

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. 147838-001

Blue Cross Blue Shield of Michigan,

Respondent.

Issued and entered
this 11th 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 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 May 22, 2015.

The case involves medical issues so it was assigned to an independent review organization which submitted its recommendation on June 3, 2015.

II. FACTUAL BACKGROUND

The Petitioner's health care benefits are defined in a booklet called *MESSA Choices/Choices II Group Insurance for School Employees* (the coverage booklet).

The Petitioner has inflammatory bowel disease and was treated with the drug Remicade (infliximab). His physician ordered the Anser IFX diagnostic test to monitor his response to Remicade. The test was performed on March 15, 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 investigational or experimental for treating 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 March 11, 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

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

The patient was denied coverage for the Prometheus Anser IFX diagnostic test performed on 3/15/2013 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 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. . . .

BCBSM's Argument

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

. . . After review, it was determined that the denial of payment must be maintained. The BCBSM/BCN Joint Uniform Medical Policy Committee (JUMP) has determined that procedure code 84999 [Anser IFX test] is considered investigational/experimental.

* * *

A board-certified M.D. in Family Practice reviewed the submitted documentation and determined:

This 36 year old member . . . had the Prometheus Anser IFX testing done. Per the BCBSM Medical Policy ‘Measurement of Serum Antibodies to Infliximab,’ 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.

The BCBSM Medical Policy titled *Measurement of Serum Antibodies to Infliximab and Adalimumab* explains:

Measurement of antibodies to either infliximab or adalimumab in a patient receiving treatment either for 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.

Therefore, because procedure code 84999 is considered experimental/investigational, our denial of payment must be maintained. Prometheus Laboratories Inc. does not participate with BCBSM, therefore, it may ask the member for payment.

Director’s Review

The Petitioner’s health plan covers diagnostic laboratory services (coverage booklet, p. 31). However, the coverage booklet (p. 53) has this exclusion:

The following exclusions and limitations apply to the MESSA Choices/Choices II program. These are in addition to limitations appearing elsewhere in this booklet:

* * *

- Experimental treatment (including experimental drugs or devices) or services related to experimental treatment except as approved by the BCBSM or MESSA medical director. In addition, we do not pay for administrative costs related to experimental treatment or for research management.

“Experimental or investigational treatment” is defined in the coverage booklet (p. 66):

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 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 internal medicine, subspecialty in gastroenterology, and is published in the peer reviewed medical literature and is in active clinical practice. The IRO report included the following analysis and recommendation:

Clinical Rationale for the Decision:

While the Anser IFX diagnostic test is Federal Food and Drug Administration (FDA) approved for the determination of antibodies to infliximab, which is the extent of the FDA approval for this assay, the routine use of such a test is not considered standard of care for the management of inflammatory bowel disease such as Crohn's Disease. Although antibodies can develop during the course of the use of infliximab, the decision to continue, discontinue, or change the dose of infliximab therapy remains a clinical one based on observation of the patient and their response to the therapy as provided. As such, the use of the Anser IFX test in this type of clinical condition is still considered experimental/investigational.

The management of inflammatory bowel disease with biologic therapy is directed by the clinical response of the patient to the medication. If the therapy is proving less than beneficial the dose can be increased. If benefit is not seen then the therapy is discontinued, regardless of whether there is the presence of an antibody. Furthermore, if there is the presence of an antibody but the patient is tolerating the therapy and benefitting from the therapy there is no indication to discontinue the treatment based solely on a laboratory result such as the Anser IFX diagnostic test. As such, the balance of the scientific literature does not demonstrate that the expected benefits of the Anser IFX diagnostic test are more likely to be beneficial to this enrollee than the available approach for the management of inflammatory bowel disease with biologic therapy.

* * *

Although antibodies to Infliximab can occur and lead to resistance to therapy, routine assay of antibody level to Infliximab are not standard of care. The decision to continue, or increase the dose of Remicade, is based upon the clinical response of the patient. Whether to continue or discontinue Infliximab is determined by the patient's clinical status and not based on antibody assays to Infliximab. A diminished or suboptimal response to infliximab can be managed in several ways: shortening the interval between doses, increasing the dose, switching to a different anti-TNF (tumor necrosis factor) agent, or switching to a non-anti-TNF agent.

As noted above in the review of the available literature, there is no consensus on the use of this assay or its results; there is no agreement on the levels to be considered meaningful for this assay; and there is no literature to support the use of the Anser IFX assay as having a positive effect on healthcare outcomes at this

time. The medical literature has not demonstrated that the expected benefits of the requested health care service are more likely to be beneficial to the enrollee than any available standard health care service. There are no guidelines or national bodies that support its use. Therefore, measurement of antibodies to infliximab in a patient receiving treatment with infliximab, either alone or as a combination test which includes the measurement of serum infliximab levels, is not medically necessary.

Recommendation:

It is the recommendation of the reviewer that the denial issued by [BCBSM] for the Anser IFX diagnostic test performed on March 15, 2013 be upheld.

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 11, 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