

**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. 147438-001**

**Blue Care Network of Michigan,**

**Respondent.**

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**Issued and entered**  
**this 22<sup>nd</sup> day of May 2015**  
**by Randall S. Gregg**  
**Special Deputy Director**

**ORDER**

**I. PROCEDURAL BACKGROUND**

On April 20, 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.*

The Petitioner receives group health care benefits through Blue Care Network of Michigan (BCN), a health maintenance organization. The Director notified BCN of the external review request and asked for the information it used to make its final adverse determination. BCN provided its initial response on April 22, 2015. After a preliminary review of the material submitted, the Director accepted the request on April 27, 2015. BCN submitted additional information on April 28, 2015.

The case involves medical issues so it was assigned to an independent review organization which submitted its recommendation to the Director on May 11, 2015.

**II. FACTUAL BACKGROUND**

The Petitioner's health care benefits are defined in the BCN *Classic HMO for Small Group Certificate of Coverage* (the certificate).<sup>1</sup>

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<sup>1</sup> Dated January 1, 2015.

The Petitioner has Crohn's disease and was treated with the prescription drug Remicade (infliximab). Her physician ordered the Anser IFX diagnostic test to monitor her response to Remicade. The test was performed on August 21, 2014, by [REDACTED] 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 March 16, 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 April 11, 2015, submitted with the external review request, the Petitioner's authorized representative said:

The patient was denied coverage for the [REDACTED] Anser IFX diagnostic test performed on 08/21/2014 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 your request for coverage of the Anser IFX test, and upheld the previous denial.

We based our decision on the fact that the test rendered has no assigned procedure code and any unlisted procedure requires clinical review to determine medical necessity for coverage. Since the records submitted did not provide any basis for medical necessity, the service cannot be approved. In addition, the Anser IFX test is considered experimental and [the Petitioner's] certificate excludes experimental procedures.

Director's Review

In its final adverse determination, BCN said the Anser IFX test was not medically necessary and was considered to be experimental. In its response to this external review, BCN did not advance its argument about medical necessity so the sole issue here is whether the Anser IFX test is experimental for the treatment of the Petitioner's Crohn's disease.

The certificate (pp. 58-59) excludes coverage for services, including diagnostic tests, that are related to experimental or investigational procedures. "Experimental or investigational" is defined in the certificate (p. 55) as:

a service that has not been scientifically demonstrated to be as safe and effective for treatment of the Member's condition as conventional or standard treatment in the United States.

BCN's medical policy title "Measurement of Serum Antibodies to Infliximab and Adalimumab" also 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 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 and is familiar with the medical management of patients with the member's condition. The IRO report included the following analysis and recommendation:

**Recommended Decision:**

The MAXIMUS physician consultant determined that the [REDACTED] Anser IFX test performed on 8/21/14 was experimental/investigational for treatment of the member's condition.

**Rationale:**

\* \* \*

The results of the consultant's review indicate that this case involves a 23 year-old female who has a history of Crohn's disease. At issue in this appeal is whether the [REDACTED] Anser IFX test performed on 8/21/14 was experimental/investigational for treatment of the member's condition.

The member's Crohn's disease involves her proximal bowel as well as her colon. The member previously underwent an ileo-colonic resection in 2008. Following this surgery, the member has been on Remicade 5mg/kg every 6 weeks. The member underwent a recent upper endoscopy and colonoscopy, which demonstrated relatively quiescent disease. Biopies from the stomach and colon revealed granulomas. The neo-terminal ileum was healthy. The member is relatively asymptomatic with 3 to 4 bowel movements per day. According to the laboratory results provided for review, the member was not anemic. The member underwent the Anser IFX test on 8/21/14. The results of this testing demonstrated a detectable level of the drug with undetectable antibodies to the drug.

The MAXIMUS physician consultant noted that monitoring of patients on infliximab with measurement of infliximab levels and antibodies to infliximab continues to be an area of intense investigation. In general, infliximab levels correlated inversely with disease activities. The physician consultant explained that the target level of infliximab necessary to achieve clinical benefit remains unknown. The physician consultant also explained that it is not clear how the drug level obtained by the Anser IFX assay would be used to direct further care for the member. The member's infliximab level came back at approximately 21 ng/ml. The consultant noted that the target value has been investigated and is likely between 3 to 7 ng/ml, but this remains speculative. The consultant explained that there is no controlled data which has identified the optimal drug level. The physician consultant also explained that issues of how the patient is doing on the drug, how they are responding to treatment, whether they are losing response and whether they are having severe adverse side effects are more important than the drug level in directing care. There are no randomized prospective trials demonstrating that treatment guided by through infliximab

levels is superior to optimal clinical care. The physician consultant indicated that high quality evidence to support the use of the Anser IFX assay is lacking at this time.

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 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 BCN's final adverse determination of March 16, 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



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Randall S. Gregg  
Special Deputy Director