

**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. 150398-001**

**Blue Care Network of Michigan,**  
**Respondent.**

---

Issued and entered  
this 2<sup>nd</sup> day of December 2015  
by Randall S. Gregg  
Special Deputy Director

**ORDER**

**I. PROCEDURAL BACKGROUND**

██████████ (Petitioner) was denied coverage for a diagnostic test by her health plan, Blue Care Network of Michigan (BCN).

On October 19, 2015, ██████████, the Petitioner's authorized representative, filed a request with the Director of Insurance and Financial Services for an external review of that denial under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.*

The Petitioner receives health care benefits through BCN, a health maintenance organization. The Director immediately 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 and, after a preliminary review of the material submitted, the Director accepted the request on November 2, 2015.

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

**II. FACTUAL BACKGROUND**

The Petitioner's health care benefits are defined in the BCN *Certificate of Coverage For Individuals* (the certificate).<sup>1</sup>

The Petitioner has Crohn's disease and has been treated with the prescription drug Humira

---

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

(adalimumab). Her physician ordered the Anser ADA diagnostic test to monitor her response to Humira. The test was performed on February 23, 2015, by Prometheus Laboratories, Inc., a non-participating provider. The charge was \$2,500.00.

BCN denied coverage, saying the test was investigational or experimental for the treatment of 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 September 10, 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 October 10, 2015, submitted with the external review request, the Petitioner's authorized representative said:

We have requested this external review on behalf of [the Petitioner]. On 09/10/2015 [BCN] denied the PROMETHEUS Anser ADA diagnostic test performed on 02/23/2015 as being Experimental / Investigational.

Anti-TNF agents, such as Humira (adalimumab), have demonstrated efficacy for induction and maintenance of remission in patients with moderate to severe CD [*Crohn's disease*] or UC [*ulcerative colitis*] or both but the response is not universal. More than one third of patients do not respond to induction therapy (primary nonresponse) and even among initial responders, the response wanes overtime. [Her physician] has been treating [the Petitioner] with Adalimumab for her IBD [inflammatory bowel disease]. She had begun to exhibit symptoms / or loss of response that may be attributed to subtherapeutic levels of Adalimumab (ADA) and / or the presence of antibodies to Adalimumab (ATA).

\* \* \*

Based on [the Petitioner's] symptoms, the clinician's medical findings and assessment as well as the evidence presented . . . we are asking that you overturn the denial of this service as Experimental / Investigational and provide coverage at an in-network benefit level. This patient should not be penalized for obtaining a test which her physician believed could play a critical role in assessing and managing her response to Humira.

#### BCN's Argument

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

Our grievance panel . . . reviewed your request for retro-authorization and payment for the above date of service [for the Anser ADA test], and upheld the previous denial.

The Panel determined that Blue Care Network (BCN) cannot authorize the service as the requested service is experimental. The denial is based on our enclosed medical policy titled, "Measurement of Serum Antibodies to Infliximab and Adalimumab." This policy states the effectiveness of this treatment has not been established to be equal to or better than traditional therapy. BCN does not pay for services, treatment or drugs that are experimental or investigational. Also, the requested service is not eligible for coverage under the terms of the member's enclosed Individual Certificate, section 9.4 titled "Non-Covered Services".

### Director's Review

In its final adverse determination, BCN said the Anser ADA test was considered to be experimental. The certificate (pp. 57, 60) excludes coverage for treatment and services, including diagnostic tests that are related to experimental or investigational procedures. "Experimental or investigational service" is defined in the certificate (p. 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 ADA 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 internal medicine and 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 Anser ADA testing performed on 2/23/15 was experimental / investigational and not medically necessary for diagnosis and treatment of the member's condition.

#### **Rationale:**

\* \* \*

The member appears to have isolated colonic disease. The member had a known colonic stricture near the hepatic flexure and also had a tight anal stricture, which has required dilation. The member developed worsening diarrhea and the treatment plan was to check Humira drug and antibody levels, as well as to add budesonide therapy. On 2/23/15, the member underwent the Anser ADA test, which demonstrated detectable levels of drug and undetectable antibody to drug.

The MAXIMUS physician consultant explained that the advantage of measuring serum drug levels and antibody titers over empiric dose changes has not been demonstrated in controlled randomized trials. In this case, the provider wished to get the adalimumab level greater than 5. However, the physician consultant indicated that there is sparse data demonstrating that this is an important goal. The consultant noted that in general, higher drug levels correlate inversely with disease activity, but this is highly variable from patient to patient. The consultant explained that Anser ADA testing is experimental / investigational and its clinical utility, if any, remains to be fully defined.

Pursuant to the information set forth above and available documentation, the MAXIMUS physician consultant determined that the Anser ADA testing performed on 2/23/15 was experimental / investigational and not medically necessary for diagnosis and 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. 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 ADA test is experimental for the treatment of the Petitioner's condition and is therefore not a benefit under the terms of the certificate.

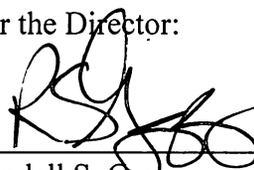
#### V. ORDER

The Director upholds BCN's final adverse determination of September 10, 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