

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. 151407-001

Blue Care Network of Michigan,

Respondent.

Issued and entered
this 22nd day of January 2016
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

██████████ (Petitioner) was denied coverage for a test by her health plan, Blue Care Network of Michigan (BCN).

On December 21, 2015, ██████████, the Petitioner's authorized representative, filed a request with the Department of Insurance and Financial Services for an external review of BCN's denial under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.*

The Petitioner receives group health care benefits through BCN, a health maintenance organization. The Director immediately notified BCN of the external review request and asked for the information used to make its final adverse determination. BCN furnished the information on December 23, 2016. On December 30, 2016, after a preliminary review of the information submitted, the Director accepted the case for review.

An independent review organization evaluated the medical issues in this case and provided its analysis and recommendation to the Director on January 13, 2016.

II. FACTUAL BACKGROUND

The Petitioner's health care benefits are described in the *Certificate of Coverage BCN Classic for Large Groups* (the certificate).

The Petitioner has colon cancer. Her physician recommended the Oncotype DX Colon Cancer Assay to help determine the best course of treatment. The test was performed on March 31, 2015; the cost was \$4,330.00.

BCN denied coverage for the test, saying that it was investigational or experimental in the treatment of the Petitioner's condition. The Petitioner appealed the denial through BCN's internal grievance process. At the conclusion of that process, BCN issued a final adverse determination on October 29, 2015, upholding its denial. The Petitioner now seeks review of that final adverse determination from the Director.

III. ISSUE

Is the Oncotype DX colon cancer test experimental or investigational as part of the Petitioner's cancer treatment?

IV. ANALYSIS

Petitioner's Argument

The Petitioner's authorized representative wrote on December 16, 2015, in support of the test:

I am respectfully submitting an appeal in regards to [the Petitioner], a Blue Care Network of MI HMO subscriber who was diagnosed with early stage colon carcinoma. . . . [The Petitioner] had the Oncotype DX Colon Cancer Assay performed to assist in determining an appropriate, individualized, post-surgical treatment decision, as recommended and ordered by her physician. . . . [BCN] has denied this Oncotype DX claim based on a presumption this test was experimental / investigational. We are requesting an independent, external review with the enclosed supporting documentation.

BCN's Argument

In its final adverse determination, BCN wrote:

Our step two grievance panel, which consisted of a Senior Medical Director and a Manager, reviewed your request for the [Oncotype test] and upheld the previous denial.

The requested service is considered experimental and investigational, which is not a covered benefit for [the Petitioner].

Director's Review

The certificate has this exclusion (p. 57):

9.4 Non-Covered Services

We do not pay for these services.

* * *

- Services outside the scope of practice of the servicing provider. All facility, ancillary and physician services, including diagnostic tests, related to experimental or investigational procedures

The issue of whether the Oncotype DX Colon Cancer Assay is investigational or experimental 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 physician reviewer is board certified in oncology, has been in active practice for more than 10 years, and is familiar with the medical management of patients with the Petitioner's condition. The IRO report included this analysis:

The member had stage II disease and her treating provider ordered the Oncotype DX colon cancer assay to help with the decision whether to treat with chemotherapy. The MAXIMUS physician consultant noted that an article supplied by the representative in support of this request stated that the Oncotype DX colon cancer test can be used with T stage and mismatch repair status to assess prognosis, but that more work is needed. The physician consultant noted that another article states that the Oncotype colon cancer assay may be of value in identifying high risk stage II disease. The consultant explained that National Comprehensive Cancer Network guidelines state that the Oncotype DX colon cancer test does not predict response to chemotherapy. The physician consultant also explained that although the Oncotype DX colon cancer test may identify high risk patients, it does not predict response to chemotherapy and is considered experimental at this time. [Citations omitted.]

Pursuant to the information set forth above and available documentation, the MAXIMUS physician consultant determined that the Oncotype DX Colon Cancer Assay performed on 3/31/14 was 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 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, finds that the Oncotype DX Colon Cancer Assay is investigational in the treatment of the Petitioner's condition and is therefore not a covered benefit under the terms of the certificate.

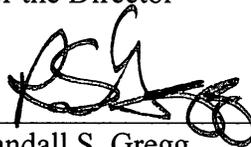
V. ORDER

The Director upholds BCN's final adverse determination of October 29, 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