

STATE OF MICHIGAN
DEPARTMENT OF INSURANCE AND FINANCIAL SERVICES
Before the Director of Insurance and Financial Services

In the matter of:

██████████
Petitioner

v

HealthPlus of Michigan
Respondent

File No. 150298-001

Issued and entered
this 10th day of November 2015
by **Randall S. Gregg**
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On October 12, 2015, ██████████, authorized representative of ██████████ (Petitioner), filed a request with the Department of Insurance and Financial Services for external review under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.* The Director accepted the request on October 19, 2015.

The Petitioner receives health care benefits through HealthPlus of Michigan Inc., a health maintenance organization. The benefits are defined in the HealthPlus *Group Subscriber Contract-NG* and *Benefit Rider GA*.

To address the medical issues in the case, the Director assigned it to an independent medical review organization which provided its analysis and recommendation on November 2, 2015.

II. FACTUAL BACKGROUND

The Petitioner has a history of skin cancer on his back. He had a successful surgery in 2012. In January 2015 the Petitioner saw an oncologist who ordered the DecisionDX-melanoma assay to determine if he was high risk for recurrence of the cancer.

The test was performed on February 2, 2015, by Castle Biosciences, Inc. HealthPlus denied coverage for the test, ruling it was investigational or experimental for the treatment of the Petitioner's condition and was therefore not a covered benefit.

The Petitioner appealed the denial through the HealthPlus internal grievance process. At the conclusion of that process, HealthPlus issued a final adverse determination dated August 27,

2015, affirming its denial. The Petitioner now seeks review of that final adverse determination from the Director.

III. ISSUE

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

IV. ANALYSIS

HealthPlus's Argument

In its final adverse determination to the Petitioner's authorized representative, HealthPlus stated that it does not provide coverage for investigational or experimental treatment, stating in part:

[T]here is insufficient published literature to establish clinical validity, efficacy, and safety of the service(s). Therefore, it is considered investigational and/or experimental and not covered by [Petitioner's] coverage.

Petitioner's Argument

In a letter dated October 6, 2015, accompanying the request for an external review, Petitioner's authorized representative wrote:

Clinical Need: The treatment approach for melanoma for [the Petitioner] would normally consist of surgical excision, followed sometimes by sentinel lymph node interrogation and further systemic work-up. Patients with thinner melanomas and/or those with a negative sentinel lymph node are generally considered at low risk for metastasis. However, up to 10% of this population is actually at high risk (biologically). Unfortunately, histopathologic staging cannot accurately identify these high risk patients.

Clinical Use: The DecisionDx-Melanoma assay was developed and clinically validated through a 268 patient, prospectively designed study which identified a panel of genes that is more accurate in identifying high versus low risk tumors than today's current histopathology-based tools. The need to identify which patients are at high risk (Class 2) from those patients at low risk (Class 1) is clear. In conjunction with other clinical assessments, results from the DecisionDx-Melanoma assay will assist in formulating appropriate surveillance and treatment plans.

Given the aggressive nature of this disease, the importance of the treatment decisions for which this assay is used, and the fact that Castle is the only laboratory through which DecisionDx-Melanoma can be obtained, please consider paying this claim in full at the in-network benefit level.

Petitioner's authorized representative also provided a letter from Petitioner's physician and numerous medical literature articles to support the medical necessity of the test in Petitioner's case.

Director's Review

Benefit Rider GA includes this provision cited by HealthPlus in its final adverse determination:

Section 2.2 EXCLUSIONS

Services and products not specifically identified by the Rider are not Covered Services, including but not limited to:

* * *

- L. Medical, surgical, or psychiatric procedures, treatment or devices, pharmacological regimens (except for antineoplastic drugs required to be covered in accordance with Section 3406e of the Insurance Code), and associated health care services, which are considered Experimental in nature under accepted standards of practice. Something may be considered by HPM to be Experimental if one of the following circumstances applies:

* * *

- 6. Published literature indicates that further research is needed to define factors such as safety, efficacy, or toxicity.

The *Group Subscriber Contract-NG* (page 3) defines "experimental" as:

"Experimental" means that a service is of doubtful medical usefulness or effectiveness to the Member, as assessed by local medical community standards.

The question of whether the Decision DX-Melanoma test was experimental in the treatment of 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 board certified in oncology and is familiar with the medical management of patients with the Petitioner's condition. The IRO reviewer's report included the following analysis and recommendation:

[A]ccording to the American Joint Committee on Cancer Staging Manual, 7th Edition, the member has an excellent prognosis with a 10 year survival of greater than 90%....[A]t the time of these services, the only approved adjuvant therapy for this diagnosis was interferon. The National Comprehensive Cancer Network guidelines state that genetic testing on the tumor is not warranted outside of a clinical trial for the member's diagnosis....[W]hile one article states that genetic

profiling along with the American Joint Committee on Cancer stage, Breslow category, age and ulceration of are of prognostic value, this article does not state that adjuvant therapy should be utilized based on the results of genetic profiling. (Gerami P, et al. Development of a prognostic genetic signature to predict the melanoma risk associated with cutaneous melanoma. *Clin Cancer Res.* 2015 Jan 1;21(1):175-87.)

Pursuant to the information set forth above and available documentation...the Decision DX Melanoma assay performed on 2/5/15 was experimental/ investigational for diagnosis and treatment of the member's condition.

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 Melanoma Assay is experimental in the treatment of the Petitioner's condition, and is therefore not a covered benefit.

V. ORDER

The Director upholds HealthPlus's final adverse determination dated August 27, 2015.

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