

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. 154827-001-SF

Plymouth-Canton Community Schools, Plan Sponsor
and
Blue Cross Blue Shield of Michigan, Plan Administrator
Respondents

Issued and entered
this 24th day of August 2016
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On July 28, 2016, ██████████ (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 performed in May 2015. The denial was issued by Blue Cross Blue Shield of Michigan (BCBSM), the administrator of the Petitioner's health benefit plan which is sponsored by Plymouth-Canton Community Schools.

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 plan's benefits are described in BCBSM's *Community Blue Group Benefits Certificate ASC*.

On August 4, 2016, after a preliminary review of the information submitted, the Director accepted the request for review. The Director notified BCBSM of the appeal and asked it to provide the information used to make its final adverse determination.

BCBSM submitted its response on August 10, 2016.

This case involves medical issues so the Director assigned it to an independent review organization which provided its analysis and recommendation to the Director on August 18, 2016.

II. FACTUAL BACKGROUND

The Petitioner is 56 years old and has cancer. He requested coverage for a medical test called FoundationOne. The test was processed by Foundation Medicine, Inc. of Cambridge, Massachusetts. The cost of the test was \$5,800.00. BCBSM denied coverage ruling that it was investigational for the treatment of the Petitioner's condition and was therefore not a covered benefit.

The Petitioner appealed the denial through BCBSM's internal grievance process. At the conclusion of that process, on June 13, 2016, BCBSM issued a final adverse determination affirming its denial. The Petitioner now seeks the Director's review of that final adverse determination.

III. ISSUE

Is the FoundationOne test investigational in the treatment of the Petitioner's condition?

IV. ANALYSIS

BCBSM's Argument

In its final adverse determination, BCBSM wrote:

The laboratory services rendered are considered investigational. [Petitioner's] health care plan does not cover investigational or experimental services. Therefore, payment cannot be approved.

At the time of service, [Petitioner] was covered by Plymouth-Canton Community Schools PPO Plan. As explained in the *Community Blue Group Benefits Certificate ASC (Section 7 Definitions)* page 142, experimental treatment is considered treatment that has not been scientifically proven to be as safe and effective for treatment of the patient's condition as conventional treatment. Page 127, (**Section 6: General Conditions of Your Contract**), explains that *we do not pay for experimental treatment or services related to experimental treatment.*

To ensure all consideration was given to the appeal, an associate medical director, a board-certified M.D. in Internal Medicine reviewed the appeal, [Petitioner's] claims, and his health care plan benefits for BCBSM. Our medical consultant determined:

[Petitioner's] doctor ordered the FoundationOne panel of genetic tests because he has been diagnosed with cancer. This testing proposes to assist in determining what treatment may work best for [Petitioner]. According to the [BCBSM] medical policy, "Expanded Molecular Panel Testing of Cancers to Identify Targeted Therapies," this testing is considered experimental/ investigational. The evidence is insufficient to draw conclusions regarding the clinical utility of this testing. Therefore, we are unable to approve.

Petitioner's Argument

In the external review request the Petitioner stated:

I am requesting full payment for the balance due to FoundationOne (\$3,695.76). Testing was done to determine gene alterations that may be associated with activity of certain *FDA approved drugs* that could be used to treat the rare cancer I have – appendiceal adenocarcinoma with peritoneal metastasis.

Director's Review

The question of whether the FoundationOne testing procedure is experimental or investigational 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 for more than ten years who is board certified in oncology and is familiar with the medial management of patient with the Petitioner's condition. The IRO report included the following analysis and recommendation:

[M]etastatic appendiceal carcinoma is treated as colon cancer and standard therapy would involve 5FU based chemotherapy with 5FU, oxaloplatin and leukovirin (FOLFOX) or 5FU, irintocan and leukovirin (FOLFIRI). (National Comprehensive Cancer Network Compendia: Colorectal Cancer. Updated 2014.) ... [T]here is no literature support or basis in the compendia to treat this diagnosis based on actionable mutations, other than EGFR/KRAS/NRAS ...

Foundation One testing was not consistent with the standard of care.

Pursuant to the information set forth above and available documentation ... the FoundationOne testing performed on 5/12/15 was experimental/investigational for 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. The Director, discerning no reason why the IRO's recommendation should be rejected in the present case, finds that the FoundationOne testing is experimental/investigational in the treatment of the Petitioner's condition and therefore is not a covered benefit under the certificate.

V. ORDER

The Director upholds BCBSM's final adverse determination.

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