

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. 153141-001-SF

City of Lansing, Plan Sponsor
and
Blue Cross Blue Shield of Michigan, Plan Administrator
Respondents

Issued and entered
this 10th day of May 2016
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On April 8, 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 issued by Blue Cross Blue Shield of Michigan (BCBSM), the administrator of the Petitioner's health benefit plan which is sponsored by the City of Lansing.

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 two BCBSM documents: the *Professional Service Group Benefit Certificate* and the *Master Medical Supplemental Benefit Certificate Catastrophic Coverage Plan Option 2*.

On April 15, 2016, after a preliminary review of the information submitted, the Director accepted the Petitioner's request. The Director notified BCBSM of the appeal and requested the information BCBSM to make its final adverse determination. BCBSM furnished its response on April 26, 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 April 29, 2016.

II. FACTUAL BACKGROUND

The Petitioner has a pancreatic cyst. As part of her treatment, her physician prescribed the PathFinder TG test. The total charge for the test was \$4,150.00. 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. At the conclusion of that process, on February 25, 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

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

IV. ANALYSIS

BCBSM's Argument

In its final adverse determination, BCBSM explained the reasons for its denial:

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

[Petitioner] had genetic testing performed to assist in determining her risk of cancer. According to the Blue Cross Blue Shield of Michigan medical policy "Genetic Testing – Molecular Anatomic Pathology (PathFinder TG)," molecular testing using the PathFinder TG system is investigational/experimental. The impact of this technology on health outcomes compared with existing alternatives (i.e., incremental value) is not known.

* * *

An investigational status means that the safety and effectiveness of a particular technology has not been definitively determined....Investigational medical policies are reviewed regularly to guarantee that the investigational status continues to be supported by the evidence.

Therefore, based on our medical consultant's determination that the services are considered investigational, together with the terms of [Petitioner's] coverage, which explains that investigational/experimental services are not payable, we must maintain our denial.

Petitioner's Argument

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

The *PathFinder TG* 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 PathFinder TG test included the patient's clinical history and medical rationale for referring for further analysis. PathFinder TG 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.

PathFinder TG 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

The question of whether the PathFinder TG test is investigational was presented to an independent review organization (IRO) for analysis and a recommendation 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 IRO reviewer's report included the following analysis and recommendation:

In March 2014, the member underwent an endoscopic ultrasound to further investigate the pancreatic cyst. A 4 x 2.5 cm cyst in the body of the pancreas was identified. There were multiple septations. The lesion did not communicate with the pancreatic duct and did not have a solid component. Initial cytology was negative for malignant appearing cells. The cyst fluid was sent to Redpath for molecular and genetic testing with the PathFinder TG test, which suggested the cyst would exhibit benign behavior. This battery of testing was denied by the Health Plan, which considers it to be experimental/investigational.

[I]n the diagnostic evaluation of pancreatic cysts, the principal concern is whether the lesion is premalignant or likely to remain benign....[C]haracteristics

that are concerning for malignancy include the age of the patient, lesion size, communication with the main pancreatic duct, CEA concentration in the fluid and cytology....[T]here is very little data to support molecular testing of the fluid to gain additional prognostic information and this panel of testing is not recommended as part of the recent American Gastroenterological Association (AGA) guidelines on the management of pancreatic cystic lesions....[T]his testing is currently not the standard of care.

Pursuant to the information set forth above and available documentation...the PathFinder TG testing performed on 4/10/14 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 PathFinder TG lab test is experimental/investigational, not the standard of care for the Petitioner's condition, and is therefore not a covered benefit.

V. ORDER

The Director upholds BCBSM's final adverse determination dated February 25, 2016.

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