

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. 152112-001

Blue Care Network of Michigan,
Respondent.

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

ORDER

I. PROCEDURAL BACKGROUND

██████████ (Petitioner) was denied coverage for a diagnostic test by his health plan, Blue Care Network of Michigan (BCN).

On February 8, 2016, ██████████, the Petitioner's authorized representative, filed a request with the Director of Insurance and Financial Services for an external review of that denial under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.*

The Petitioner receives group health care benefits through Blue Care Network of Michigan (BCN), a health maintenance organization. The Director immediately notified BCN of the external review request and asked for the information it used to make its final adverse determination. BCN initially responded on February 10, 2016. After a preliminary review of the material submitted, the Director accepted the request on February 17, 2016. BCN submitted additional information on February 19, 2016.

The case involves medical issues so it was assigned to an independent review organization which submitted its recommendation to the Director on March 2, 2016.

II. FACTUAL BACKGROUND

The Petitioner's health care benefits are defined in the *Certificate of Coverage BCN*

Classic for Large Groups (the certificate).

The Petitioner has Crohn's disease and was treated with the prescription drug Remicade (infliximab). His physician ordered the Anser IFX diagnostic test to monitor his response to Remicade. The test was performed on January 2, 2015, by Prometheus Laboratories, Inc., a non-participating provider. The charge was \$2,500.00.

BCN 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 BCN's internal grievance process. At the conclusion of that process BCN issued a final adverse determination dated December 9, 2015, affirming its decision. The Petitioner now seeks a review of that final adverse determination by 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

In a letter dated January 26, 2016, submitted with the external review request, the Petitioner's authorized representative said:

The [Petitioner] was denied coverage for the Prometheus Anser IFX diagnostic test performed on 01/02/2015 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 patient's response to infliximab. Those publications, as well as the additional, published and peer reviewed literature . . . clearly demonstrates that this technology cannot be considered unproven, experimental, nor 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 enclosed, and the additional information listed above, we are asking that the denial for the Anser IFX be overturned and the claim processed utilizing the patient's in-network benefits. . . .

BCN's Argument

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

Our Step Two Grievance Panel . . . reviewed the documentation you submitted, the member's BCN Classic for Large Groups Certificate of Coverage and the Blue Care Network / BCBSM Measurement of Serum Antibodies to Infliximab and Adalimumab Medical Policy. After thorough review of the case, the Panel maintained the previous denial. We based our decision on the Blue Care Network / BCBSM Measurement of Serum Antibodies to Infliximab and Adalimumab Medical Policy, which indicates that that test is experimental and investigational and therefore not a covered benefit. Additionally, the service was performed by an out of network lab.

As stated in the member's BCN Classic for Large Groups Certificate of Coverage Exclusions sections: 9.1 Unauthorized and Out of Network Services-Except for Emergency care as specified in Section 8 health, medical and hospital services listed in this Certificate are covered only when Provided by a Participating Provider and Preauthorized by BCN for select services. 9.4 Non-Covered Services-Coverage does not include the following services: All facility, ancillary and physician services, including diagnostic tests, related to experimental or investigational procedures.

Director's Review

BCN denied coverage for the Anser IFX test because it was considered to be experimental or investigational. BCN's medical policy, "Measurement of Serum Antibodies to Infliximab and Adalimumab," says:

Medical Policy Statement

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.

The certificate (p. 58) excludes coverage for services that are not medically necessary. "Medically necessary" is defined (certificate, pp. iv-v) to exclude services that BCN regards as experimental.

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 and a

recommendation 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; is familiar with the medical management of patients with the member's condition; and has been in 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 1/2/15 was 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 20 year-old male who has a history of Crohn's disease. At issue in this appeal is whether the Prometheus Anser IFX test performed on 1/2/15 was experimental / investigational for diagnosis and treatment of the member's condition.

According to the records provided for review, the member became symptomatic before his infusions of Remicade, which were every 6 weeks. Based on this, it was empirically decided to increase the dose to 400 mg every 4 weeks prior to receiving the results of the Anser IFX test. With this empiric switch, the member began to do better without abdominal pain or diarrhea. The results of the Anser IFX performed on 1/2/15 demonstrated an undetectable level of infliximab and the presence of antibodies to infliximab. Despite the results of the Anser IFX test, it was elected to discontinue the member's Remicade. In March 2015, there was a discussion about switching the member to another agent.

The MAXIMUS physician consultant explained that while in theory, measurement of drug and antibody levels may be useful, but such measurements have not been established to be useful in everyday clinical practice. In this case, the member was empirically switched to a higher frequency of Remicade and did well. The physician consultant noted that there was evidence that Remicade was losing effect in this case, and a switch to another agent was inevitable. However, the member did pretty well on the more frequent dosing schedule and this was continued. The consultant noted that perhaps a switch to another agent would have been needed in 3 to 12 months, but this was not predictable. The physician consultant explained that the results of the Anser IFX did not contribute to the treatment plan in this case.

Pursuant to the information set forth above and available documentation, the MAXIMUS physician consultant determined that the Prometheus Anser IFX test

performed on 1/2/15 was experimental / investigational for diagnosis and treatment of the member's condition. [References 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; the IRO's analysis is based on extensive experience, expertise, and professional judgment. In addition, the Director finds that the IRO's recommendation is not contrary to any provision of the Petitioner's certificate of coverage. MCL 550.1911(15).

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

In resolving this case on the basis that the diagnostic test was experimental, the Director does not need to address BCN's alternative argument that the test was an unauthorized out-of-network service excluded from coverage under subsection 9.1 of the certificate.

V. ORDER

The Director upholds BCN's final adverse determination of December 9, 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