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. 147439-001**

Blue Care Network of Michigan
Respondent

Issued and entered
this 21st 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 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 April 23, 2015. After a preliminary review of the material submitted, the Director accepted the request on April 27, 2015. BCN submitted additional information on April 29, 2015.

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

II. FACTUAL BACKGROUND

The Petitioner has a history of ulcerative colitis and has been 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 April 4, 2014, by , The charge was $2,500.00.

BCN denied coverage. The Petitioner appealed the denial through BCN's internal grievance process. At the conclusion of that process BCN issued a final adverse determination dated February 27, 2015, 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 told the Petitioner's authorized representative:

> Our step two grievance panel...reviewed your request for retro-authorization and payment for lab services with [redacted], and upheld the previous denial. The Panel has maintained the denial as the service is experimental/investigational, and therefore, not a benefit.

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.

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

BCN's *Classic for Large Groups* certificate of coverage, on page 59, excludes coverage for services that are experimental or investigational. Experimental or investigational is defined in the certificate (page 56) 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."

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 gastroenterology and is familiar with the medical management of patients with the member's condition. The IRO report included the following analysis and recommendation:

> In March 2014, the member experienced an exacerbation of symptoms with bloody diarrhea along with tenesmus, which coincided with starting metformin for diabetes. For management, the member was placed on a large dose of oral prednisone. The member was scheduled for a colonoscopy to assess mucosal activity. The member underwent the Prometheus Anser IFX on 4/4/14. This test demonstrated the presence of the drug at 2.5 μg/ml at trough with undetectable antibodies to infliximab.
>
> [T]here are hypothetical algorithms developed to optimize the use of biologics in the management of inflammatory bowel disease....[T]he hypothesis in these algorithms is that in a patient who is developing a non-response one of two processes may be occurring and either the patient has a suboptimal level of drug, they have developed antibodies to the drug or they simply require a switch in drug class as the mechanism of inflammation is not tumor necrosis factor drive[n]....[O]ne could construct a 2 x 2 table based on this algorithm and use it to drive therapy, which would be extremely helpful if it were proven to guide management. However...the testing became available to practitioners before the hypothesis was proven....[T]here remains no controlled prospective data that supports the hypothetical algorithm and the optimal target levels for biologics in the setting of inflammatory bowel disease is not known....[I]ssues 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 that the drug level in directing care. Well-designed and

> conducted trials are needed before the use of the Anser IFX can be applied widely.
>
> Pursuant to the information set forth above and available documentation…the [redacted] Anser IFX test performed on 4/4/14 was experimental/investigational for treatment of the member's 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.

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.

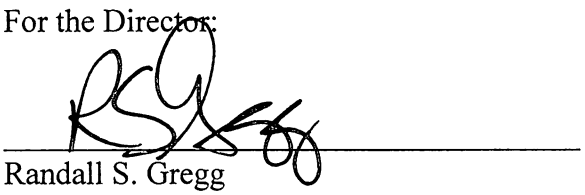
V. ORDER

The Director upholds BCN's final adverse determination of February 27, 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