

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. 145523-001

Blue Cross Blue Shield of Michigan,

Respondent.

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Issued and entered  
this 28<sup>th</sup> day of January 2015  
by Randall S. Gregg  
Special Deputy Director

**ORDER**

**I. PROCEDURAL BACKGROUND**

On December 26, 2014, ██████████, 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 January 6, 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 January 13, 2015.

The case involves medical issues so it was assigned to an independent review organization which submitted its report on January 20, 2015.

**II. FACTUAL BACKGROUND**

The Petitioner's health care benefits are defined in BCBSM's *Simply Blue Group Benefits Certificate*<sup>1</sup> (the certificate).

The Petitioner has Crohn's disease and was treated with infusions of Remicade (infliximab). Her physician ordered the Anser IFX test to monitor her response to the Remicade.

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<sup>1</sup> BCBSM form no. 787B, approved 10/12.

The test was performed on July 5, 2013, by [REDACTED] a non-participating provider. The charge was \$2,500.00.

BCBSM 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 BCBSM's internal grievance process. At the conclusion of that process BCBSM issued a final adverse determination dated October 29, 2014, affirming its denial. The Petitioner now seeks a review of that adverse determination from the Director.

### III. ISSUE

Is the Anser IFX testing experimental or investigational for the treatment of the Petitioner's condition?

### IV. ANALYSIS

#### BCBSM's Argument

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

A board-certified M.D. in Internal Medicine and a Grievance and Appeals Coordinator reviewed [the Petitioner's] claim, the medical documentation, your appeal, and [the Petitioner's] health care plan benefits for Blue Cross Blue Shield of Michigan (BCBSM). After review, our denial is maintained. The BCBSM/BCN Joint Uniform Medical Policy Committee (JUMP) has determined that the Anser IFX (Procedure 84999) is investigational. Therefore, [the Petitioner] remains responsible for the charge (\$2,500.00).

\* \* \*

An investigational status means that the safety and effectiveness of a particular technology has not been definitively determined. An established technology means that the safety and effectiveness have been definitively determined. Investigational medical policies are reviewed regularly to guarantee that the investigational status continues to be supported by the evidence.

[The Petitioner] is covered under the *Simply Blue Benefits Certificate*. As explained in *Section 6: General Conditions of Your Contract* (Page 6.3), we do not pay for experimental treatment or services including experimental drugs or devices).

In order to give your appeal full consideration, a board-certified M.D. in Internal Medicine reviewed [the Petitioner's] claim, your appeal, the medical documentation, and [the Petitioner's] health care plan benefits for Blue Cross Blue Shield of Michigan (BCBSM). The medical consultant confirmed that the Anser IFX test performed to measure Infliximab concentrations and antibodies is

considered experimental/investigational per BCBSM Medical Policy titled *Measurement of Serum Antibodies to Infliximab*. The clinical utility of this test has been not established. As a result of the medical consultant's review and the provisions of [the Petitioner's] policy, payment cannot be approved.

### Petitioner's Argument

On the request for external review form, the Petitioner's authorized representative said:

. . . It should be noted that this patient has been diagnosed with Crohns Disease and was placed on infliximab. The patient was not responding to the drug which forced the referring physician to order this test. The results of the Anser IFX test caused the physician to change the patient's treatment. The patient was then placed on another drug. It was medically necessary for this proven test to be ordered/performed.

In a separate letter dated December 23, 2014, the Petitioner's authorized representative further said:

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 listed below, clearly demonstrate 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 this assay can be utilized by a clinician as "an effective management tool."

\* \* \*

It should also be noted that this test was developed and its performance characteristics determined by Prometheus Laboratories Inc. Please note, that as a lab developed test (LDT) neither pre-market clearance nor pre-market approval under the Federal Food, Drug and Cosmetic Act . . . is required for this test to be lawfully marketed at this time.

### Director's Review

The certificate has this exclusion (p. 6.3):

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. 7.10) 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 is experimental or investigational is a medical question that 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 peer reviewed medical literature, and is in active practice and is familiar with the medical management of patient with the Petitioner’s condition. The IRO report included the following analysis and recommendation:

**Recommended Decision:**

The MAXIMUS physician consultant determined that the Anser IFX assay that the member underwent on 7/5/13 was investigational for diagnosis and treatment of her condition.

**Rationale:**

\* \* \*

The results of the consultant's review Indicate that this case Involves a ■ year-old female who has a history of a Crohn's disease. The member has a history of steroid use and was being treated with infliximab. The member underwent the Anser IPX assay on 7/5/13, which demonstrated an undetectable level of the drug and the presence of antibodies to infliximab.

\* \* \*

The MAXIMUS physician consultant explained that the use of infliximab levels and antibody to infliximab levels to guide therapy in patients with inflammatory bowel disease is an area of active research. Many studies have looked at the correlation between drug levels and disease activity as well as the inverse relation between drug and antibody levels. The physician consultant indicated that the quality of evidence is lacking because nearly all studies have looked at large cohorts retrospectively and studied stored serum. The consultant also indicated that prospective trials have not yet shown that treatment adjustments guided by drug levels is superior to standard care. Many patients on standard dosing have levels that are "too high" or "too low." The physician consultant explained that while drug levels are thought to be important, exactly how to use this information has not been established. The consultant also explained that using trough levels of the

drug to determine whether a patient can discontinue Remicade (infliximab) is not standard of care at this time.

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 7/5/13 was investigational for diagnosis and treatment of her 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 October 29, 2014. BCBSM is not required to cover the Petitioner's Anser IFX testing performed on July 5, 2013.

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.

Annette E. Flood  
Director

For the Director:



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Randall S. Gregg  
Special Deputy Director