

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. 153261-001

Blue Cross Blue Shield of Michigan
Respondent

Issued and entered
this 17th day of May 2016
by Randall S. Gregg
Special Deputy Director

ORDER

I. BACKGROUND

On April 15, 2016, ██████████, authorized representative of ██████████ (Petitioner), filed a request with the Director of Insurance and Financial Services for an external review under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.* After a preliminary review of the material submitted, the Director accepted the request on April 22, 2016.

The Petitioner receives health coverage through a group plan underwritten by Blue Cross Blue Shield of Michigan (BCBSM). The benefits are described in BCBSM's *Community Blue Group Benefits Certificate LG*. The Director notified BCBSM of the external review request and asked for the information it used to make its final adverse determination. BCBSM provided its response on April 29, 2015.

Because the case involves a medical issue, it was assigned to an independent medical review organization which provided its analysis and recommendation to the Director on May 4, 2016.

II. FACTUAL BACKGROUND

The Petitioner had a thyroid nodule in 2008 which was found to be benign. In February 2015 her physician found another nodule. A biopsy was performed on April 13, 2015 and specimens were sent to Veracyte, a California company, for testing using its Afirma FNA Thyroid Analysis to determine whether the nodule was cancerous. The amount charged for the test was \$4,875.00. BCBSM denied coverage, ruling that the test is investigational.

The Petitioner appealed the denial through BCBSM's internal grievance process. At the conclusion of that process, BCBSM issued a final adverse determination dated March 2, 2016, affirming its denial. The Petitioner now seeks the Director's review of that denial.

III. ISSUE

Did BCBSM properly deny coverage for the Petitioner's April 13, 2015 Afirma FNA Thyroid Analysis test as experimental or investigational?

IV. ANALYSIS

Respondent's Argument

In its final adverse determination to the Petitioner, a BCBSM representative wrote:

We denied payment for the laboratory service because the Affirma test is considered investigational...After careful review I confirmed the denial is appropriate and must be maintained. [Petitioner's] health care Plan does not cover investigational or experimental services. Therefore, payment cannot be approved.

* * *

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

[Petitioner] had developed a new thyroid nodule which was biopsied. In addition to cytopathology, the Affirma test was completed. This test, per Blue Cross Blue Shield of Michigan medical policy, is considered experimental/investigational. Its clinical utility in the management of thyroid nodule has not been firmly established.

* * *

[B]ased on our medical consultant's determination that the service is considered investigational, together with the terms of [Petitioner's] coverage stating experimental/investigational services are not payable, we must maintain our denial.

Petitioner's Argument

In an appeal letter filed with the request for an external review, the Petitioner's authorized representative stated:

Thyroid nodules (tumors) are very common, and have a prevalence of 50% in people over the age of 50. The standard of care for patients identified as having a thyroid nodule is to undergo numerous diagnostic procedures to rule-out cancer (e.g. thyroid stimulating hormone testing, ultrasound review, and fine needle aspirate biopsy). When thyroid nodules are biopsied, a small sample is extracted to undergo pathologic review to inform whether or not the patient has cancer and requires surgery. Pathologists classify these nodules into one of three categories: malignant (cancerous), benign, or indeterminate (i.e. not clearly benign or malignant).

[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 molecular test that reports a benign or suspicious result when analyzing thyroid nodule fine needle aspirate biopsy specimens that are indeterminate. The Afirma 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.

* * *

The literature on the Afirma Thyroid FNA Analysis demonstrates that it is a well-validated test in the areas of analytic validity, clinical validity, clinical utility. Major national technology assessment bodies and health insurance companies have evaluated these peer-review studies and determined Afirma to be “proven” for assessing intermediate thyroid nodules. As a result, the Afirma Thyroid FNA Analysis is a covered medical benefit for 135 million insured lives nationwide.

Director’s Review

The *Community Blue Group Benefits Certificate LG* (page 133) excludes coverage for experimental treatment or services related to experimental treatment. The certificate (page 150) 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 experimental treatment is referred to as “investigational” or “experimental services.”

The question of whether the Afirma test is experimental for the Petitioner 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 twelve years who is board certified in endocrinology and metabolism and is familiar with the medical management of patients with the Petitioner’s condition. The IRO reviewer’s report included the following analysis and conclusion:

Recommended Decision:

[T]he Afirma testing on 4/13/15 was not experimental/investigational for diagnosis and treatment of the member's condition.

Rationale for the Decision:

* * *

While a fine needle aspiration (FNA) biopsy of a suspicious thyroid nodule is typically an accurate means of assessing whether the nodule is benign or malignant, approximately 15% of fine needle aspiration biopsy results are considered to be indeterminate. (*N Engl J Med.* 2012;367:705-15.)...[U]ntil recently, the only way to establish whether an indeterminate nodule was in fact thyroid cancer was via surgical excision, even though the majority of the cases turn out to be benign. (*Am J Surg.* 2004 Nov; 188(5):459- 62.) A relatively new test, the Afirma Thyroid FNA Analysis from Veracyte utilizes a gene expression classifier in order to help determine the likelihood of malignancy of nodules with indeterminate cytology on fine needle biopsy...[T]his testing decreases the need for unnecessary surgeries...[B]ecause it is very sensitive and has a high negative predictive rate, a negative Afirma result is rather suggestive of a benign nodule and can therefore preclude surgical procedures. (*Thyroid.* 2012 Oct;22(10):996-1001.)

Pursuant to the information set forth above and available documentation...the Afirma testing on 4/13/15 was not 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 IRO's 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 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 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 Afirma Thyroid FNA Analysis was not experimental or investigational in the treatment of Petitioner's condition and is, therefore, a covered benefit under the terms of the certificate.

V. ORDER

The Director reverses BCBSM's March 2, 2016 final adverse determination.

BCBSM shall immediately provide coverage for the Petitioner's April 13, 2015 Afirma Thyroid FNA Analysis test. See MCL 550.1911(17). BCBSM shall, within seven days of providing coverage, furnish the Director with proof it has implemented this order.

To enforce the 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 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 sixty 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