

**STATE OF MICHIGAN**  
**DEPARTMENT OF INSURANCE AND FINANCIAL SERVICES**  
**Before the Director of Insurance and Financial Services**

In the matter of:

██████████  
Petitioner

v

Blue Care Network of Michigan  
Respondent

File No. 154012-001

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Issued and entered  
this 8<sup>th</sup> day of July 2016  
by Randall S. Gregg  
Special Deputy Director

**ORDER**

**I. PROCEDURAL BACKGROUND**

On June 6, 2016, ██████████, 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 benefits are defined in BCN's *Classic for Large Groups* certificate of coverage.

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 June 16, 2016. After a preliminary review of the material submitted, the Director accepted the request on June 13, 2015.

The case involves a medical issue so it was assigned to an independent review organization which submitted its analysis to the Director on June 27, 2015.

**II. FACTUAL BACKGROUND**

The Petitioner is an eight-year-old male with Crohn's disease. He receives treatment for his condition with infliximab every eight weeks and Imuran daily. His physician ordered the Anser IFX diagnostic test to monitor his response to infliximab. The test was performed on November 19, 2014 by Prometheus Laboratories, Inc., a

California company that created the test and is the only laboratory that performs the test. Prometheus Laboratories is not a BCN participating provider. The charge for the test was \$2,500.00.

BCN denied coverage indicating the test was experimental/investigational. The Petitioner appealed the denial through BCN's internal grievance process. At the conclusion of that process, BCN issued a final adverse determination dated April 21, 2016, affirming its denial. The Petitioner now seeks a review of that 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

#### BCN's Argument

In its final adverse determination, BCN wrote:

The Panel ... reviewed the documentation submitted with your grievance and the member's benefits and have maintained the denial as the procedure is considered experimental/investigational. Also, Blue Care Network is a Michigan based HMO and Prometheus Laboratories is out of network.

Please reference the enclosed BCBSM/BCN Medical Policy titled "Measurement of Serum Antibodies to Infliximab and Adalimumab" and the members Classic for Large Groups Certificate, sections 9.1 titled "Unauthorized and Out of Network Services" and 9.4 titled "Non Covered Services".

#### Petitioner's Argument

In a letter dated April 11, 2015, accompanying the request for an external review, the Petitioner's authorized representative 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 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 this assay can be utilized by a clinician as an “an effective management tool.”

### Director’s Review

In denying coverage for the Petitioner’s Anser IFX test, BCN cited two reasons for its decision: the test was experimental in nature and the test was performed by a nonparticipating provider. With respect to BCN’s conclusion that the test was experimental, BCN’s *Classic for Large Groups* certificate (pages iv and 55-56) excludes coverage for services that are experimental or investigational. Experimental or investigational is defined in the certificate (page 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.”

In denying coverage, BCN also relied on its medical policy titled, “Measurement of Serum Antibodies to Infliximab and Adalimumab” which states on page 2:

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 or investigational for the 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 reviewer is a physician in active practice who is board certified in pediatrics with subspecialty certification in pediatric gastroenterology and is familiar with the medical management of patients with the member’s condition. The IRO report included the following analysis and recommendation:

The Anser IFX test is frequently ordered by gastroenterologists striving to provide evidence based care for their patients who have inflammatory bowel disease (IBD) receiving infliximab. Patients who have IBD who demonstrate symptomatic, endoscopic, and or histological remission of their disease on infliximab are typically given this medication every eight weeks. If these patients develop a recurrence of their symptoms while receiving infliximab, it is possible they are losing response to this medication. The Anser IFX test determines whether or not patients have developed antibodies to infliximab, and also determines the level of infliximab in the bloodstream at the time the blood for the test is drawn. Having this information allows a clinicians to better guide the medical management of patients who have IBD receiving infliximab. If antibodies

to infliximab are present, the patient may not be able to regain response to the drug. If the infliximab concentration in the blood is low, but no anti-infliximab antibodies are present, a higher dosage of infliximab or more frequent dosing may cause the patient to regain response.

The references below discuss the utility of anti-infliximab testing in greater detail. Clinicians have had the ability to test for such antibodies for quite some time. This testing should not be considered "experimental" or "investigational", as it provides patients with high quality, evidence-based care. There is no alternative standard health care services to the Anser IFX test. This is the only test commercially available that determines both a patient's serum infliximab level and whether or not antibodies to infliximab are present. It is suspected that the majority of practicing pediatric gastroenterologists who care for children who have IBD would have done the exact same thing if caring for a patient with this enrollee's clinical circumstance, their decision to do so being supported by evidence-based medicine.

As the enrollee in question was experiencing symptoms of IBD while receiving infliximab, ordering the Anser IFX test was a very reasonable and appropriate thing for his treating physician to do. Both the serum infliximab level and whether or not antibodies to infliximab are present were needed to help the enrollee's gastroenterologist determine how best to treat his disease. Therefore, for the reasons noted above, the Anser IFX laboratory test was not experimental/ investigational for this enrollee.

[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.

The Director, discerning no reason why the IRO's recommendation should be rejected in this case, finds that the Anser IFX test is not experimental or investigational in the treatment of the Petitioner's condition.

BCN also denied coverage because the test was performed by a nonparticipating provider. Section 9.1 of BCN's *Classic for Large Groups* certificate provides:

Except for Emergency care ... health, medical and hospital services listed in this Certificate are covered only when...provided by a Participating Provider ...

However, BCN must also comply with the requirements of the Michigan Insurance Code which pertain to health maintenance organizations. Section 3519(3) of

the Code, MCL 500.3519(3), provides: "all health maintenance organization contracts shall include, at a minimum, basic health services." Basic health services includes diagnostic laboratory and diagnostic and therapeutic radiological services. See MCL 500.3501(b)(vii).

The Anser IFX test has been determined by the IRO to be medically necessary in the treatment of the Petitioner's condition. The provider is the creator of the test and appears to be the only provider offering the test. In this circumstance, the mandate of the Insurance Code must take precedence over BCN's policy provision limiting coverage to services obtained from participating providers.

BCN must provide coverage for the Petitioner's November 19, 2014 Anser IFX test.

#### V. ORDER

The Director reverses BCN's final adverse determination of April 21, 2016.

BCN shall immediately provide coverage for the Petitioner's Anser IFX test provided November 29, 2014. See MCL 550.1911(17). Further, BCN shall, within seven days of providing coverage, furnish the Director with proof it has implemented this order.

To enforce this order, the Petitioner may report any complaint regarding its implementation to the Department of Insurance and Financial Services, Health Care Appeals Section, at this toll free number: (877) 999-6422.

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