

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. 148648-001

Blue Cross Blue Shield of Michigan,

Respondent.

Issued and entered
this 6th day of August 2015
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On July 2, 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 July 10, 2015, after a preliminary review of the information submitted, the Director accepted the request.

The Petitioner receives health care benefits through a group 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 July 16, 2015.

The case involves medical issues so it was assigned to an independent medical review organization which submitted its recommendation to the Director on July 29, 2015.

II. FACTUAL BACKGROUND

The Petitioner's health care benefits are defined in BCBSM's *Simply Blue Health Savings Account Group Benefits Certificate With Prescription Drugs*¹ (the certificate).

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

¹ BCBSM form no. 685C, approved 10/12.

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 December 9, 2013, by Prometheus Laboratories, Inc., a non-participating provider. The charge for the test was \$2,500.00.

BCBSM denied coverage, saying the test was experimental or investigational 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 May 20, 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

Petitioner's Argument

The Petitioner's authorized representative included a letter dated June 26, 2015, with the external review request that explained the Petitioner's position:

The [Petitioner] was denied coverage for the Prometheus Anser IFX diagnostic test performed on 12/09/2013 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:

The BCBSM/BCN Joint Uniform Medical Policy Committee (JUMP) has determined that the service in question [*i.e.*, the *Anser IFX test*], unlisted chemistry procedure (procedure code 84999), is experimental. Experimental or investigational services are not covered under [the Petitioner's] contract. As a result, payment cannot be approved and the [Petitioner] remains liable for the non-covered service in the amount of \$2,500.00.

* * *

A board-certified M.D. in Internal Medicine reviewed the claim, the appeal, and [the Petitioner's] health care plan benefits for [BCBSM] and determined that:

“According to the BCBSM Medical Policy titled “Measurement of Serum Antibodies to Infliximab/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 Crohn's disease 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 and has been in active practice for more than [REDACTED] years. The IRO report included this analysis and recommendation:

Recommended Decision:

The MAXIMUS physician consultant determined that the Anser IFX assay that the member underwent on 12/9/13 was experimental/investigational for diagnosis and treatment of his condition.

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 50 year-old male who has a diagnosis of a Crohn's ileitis, which has been confirmed radiologically and on colonoscopy. At issue in this appeal is whether the Anser IFX assay that the member underwent on 12/9/13 was investigational for diagnosis and treatment of his condition.

The member has been treated for at least 3 years with maintenance Remicade infusions. He has been co-treated with immune modulators. In October 2013, the member complained of increasing diarrhea and some right lower quadrant pain, which was in addition to his chronic gastroesophageal reflux and dyspepsia symptoms. On 12/9/13, the member underwent the Anser IFX assay, which demonstrated detectable levels of infliximab and the absence of antibodies to this drug.

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. In general, infliximab levels correlate inversely with disease activity. The physician consultant indicated that however, the target level of infliximab necessary to achieve clinical benefit remains unknown. The target value has been investigated in one study and is likely between 3 and 7 ng/ml. ... However, the consultant explained that there are no controlled data which have identified the optimal drug level and the issue remains speculative. The physician consultant also explained that issues of how a patient is doing on the drug, whether the patient is responding or losing response and whether the patient is having severe adverse side effects, such as infusion reactions, are more important than drug level. To attempt to answer this question in the case of a patient who is failing therapy, one can set up a hypothetical 2 x 2 table categorizing drug levels as high or low and antibody levels as high or low. However, the physician consultant explained that this algorithmic approach has

not been validated prospectively to establish that it results in clinical benefit for patients.

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 12/9/13 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 May 20, 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