predict. There is no simple way to tell whether micrometastases are present at the time of original diagnosis. 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 enrollee's clinical course is even more complicated by the presence of recently diagnosed asymptomatic adenocarcinoma of the lung as well. Therefore, for the reasons noted above, the DecisionDx-UM laboratory test was not experimental / investigational for this enrollee. [References omitted.]

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 plan's final adverse determination of March 31, 2016 is reversed. The plan shall immediately cover the Petitioner's November 18, 2014, DecisionDx-UM test, MCL 550.1911(17), 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 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