

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. 151100-001

Blue Cross Blue Shield of Michigan,

Respondent.

Issued and entered
this 30th day of December 2015
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

██████████ (Petitioner) was denied coverage for a diagnostic test by Blue Cross Blue Shield of Michigan (BCBSM), his health care insurer.

On December 1, 2015, ██████████, the Petitioner's authorized representative,¹ 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 December 8, 2015, after a preliminary review of the information submitted, the Director accepted the request.

The Petitioner receives health care benefits through a plan from the Michigan Education Special Services Association (MESSA) that is underwritten by 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 responded on December 15, 2015.

The case involves medical issues so it was assigned to an independent review organization which submitted its recommendation on December 21, 2015.

II. FACTUAL BACKGROUND

The terms of the Petitioner's coverage are defined in the *MESSA Choices / Choices II* benefit booklet (the booklet).

The Petitioner has Crohn's disease. He has been treated with the drug Remicade (infliximab).

¹ The Petitioner is a minor ██████████. His father authorized ██████████ to represent him in this external review.

His physician ordered a test called the Anser IFX to monitor his response to the Remicade. The test was performed on August 7, 2014, by Prometheus Laboratories, Inc.; the charge was \$2,500.00.

BCBSM denied coverage, saying the test was investigational or experimental for the Petitioner's condition and therefore 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 November 12, 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 treatment of the Petitioner's condition?

IV. ANALYSIS

BCBSM's Argument

In its final adverse determination, BCBSM said that a physician who is board certified in internal medicine reviewed the Petitioner's case and concluded:

This request is for a member with a diagnosis of Crohn's disease (an inflammatory bowel disease). The doctor ordered the Prometheus IFX test. The Prometheus Anser IFX test for inflammatory bowel disease is experimental and investigational as its benefit has not been established according to the Blue Cross Blue Shield of Michigan medical policy titled "Serum Markers for the Diagnosis of inflammatory Bowel Disease."

Petitioner's Argument

In a November 21, 2015, letter included with the request for an external review, 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 . . . 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."

Director's Review

The booklet (p. 54) excludes coverage for “experimental treatment (including experimental drugs or devices) or services related to experimental treatment except as approved by the BCBSM. . . .”

“Experimental or investigational treatment” is defined in the booklet (p. 71) as

[t]reatment 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 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 board certified in gastroenterology and has been in active practice for more than 15 years. The IRO report included the following analysis and recommendation:

Recommended Decision:

The MAXIMUS physician consultant determined that the Prometheus Anser IFX test performed on 8/7/14 was not experimental/investigational for diagnosis and treatment of the member's condition.

Rationale:

* * *

The results of the consultant’s review indicate that this case involves a [REDACTED] who has a history of Crohn’s disease. At issue in this appeal is whether the Prometheus Anser IFX test performed on 8/7/14 was experimental / investigational for diagnosis and treatment of the member’s condition.

The member has Crohn’s disease with both extensive small bowel and colon involvement. The member’s course was complicated by C difficile infection resulting in poor appetite and nausea, along with diarrhea. The member was having a large amount of blood with the bowel movements. Despite Remicade infusions started on 3/5/14 and a prolonged vancomycin taper, it was the impression of the member’s treating provide[r] that he was not responding well. The Anser IFX test performed on 8/7/14 demonstrated both an undetectable drug level and undetectable antibodies to infliximab.

The MAXIMUS physician consultant explained that this member’s case is complex in that he had active inflammatory bowel disease treated with Remicade and an infection with C difficile, which required a prolonged treatment with vancomycin. The physician consultant indicated that the member continued not to improve and it was unclear whether this was due to refractory inflammatory bowel disease, underdosing with Remicade, antibodies to Remicade or residual C difficile infection. The consultant explained that was reasonable to order the Anser IFX test in this case in order to put some sort of order to this clinical problem. The physician consultant noted that the results were helpful as it appears that the member was underdosed with Remicade. The consultant noted that it

could be postulate that this occurred because the C difficile caused colonic inflammation, which increased fecal loss of the drug.

Pursuant to the information set forth above and available documentation, the MAXIMUS physician consultant determined that the Prometheus Anser IFX test performed on 8/7/14 was not experimental / investigational for diagnosis and treatment of the member's 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. Furthermore, it 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 this case, finds that the Anser IFX test is not experimental / investigational for the management of the Petitioner's condition and is therefore a benefit under the terms of the booklet.

V. ORDER

The Director reverses BCBSM's final adverse determination of November 12, 2015.

BCBSM shall immediately cover the Petitioner's August 7, 2014, Anser IFX test. 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 the Department of Insurance and Financial Services, Health Care Appeals Section, toll free 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 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