

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. 148059-001

Blue Cross Blue Shield of Michigan,

Respondent.

Issued and entered
this 24th day of June 2015
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On May 27, 2015, ██████████, 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.* On June 3, 2015, after a preliminary review of the information submitted, the Director accepted the request.

The Petitioner receives health care benefits through an individual plan that is underwritten by Blue Cross Blue Shield of Michigan (BCBSM). The Director immediately notified BCBSM of the external review request and asked for the information it used to make its final adverse determination. BCBSM submitted the material on June 10, 2015.

The case involves medical issues so it was assigned to an independent medical review organization which submitted its recommendation to the Director on June 17, 2015.

II. FACTUAL BACKGROUND

The Petitioner's health care benefits are defined in BCBSM's *Flexible Blue II Individual Market Certificate*¹ (the certificate).

The Petitioner has Crohn's disease, an inflammatory bowel disease, which was treated

¹ BCBSM form no. 751A, approved 10/12.

with the prescription drug Remicade (infliximab). His physician ordered the Anser IFX diagnostic test to monitor his response to the Remicade. The test was performed on November 6, 2013, by [REDACTED] a non-participating provider. The charge for the test was \$2,500.00.

BCBSM denied coverage, saying the test was investigational or experimental for treating the Petitioner's condition and therefore not a covered benefit. The Petitioner appealed that denial through BCBSM's internal grievance process. At the conclusion of that process BCBSM issued a final adverse determination dated March 26, 2015, affirming its decision. The Petitioner now seeks a review of that final adverse determination from the Director.

III. ISSUE

Was the Anser IFX test experimental or investigational for the treatment of the Petitioner's condition?

IV. ANALYSIS

Petitioner's Argument

The Petitioner's authorized representative included a letter dated May 19, 2015, with the external review request that explained the Petitioner's position:

The [Petitioner] was denied coverage for the [REDACTED] Anser IFX diagnostic test performed on 11/06/2013 due to the service being experimental/investigational service. . . .

We respectfully dispute all of the criteria that were used to deny Anser IFX testing for this patient. In our previous appeals we provided five peer-reviewed publications that address the importance of measuring levels of infliximab as well as antibodies to infliximab (ATI). There is an ever increasing body of evidence that demonstrates the impact that increasing levels of ATI can have on a patients response to infliximab. Those publications, as well as the additional, published and peer reviewed literature . . . clearly demonstrate that this technology cannot be considered unproven, experimental, or not medically necessary. These, as well as many other publications provide support that the use of the data provided by the assay can be utilized by a clinician as an "an effective management tool."

* * *

Based on the totality of all the documentation . . . we are asking that the denial for the Anser IFX be overturned and the claim processed utilizing the patient's in-network benefits. . . .

BCBSM's Argument

In its final adverse determination, BCBSM told the Petitioner's authorized representative:

. . . After review, our denial of payment is maintained because the service [*Anser IFX test*] is deemed experimental/investigational. Investigational services are not a benefit and payment cannot be approved.

* * *

A board-certified M.D. in Family Practice reviewed the claim, your appeal, and [the Petitioner's] health care plan benefits for [BCBSM], and determined based on BCBSM current medical policy "Measurement of Serum Antibodies to Infliximab and Adalimumab," measurement of antibodies to either infliximab or adalimumab, whether alone or as a combination test which includes the measurement of serum infliximab or adalimumab levels, is considered experimental/investigational. The use of these tests has not been clinically proven to improve patient clinical outcomes or alter patient management.

Director's Review

The Petitioner's health plan covers diagnostic laboratory services (p. 4.13). However, the certificate (p. 7.3) has this exclusion:

Services That Are Not Payable

We do not pay for experimental treatment (including experimental drugs or devices) or services related to experimental treatment. . . . In addition, we do not pay for administrative costs related to experimental treatment or for research management.

"Experimental treatment" is defined in the certificate (p. 8.11) as

[t]reatment 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 Anser IFX test was experimental or investigational for the treatment of Petitioner's condition 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 physician reviewer is board certified in gastroenterology and has been in active practice for more than 18 years. The IRO report included the following analysis and recommendation:

Rationale

The MAXIMUS independent physician consultant, who is familiar with the medical management of patients with the member's condition, has examined the medical record and the arguments presented by the parties.

The results of the consultant's review indicate that this case involves a now 24 year-old male who has a history of a Crohn's disease. At issue in this appeal is whether the Anser IFX assay that the member underwent on 11/6/13 was investigational for diagnosis and treatment of his condition.

The member has a 10 year history of Crohn's disease and had severe protein-caloric malnutrition. The member has been on a variety of steroids, immune suppressants and biologic agents including Tysabri. While transitioning between biologic agents, the member underwent the Anser IFX assay on 11/06/13. This test demonstrated a detectable level of drug as well as a detectable level of antibodies to infliximab.

The MAXIMUS physician consultant explained that monitoring patients on infliximab with measurement of infliximab levels and antibodies to infliximab continues to be an area of intense investigation. The purpose of measuring Remicade (infliximab) levels and antibody to infliximab levels in cases, such as the member's case, would be to clarify why a patient is losing response to therapy. By measuring both components, one can set up a hypothetical algorithm categorizing drug levels as high or low and antibody levels as high or low. Decisions can be made to increase the dose or switch to another biologic based on the results. However, the physician consultant explained that this algorithmic approach has not been validated prospectively to establish that it results in clinical benefit for patients. The consultant noted that what has been shown is that in a majority of patients, the dose of Remicade is too low and also physician consultant indicated that the role of the Anser IFX assay in guiding clinical treatment decisions has not been established at this time.

Pursuant to the information set forth above and available documentation, the MAXIMUS physician consultant determined that the Anser IFX assay that the member underwent on 11/6/13 was experimental/investigational for diagnosis and treatment of his condition. [Citations omitted]

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 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. MCL 550.1911(15).

The Director, discerning no reason why the IRO's recommendation should be rejected in this case, finds that the Anser IFX test is experimental or investigational for the treatment of the Petitioner's condition and is therefore not a benefit under the terms of the certificate.

V. ORDER

The Director upholds BCBSM's final adverse determination of March 26, 2015.

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