

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. 148056-001

Blue Cross Blue Shield of Michigan,
Respondent.

Issued and entered
this 26th day of June 2015
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On May 27, 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 June 3, 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 June 9, 2015.

The case involves medical issues so it was assigned to an independent review organization which submitted its recommendation on June 16, 2015.

II. FACTUAL BACKGROUND

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

The Petitioner has inflammatory bowel disease (Crohn's disease) and was treated with the

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

drug Remicade (infliximab). Her physician ordered the Anser IFX diagnostic test to monitor her response to Remicade. The test was performed on September 23, 2013, by [REDACTED] 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 April 1, 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 his progress note dated September 23, 2014, the Petitioner's physician explained why the test was ordered:

History of Present Illness

This is a patient with longstanding Crohn's of the small and large intestine, currently managed with Remicade. She did have her interval cutback from 11 to 12 weeks to 2 months, and her dose increased to 10 mg/kg because of a flare of her disease. Now she comes in complaining of numerous illnesses, which she suspects are secondary to too much immune suppression. She did have a severe viral gastroenteritis in July, followed by shingles, which fortunately did respond to antivirals and to Neurontin. She is asymptomatic at this time. This was followed by another respiratory viral illness. However, her Crohn's is actually in good control. She has no pain. Her weight is good. She has rare diarrhea. She has no joint symptoms or eye problems. However, she did have some basal cell cancers removed, which are probably an issue with immune suppression. We did discuss options. At this point, I think I need to measure Remicade level and antibodies, and see if she is needing a change in medicine or a reduction in medication....

In a May 20, 2015, letter that was included with the request for an external review, the Petitioner's authorized representative said:

The [Petitioner] was denied coverage for the [REDACTED] Anser IFX diagnostic test performed on 09/23/2013 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 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 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, our denial of payment is maintained because the service [the Anser IFX test] is deemed experimental/investigational. Investigational services are not a benefit and payment cannot be approved.

* * *

A board-certified M.D. in Family Practice reviewed the claim, your appeal, and [the Petitioner's] health care plan benefits for [BCBSM], and determined based on BCBSM current 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.

We must administer benefits within the provisions of [the Petitioner's] group plan coverage.

Director's Review

The Petitioner's health plan covers diagnostic services (certificate, pp. 4.12 - 4.13). However, the certificate has this exclusion in Section 7 (p. 7.3):

Services That Are Not Payable

We do not pay for experimental treatment (including experimental drugs and devices) or services related to experimental service, except as explained under “Services That Are Payable” below. 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 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 certified by the American Board of Internal Medicine with a subspecialty in gastroenterology; is published in the peer reviewed medical literature; and is in active clinical practice. The IRO report included the following recommendation and analysis:

Reviewer’s Decision and Principal Reasons for the Decision:

It is the determination of this reviewer that the Anser IFX diagnostic test performed on September 9, 2013 was considered experimental/investigational for the treatment of the enrollee's condition.

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 that is the extent of the FDA approval for this assay. The routine use of the Anser IFX diagnostic 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.

Based on the clinical information provided, the enrollee suffered from inflammatory bowel disease and had been receiving Remicade. At the time of the request the enrollee’s clinical response had decreased to the use of Remicade.

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 is 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.

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 April 1, 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