

**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. 150243-001**

**Blue Care Network of Michigan**  
**Respondent**

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Issued and entered  
this 5<sup>th</sup> day of November 2015  
by Randall S. Gregg  
Special Deputy Director

**ORDER**

**I. PROCEDURAL BACKGROUND**

On October 8, 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.* On October 15, 2015, after a preliminary review of the information submitted, the Director accepted the request.

The Petitioner receives health care benefits through a group plan underwritten by Blue Care Network of Michigan (BCN), a health maintenance organization. The benefits are defined in the *BCN 10* certificate of coverage.

The Director notified BCN of the external review request and asked for the information used to make its final adverse determination. BCN furnished the information on October 16, 2015.

Because the case involves medical issues it was assigned to an independent review organization which submitted its recommendation on October 29, 2015.

**II. FACTUAL BACKGROUND**

The Petitioner has Crohn's disease and was treated with the drug Humira (adalimumab). His physician ordered the Anser ADA diagnostic test to monitor his response to Humira. The

test was performed on November 28, 2014, by [REDACTED] Laboratories, Inc. The charge was \$2,500.00.

BCN denied coverage, ruling that the test was experimental and was performed by a non-network provider. The Petitioner appealed the denial through BCN's internal grievance process. At the conclusion of that process, on August 13, 2015, BCN issued a final adverse determination affirming its denial. The Petitioner now seeks a review of that adverse determination from the Director.

### III. ISSUES

- Is the Anser ADA test experimental for the treatment of the Petitioner's condition?
- If the test is not experimental, should coverage be denied because the test was performed by a non-network provider?

### IV. ANALYSIS

In a September 30, 2015, letter included with the external review request, the Petitioner's authorized representative wrote:

Anti-TNF [tumor necrosis factor] 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 over time. [The Petitioner's doctor] has been treating [him] with adalimumab for his IBD [inflammatory bowel disease]. He 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).

\* \* \*

[T]here is a growing consensus that measuring ADA drug levels as well as ATA's is important in the management and treatment of patients to identify those who:

- Have clinical symptoms that may not correlate with active IBD
- Have antibodies to antibodies to adalimumab
- Exhibits therapeutic levels of adalimumab, but their inflammation is not TNF-driven

Based on [Petitioner's] symptoms, the clinician's medical findings and assessment as well as the evidence presented above 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 his physician believed could play a critical role in assessing and managing his response to Humira. [References omitted.]

The *BCN 10* certificate (page 11) excludes coverage for “any treatment that is not specifically covered herein and that is considered experimental/investigational by, or otherwise not approved by BCN...” An experimental or investigational service is defined in the certificate (page 22) as “a service that has not been scientifically demonstrated to be as safe and effective for treatment of the patient’s condition as conventional or standard treatment.”

The question of whether the Anser ADA test was experimental or investigational in the treatment of 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 who has been in practice for more than 18 years, is board certified in internal medicine and gastroenterology, and is familiar with the medical management of patients with the Petitioner’s condition. The IRO report included the following analysis and recommendation:

The member had active luminal and perianal disease. In the fall of 2014, the member presented with evidence of obstructive symptoms with abdominal pain and rectal bleeding. Colonoscopy demonstrated right sided colitis with luminal narrowing. This occurred despite the use of Humira. The member underwent the Anser ADA test on 11/28/14, which demonstrated a detectable level of drug and an undetectable level of antibody to drug.

Monitoring patients on adalimumab with measurement of adalimumab levels and antibodies levels correlate inversely with disease activity. However...the target level of adalimumab necessary to achieve clinical benefit remains unknown.... [T]here are no controlled data which have identified the optimal drug level to date. This issue remains speculative....[I]ssues of how a patient is doing on the drug, whether the patient is responding or losing response, are more important than drug level. For a patient failing therapy, one can set a hypothetical 2 x 2 table categorizing drug levels as high or low and antibody levels as high or low.... [A]lthough this algorithmic approach is appealing, it has not been validated using prospectively controlled data.

Pursuant to the information set forth above and available documentation...the Anser ADA testing performed on 11/28/14 was experimental/investigational for the diagnosis and treatment of the member’s condition. [References 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 *BCN 10* certificate of coverage. Having concluded that the test is experimental, it is not necessary to address the question of the non-network status of the provider.

#### V. ORDER

The Director upholds BCN’s final adverse determination of August 13, 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