

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. 154518-001

Blue Cross Blue Shield of Michigan
Respondent

Issued and entered
this 9th day of August 2016
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On July 11, 2016, ██████████ authorized representative of ██████████ (Petitioner), filed a request with the Director of Insurance and Financial Services for an external review of the denial under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.* The request for review concerns a denial of coverage issued by her health insurer, Blue Cross Blue Shield of Michigan (BCBSM), for a medical test. After a preliminary review of the material submitted, the Director accepted the request on July 18, 2016.

The Director notified BCBSM of the external review request and asked for the information it used to make its final adverse determination. BCBSM responded on July 26, 2016.

To address the medical issue in the case, the Director assigned it to an independent medical review organization, which provided its analysis and recommendation on August 1, 2016.

II. FACTUAL BACKGROUND

The Petitioner receives health care benefits through an individual plan underwritten by BCBSM. Her benefits are defined in BCBSM's *Flexible Blue II Individual Market Certificate*.

In 2013, the Petitioner was found to have a pancreatic cyst. Her physician prescribed a medical test, the PathFinderTG, developed by Interpace Diagnostics.¹ The test was

1. The Petitioner's authorized representative is an employee of Interpace Diagnostics.

performed and interpreted by RedPath Integrated Pathology, a Pittsburgh laboratory, in September 2013. The charge for the test was \$4,350.00. BCBSM denied coverage ruling that the test is investigational and, for that reason, not covered under the Petitioner's benefit plan.

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

III. ISSUE

Was the PathFinderTG test investigational in the treatment of the Petitioner's condition?

IV. ANALYSIS

BCBSM's Argument

In the final adverse determination sent to the Petitioner's representative, BCBSM wrote:

[Petitioner] is an eligible dependent covered under the *Flexible Blue II Individual Market Certificate*. In **Section 7 on Page 7.3: General Conditions of Your Contract: Experimental Treatment: Services That Are Not Payable** it states that we do not pay for experimental treatment (including experimental drugs or devices) or services related to experimental treatment.

An associate medical Director, board-certified M.D. in Internal Medicine, reviewed [Petitioner's] claim, your appeal, and [Petitioner's] health care plan benefits for [BCBSM]. Our medical consultant determined:

Documentation reviewed. The [Petitioner] has a cyst on her pancreas. A biopsy was done to determine whether it was cancerous or not. Diagnostic testing performed included the PathFinderTG mutational analysis test (procedure code 84999). According to the BCBSM medical policy, "Genetic Testing – Molecular Anatomic Pathology (PathFinderTG)" this test is considered investigational/experimental since the clinical utility has not been demonstrated ...

As a result, the service is considered experimental/investigation and payment cannot be approved.

Petitioner's Argument

In a letter dated April 4, 2016 submitted with the external review request, the Petitioner's authorized representative wrote:

The *PathFinderTG* test provides information critical for medical decision making with regard to suspected malignancies following an indeterminate diagnosis utilizing traditional pathologic and microscopic staining and analysis. It was ordered by [Petitioner's] referring physician because in her medical judgment the findings of the *PathFinderTG* test result in targeted, patient specific treatment and effective utilization of healthcare resources. Documentation provided by the referring physician in conjunction with the requisition for the *PathFinderTG* test included the patient's clinical history and medical rationale for referring for further analysis. *PathFinderTG* testing was performed only after receipt of this documentation confirming that molecular topographic genotype testing was indicated by the prudent medical judgment of the referring physician.

With a molecular-based disease as complex as cancer early and definitive diagnosis is not always possible through microscopic review. This was the case with [Petitioner]. Understanding changes that are occurring at the molecular level is the most objective way to achieve certainty in diagnosis and plan for the optimal treatment of each patient.

PathFinderTG is a covered service for Medicare beneficiaries ... and can no longer be considered "experimental/investigational" or an "unproven service." We have performed greater than 5,000 cases, and our technology has been validated in more than three dozen studies and has been the subject of more than 140 peer-reviewed articles.

Director's Review

BCBSM's *Flexible Blue II Individual Market Certificate*, on page 8.11, defines experimental treatment as:

Treatment that has not been scientifically proven to be as safe and effective for treatment of the patient's conditions as conventional treatment. Sometimes it is referred to as "investigational" or "experimental services."

The question of whether the *PathFinderTG* test is 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 12 years who is board certified in internal medicine and gastroenterology.

The reviewer's report describes the Petitioner's medical condition and the medical tests performed as part of her treatment. The reviewer summarized various published medical studies related to pancreatic cysts, then concluded:

[I]n this member's case, the cyst in question was small and incidentally found ... [N]either the precipitating radiology report nor the cytology report

from the 3/15/13 collection was provided for review to support concern for occult malignancy ... [T]he member's cyst as described at that time, had an overall benign appearance as did its appearance at the time of the endoscopic ultrasound and cytology collected by repeat procedure on 10/10/13.

Pursuant to the information set forth above and available documentation...the PathFinderTG testing performed on 9/11/13 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 PathFinderTG test is experimental/investigational and is therefore not a covered benefit.

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