

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. 152954-001

Blue Cross Blue Shield of Michigan
Respondent

Issued and entered
this 27th day of April 2016
by **Randall S. Gregg**
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On March 29, 2016, ██████████ (Petitioner) filed a request with the Department of Insurance and Financial Services for an external review under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.* On April 5, 2016, after a preliminary review of the information submitted, the Director accepted the request.

The Petitioner receives health care benefits through a group plan underwritten by Blue Cross Blue Shield of Michigan (BCBSM). The benefits are described in BCBSM's *Simply Blue with HSA* member handbook for employees and retirees under age 65 of the Dykema Gossett law firm.

The Petitioner's appeal presents a medical issue which was analyzed by an independent review organization in a report submitted to the Director on April 19, 2016.

II. FACTUAL BACKGROUND

The Petitioner is ██████████ and has a thyroid nodule. In order to determine whether the nodule might be cancerous, his physician ordered diagnostic tests which were performed on June 22, 2015. The tests, called ThyraMIR and ThyGenX, were performed by Redpath Integrated Pathology, Inc. The charges for the tests totaled \$4,975.00.

BCBSM denied coverage for the tests, ruling that they are experimental/investigational and therefore excluded under the Petitioner's benefit plan. The Petitioner appealed the denial through BCBSM's internal grievance process. At the conclusion of that process, BCBSM issued a final adverse determination dated January 29, 2016, affirming its decision. The Petitioner now seeks the Director's review of that determination.

III. ISSUE

Are the ThyraMIR and ThyGenX tests experimental/investigational in the treatment of the Petitioner?

IV. ANALYSIS

BCBSM's Argument

In its final adverse determination, BCBSM's representative wrote:

An associate Medical Director, a board-certified M.D. in Internal Medicine, has...reviewed the claim, your appeal, [Petitioner's] health care plan benefits, and the records reflecting the laboratory services at issue. The medical reviewer stated:

All documentation was reviewed. The member had a needle biopsy of the thyroid. ThyraMIR & ThyGenX testing was performed to determine the likelihood of a cancer diagnosis and assist in determining appropriate treatment. According to BCBSM Medical Policy, "Genetic Testing-Molecular Markers in Fine Needle Aspirates (FNA) of the Thyroid," genetic testing for molecular markers aspirates of the thyroid is considered to be experimental/investigational. There is insufficient evidence to support the efficacy of these tests in improving patient clinical outcomes. Additionally, BCBSM medical policy, "Genetic Testing Molecular Panel Testing of Cancers to Identify Targeted Therapies," indicates that peer-reviewed medical literature has not demonstrated the clinical utility of molecular panel testing of cancers to identify targeted therapies. Therefore, this service is experimental/investigational.

Petitioner's Argument

In his request for an external review, the Petitioner wrote:

I request review of the BCBSM's January 29, 2016 decision to deny coverage for \$4,975.00 of laboratory services ordered by [REDACTED], an experienced Board-Certified general surgeon treating me for a massive thyroid nodule. The fine-needle biopsy testing laboratory twice concluded that the sample was a follicular lesion of indeterminate significance, leaving both [REDACTED] and me with no meaningful knowledge as to whether the nodules was cancerous and forcing me to

choose between living with a possibly cancerous mass or undergoing a possibly unnecessary and risky surgery to remove a benign mass. ██████████ suggested I have the nodule genetically analyzed to gain far greater confidence as to whether or not it was benign. The genetic test showed that to a 96% certainty, the nodule was not cancerous. This allowed me to decide on a conservative, economical course of periodic monitoring of the size of the nodule and avoid the risks and expense of unnecessary thyroid surgery. BCBSM's denial of coverage is unsound, unsupported and ignores the usefulness and effectiveness of the test in my medical treatment and decision making.

Director's Review

The Petitioner's health benefit plan (page 67 of the *Simply Blue* member handbook) excludes coverage for experimental and investigational medical services.

To determine whether the ThyraMIR and ThyGenX tests are investigational/experimental, the Director commissioned an analysis of that issue by an independent review organization (IRO) 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 who is board certified in oncology and has been in active practice for more than ten years. The reviewer is familiar with the medical management of patients with the Petitioner's condition. The reviewer's report included the following analysis and recommendation:

The member had a biopsy of a thyroid nodule showing a follicular lesion of undetermined significance...[A]ccording to National Comprehensive Cancer Network (NCCN) Guidelines, if clinical suspicion for carcinoma for a thyroid nodule is not high, molecular diagnostics may be employed. (NCCN Guidelines for Thyroid Cancer, Nodule Evaluation. 2.22015, page TYHR-3)...[A]n article states that molecular profiling readily distinguishes benign and malignant thyroid tumors with excellent sensitivity and specificity. (*Ann Surg.* 2004 Sep;3:425-37)...[T]he Health Plan's criteria are therefore not consistent with current standards of care.

Pursuant to the information set forth above and available documentation...the ThyraMIR and ThyGenX testing (procedure codes 81445 and 81479) performed on 6/22/15 were not experimental/investigational for diagnosis and treatment of the member's condition.

While the Director is not required in all instances to accept the IRO's recommendation, the recommendation is afforded deference by the Director. *Ross v Blue Care Network of Michigan*, 480 Mich 153 (2008). 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 benefit plan. See MCL 550.1911(15). The Director, discerning no reason why the IRO's recommendation should be rejected in the present case, finds that the ThyraMIR and ThyGenX tests are not experimental or investigational in the Petitioner's treatment. The tests are, therefore, a covered benefit.

V. ORDER

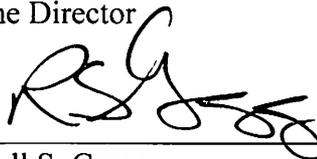
BCBSM's final adverse determination of January 29, 2016 is reversed. BCBSM shall immediately provide coverage for the Petitioner's June 22, 2015 ThyaMir and ThyGenX tests. See MCL 550.1911(17). Further, BCBSM shall, within seven days of providing coverage, furnish the Director with proof it has implemented this order.

To enforce this order, the Petitioner may report any complaint regarding its implementation to the Department of Insurance and Financial Services, Health Care Appeals Section, at this toll free telephone number: (877) 999-6442.

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 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