

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. 151556-001-SF

University of Michigan, Plan Sponsor
and
BCN Service Company, Plan Administrator
Respondents

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

ORDER

I. PROCEDURAL BACKGROUND

On January 4, 2016, ██████████, authorized representative of ██████████ (Petitioner), filed a request for external review with the Department of Insurance and Financial Services. The request for review concerns a denial of coverage for a medical test. The denial was issued by BCN Service Company, the administrator of the Petitioner's health benefit plan which is sponsored by the University of Michigan.

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 health benefit plan is such a governmental self-funded plan. The benefits are described in the *U-M Premier Care Benefit Document*.

On January 11, 2016, 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 January 26, 2015.

II. FACTUAL BACKGROUND

The Petitioner is ■ years old and has a history of melanoma of the right eye. As part of his ongoing treatment, his doctor prescribed a DecisionDX-Melanoma test to determine the likelihood of subsequent metastasis. The test was processed on August 4, 2014 by Castle Biosciences, a Dallas, Texas company that developed the test. The cost of the test is \$7,990.00.

BCN Service Company denied coverage for the test, ruling that it was investigational/experimental and therefore not a covered benefit. The Petitioner appealed the denial through BCN Service Company's internal grievance process. BCN Service Company issued a final adverse determination on November 8, 2015. The Petitioner now seeks the Director's review of that determination.

III. ISSUE

Is the DecisionDX-Melanoma test experimental or investigational in the treatment of the Petitioner's condition?

IV. ANALYSIS

In a letter dated December 30, 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.]

The Petitioner's benefit plan, as detailed in the *U-M Premier Care Benefit Document*, provides coverage for medically necessary outpatient professional diagnostic and therapeutic services, tests and treatments. The *Premier Care Benefit Document* includes the following definition of medically necessary services:

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:

- Rendered in accordance with generally accepted standard of medical practice (standards that are based on credible scientific evidence published in peer-review medical literature generally recognized by the relevant medical community, physician or provider society; recommendations and the views of physicians or providers practicing in relevant clinical areas and any other relevant factors);
- Clinically appropriate, in terms of type, frequency, extent, site and duration, and also considered effective for the member's illness, injury or disease;
- Not primarily for the convenience of the member or health care provider;
- Not regarded as experimental by BCN and
- In accordance with BCN Utilization Management Criteria for Mental Health and Substance Abuse Disorders.

In addition, the *Premier Care Benefit Document* (pages 50-51) excludes coverage for experimental and investigational medical services and defines experimental or investigational as “a service that has not been scientifically proven to be as safe and effective for treatment of the patient’s conditions as conventional treatment in the United States.”

To evaluate the question of whether the DecisionDX-Melanoma 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 board certified in ophthalmology and is familiar with the medical management of patients with the Petitioner’s condition. The reviewer’s report included the following analysis and recommendation:

Given the associate risk for metastatic disease with choroidal melanoma, the member’s treating ocular oncologist ordered the DecisionDX assay to better predict his relative risk for developing metastases. Choroidal melanoma is a relatively rare tumor, which has ultimate consequences for both vision and life-span. Metastatic disease prediction has been difficult and historically, little information could be given to a patient about the risk profile. Similarly, little data has been historically available to the oncologist to educate the patient and aid in determining the type and frequency of tests to order to follow the disease.

[W]ith the DecisionDX assay, providers have a safe tool to predict the likelihood of metastatic disease and accordingly prescribe adjuvant therapy...[T]he test also helps provide a feasible schedule for determining the frequency of testing for metastatic disease via laboratory and imaging studies. This allows for a more focused and cost-effective work-up in the ongoing surveillance of patients with the diagnosis for metastatic disease. The DecisionDX assay is being used frequently in major ocular oncology centers around the United States. [T]his member’s case was an appropriate one for the utilization of the DecisionDX assay.

Pursuant to the information set forth above and available documentation...the DecisionDX Melanoma assay performed on 8/22/14 was not experimental/ investigational for diagnosis and treatment of the member’s condition.
[Citations omitted]

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-Melanoma test is not experimental or investigational as a part of the Petitioner's treatment and, for that reason, is a covered benefit.

V. ORDER

BCN Service Company's final adverse determination of November 8, 2015 is reversed. BCN Service Company shall immediately provide coverage for the Petitioner's August 22, 2014 DecisionDX-Melanoma assay, 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