

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. 147847-001

Blue Cross Blue Shield of Michigan
Respondent

Issued and entered
this 10th day of June 2015
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On May 12, 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 May 19, 2015, after a preliminary review of the information submitted, the Director accepted the request.

The Petitioner receives health care benefits through a plan underwritten by Blue Cross Blue Shield of Michigan (BCBSM). The terms of coverage are defined in BCBSM's *MESSA Account-Based Choices (ABC) Plan 1* benefit booklet. The Director 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 May 27, 2015.

The case involves medical issues so it was assigned to an independent review organization which submitted its recommendation on June 2, 2015.

II. FACTUAL BACKGROUND

The Petitioner has ulcerative colitis. This disease is often treated with the drug infliximab. The Petitioner's nurse practitioner ordered a diagnostic test, Anser IFX, which monitors the levels of the drug infliximab and infliximab antibodies. The purpose of an Anser IFX test is to improve the medical management of patients with ulcerative colitis. The test was performed on January 8, 2014, by Prometheus Laboratories, Inc., a non-participating provider.

The charge for the test was \$2,500.00.

BCBSM denied coverage, saying the test is experimental/investigational for the Petitioner's condition and therefore is not a covered benefit. 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 10, 2015, affirming its denial. 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 medical management of the Petitioner's condition?

IV. ANALYSIS

BCBSM's Argument

In its final adverse determination, BCBSM stated that the Petitioner's appeal had been reviewed by a medical doctor board-certified in family practice who concluded that:

Per the BCBSM Medical Policy 'Measurement of Serum Antibodies to Infliximab and Adalimumab' measurement of antibodies to either infliximab or adalimumab in a patient receiving treatment with 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.

Petitioner's Argument

In an April 30, 2015, letter that was included with the Petitioner's external review request, the Petitioner's authorized representative wrote:

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 patient's response to infliximab. Those publications, as well as the additional, published and peer reviewed literature listed below, 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

this assay can be utilized by a clinician as an “an effective management tool.”
[References omitted.]

Director’s Review

The *MESSA Account-Based Choices* benefit booklet (page 45) excludes coverage for experimental treatment or services related to experimental treatment which is defined in the booklet (page 56) as:

Treatment that has not been scientifically proven to be as safe and effective for treatment of the patient’s condition as conventional treatment. Sometimes it is referred to as “experimental services.”

The question of whether the Anser IFX test was experimental or investigational for the 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 a physician, board certified in gastroenterology, who has been in practice for more than 15 years and is familiar with the medical management of individuals with the Petitioner’s condition. The IRO report included the following analysis and recommendation:

The member has macroscopic disease up to the hepatic fixture and she has moderate to severe activity. Apparently, the member did respond well at some point to infliximab. In January 2014, the member underwent the ANSER IFX test, which demonstrated an undetectable level of [the] drug and the presence of antibodies to infliximab.

[T]he use of measuring infliximab levels and antibodies to infliximab has not been shown to be superior to standard clinical management. The literature confirms that frequent measurements of drug levels can maximums the time that the drug is in the target range of 3 to 7 ug/ml. [Reference omitted.] However...it is not know that this drug level is appropriate for everyone....[B]eing in the target range did not translate into a greater period of response time compared to “blinded” dosing....[T]here remains no prospective data confirming improved patient outcomes by checking infliximab and antibody to infliximab levels in patients who are experiencing failure of treatment with Remicade.

Pursuant to the information set forth above and available documentation...the Prometheus Anser IFX test performed on 1/8/14 was experimental/investigational for 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 analysis is based on extensive experience, expertise, and professional judgment. The Director can discern no reason why the IRO’s recommendation should be rejected in this case.

The Director finds that the Anser IFX test is experimental/investigational for the treatment of the Petitioner’s condition and is therefore not a benefit under the terms of the Petitioner’s health benefit plan.

V. ORDER

The Director upholds BCBSM’s final adverse determination of March 10, 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