

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. 152433-001

Blue Cross Blue Shield of Michigan

Respondent

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Issued and entered  
this 26<sup>th</sup> day of April 2016  
by Randall S. Gregg  
Special Deputy Director

**ORDER**

**I. PROCEDURAL BACKGROUND**

On March 25, 2016, ██████████, authorized representative of ██████████ (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 1, 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 Petitioner's health care benefits are described in BCBSM's *Simply Blue Group Benefits Certificate SG*.

The medical issues in this case were evaluated by an independent review organization which provided its analysis and recommendation to the Director on April 18, 2016.

**II. FACTUAL BACKGROUND**

The Petitioner is a ██████████-year-old female who has thyroid disease. Her physician found that she had a thyroid nodule. In order to determine whether the nodule was benign or suspicious, her doctor prescribed the Afirma test which was performed in June 2015 by Veracyte, the California company that developed the test. The amount charged was \$4,875.00.

BCBSM denied coverage for the test, ruling that it was experimental/investigational. The

Petitioner appealed the denial through BCBSM's internal grievance process. BCBSM issued a final adverse determination on February 15, 2016. The Petitioner now seeks the Director's review of that determination.

### III. ISSUE

Is the Afirma test experimental/investigational in the treatment of the Petitioner's condition?

### IV. ANALYSIS

#### BCBSM's Argument

In its February 15, 2016 final adverse determination, BCBSM wrote:

The service performed, the Afirma test reported as procedure code 814 79 (unlisted molecular pathology procedure), has been determined to be experimental/investigational by the BCBSM/Blue Care Network (BCN) Joint Uniform Medical Policy Committee....The member's health care plan does not cover experimental or investigational services. Therefore, payment cannot be approved for the \$4,875.00 charge for this service.

\* \* \*

To give this appeal every consideration, a medical consultant, board-certified D.O. in Internal Medicine reviewed the member's claim, the appeal you submitted, and the member's health care plan benefits for BCBSM. The medical consultant concluded:

Documentation was reviewed. The member had an inconclusive needle biopsy of the thyroid gland. The Afirma gene expression classifier test, reported as procedure code 81479, was performed to determine the management. According to BCBSM policy "Molecular Markers in a Fine Needle Aspirates of the Thyroid" this test is considered investigational. There is insufficient evidence that the results of this test lead to changes in clinical management that create improved health outcomes.

#### Petitioner's Argument

In a February 24, 2016 letter to BCBSM, the Petitioner's representative wrote:

[Petitioner] was diagnosed with an indeterminate thyroid nodule. Indeterminate thyroid nodules present a challenge for physicians because they have been shown in clinical research to only be cancerous in 25% of cases. However, without a better diagnostic tool, clinicians have historically referred patients with indeterminate thyroid nodules to diagnostic surgery to remove the thyroid. Since only 25% of indeterminate nodules are malignant, 75% of patients with indeterminate nodules are *benign* and undergo an unnecessary surgery.

Afirma is a medical test that reports a *benign* or *suspicious* result when analyzing thyroid nodule fine needle aspirate biopsy specimens that are indeterminate. The Affirma test improves upon the pathology diagnosis by reclassifying one half of indeterminate nodules as benign, and avoiding unnecessary surgery for these patients. Patient health outcomes are improved by avoiding the risks of unnecessary surgery.

In her letter, the Petitioner's representative presented studies and other material in support of her argument that BCBSM was in error when it classified the Afirma test as experimental.

### Director's Review

The *Simply Blue* certificate, on page 132, excludes coverage for experimental treatment or services related to experimental treatment. Experimental treatment is defined on page 150 of the certificate 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."

To determine whether the Afirma lab test is experimental/investigational treatment for the Petitioner's condition, the Director presented the issue 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 who is certified by the American Board of Internal Medicine with a subspecialty in endocrinology, diabetes and metabolism. The reviewer's report included the following analysis and recommendation:

It is the determination of this reviewer that the Afirma lab test...was experimental/investigational and therefore not medically necessary for the treatment of the enrollee's condition.

#### Clinical Rationale for the Decision:

The standard of care in this clinical scenario, in the absence of risk factors such as family history of thyroid cancer, significant radiation exposure, or suspicious ultrasound features, would be to repeat a thyroid ultrasound in three (3) to six (6) months to confirm stability of the nodule (i.e., to verify that the nodule is not growing quickly). The standard of care, in the absence of the above mentioned risk factors, would NOT instead be to perform a biopsy, at least until the nodule reaches the size of 1.0 cm or more.

Afirma testing has been shown to accurately identify which thyroid nodules with indeterminate cytology are benign and therefore when unnecessary thyroid surgery can be avoided: however, Afirma testing has not been studied ("validated") in thyroid nodules less than 1.0 cm...in size. The enrollee's thyroid nodule that underwent Afirma testing was nine (9) mm. Therefore the Afirma test would be considered experimental/ investigational because it is not validated for nodules less than 1.0 cm in size.

\* \* \*

This enrollee underwent Afirma testing because cytology on fine needle aspiration of a thyroid nodule was indeterminate. Given the fact that the enrollee's nodule was nine (9) mm, the Afirma testing can only be considered experimental/investigational because it has not been validated in thyroid nodules smaller than 1.0 cm. For this reason, the medical or scientific evidence does not demonstrate that the expected benefits of the Afirma testing are more likely to be beneficial to the enrollee than any available standard health care service. As such, for the reasons noted above, the Afirma laboratory test is considered experimental/investigational and therefore not medically necessary for this enrollee. [Citations omitted.]

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 certificate of coverage. 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 Afirma test is experimental/investigational as a part of the Petitioner's treatment. It is, therefore, not a covered benefit.

#### V. ORDER

The Director upholds BCBSM's final adverse determination of February 15, 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 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:



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Randall S. Gregg  
Special Deputy Director