

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. 145995-001

Blue Cross Blue Shield of Michigan,

Respondent.

Issued and entered
this 24th day of February 2015
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On January 26, 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 February 3, 2015, after a preliminary review of the information submitted, the Director accepted the request.

The Petitioner receives health care benefits through a 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 February 12, 2015.

The case involves medical issues so it was assigned to an independent review organization which submitted its recommendation on February 17, 2015.

II. FACTUAL BACKGROUND

The Petitioner's health care benefits are defined in BCBSM's *Blue Cross Premier Gold Benefits Certificate*¹ (the certificate).

¹ BCBSM form no. 604F, state approved 03/14, federal approval 09/13.

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 April 15, 2014, by Prometheus Laboratories, Inc., 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 December 29, 2014, affirming its denial. The Petitioner now seeks a review of that adverse determination from the Director.

III. ISSUE

Was the Anser ADA test 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:

After review, the denial of payment is maintained because the service is considered to be experimental /investigational. Investigational services are not a benefit of [the Petitioner's] contract.

* * *

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.

A board-certified M.D. in Internal Medicine reviewed the claim, your appeal, and the member's health care plan benefits for [BCBSM]. Based on that information, the member's physician ordered the Anser ADA test to measure the antibodies to adalimumab for a diagnosis of Crohn's Disease. According to the BCBSM medical policy titled "Measurement of Serum Antibodies to Infliximab and Adalimumab," measurement of either of these antibodies in a patient receiving treatment of serum infliximab or adalimumab, whether alone or as a combination test, is considered experimental. 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 January 21, 2015, accompanying the request for an external review, the Petitioner's authorized representative said:

We have requested this external review on behalf of [the Petitioner]. On 12/19/2014 his insurance company BCBS MI denied the PROMETHEUS Anser ADA diagnostic test performed on 04/15/2014 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 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).

* * *

The PROMETHEUS Anser ADA Assay is propriety, fluid-phase mobility shift assay for the simultaneous detection of ATA and Adalimumab. . . .

* * *

Based on [the 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.

Director's Review

The certificate (p. 140) has this exclusion:

Services That Are Not Payable

We do not pay for experimental treatment (including experimental drugs or devices) or services related to experimental treatment. . . .

“Experimental treatment” is defined in the certificate (p. 157) 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 ADA 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 physician reviewer is board certified in internal medicine and gastroenterology and has been in active practice for more than 18 years. The IRO report included the following analysis and recommendation:

Recommended Decision:

The MAXIMUS physician consultant determined that the Anser ADA testing performed on 4/15/14 was experimental/investigational for diagnosis and treatment of the member's condition.

Rationale:

* * *

The results of the consultant's review indicate that this case involves a 48 year-old male who has a history of a Crohn's disease. At issue in this appeal is whether the Anser ADA testing performed on 4/15/14 was experimental/investigational for diagnosis and treatment of the member's condition.

The member was being treated with Humira (adalimumab) on a weekly basis. The member has relatively minimal symptoms and a colonoscopy, which demonstrated mucosal healing. In February 2014, the member stopped taking Humira for 6 weeks due to a pneumonia and his symptoms began to flare. The treating physician contemplated reducing the Humira dose to every other week. Prior to making that decision, the provider wanted to check Humira drug levels. On 4/15/14, the member underwent the Anser ADA test in order to determine adalimumab drug levels and antibodies to adalimumab. The test revealed detectable levels of adalimumab without detectable antibodies.

Monitoring patients on adalimumab with measurement of adalimumab levels and antibodies to adalimumab levels remains an area of clinical interest. In generally, adalimumab levels correlate inversely with disease activity. The presence of antibodies may portend or explain loss of response. However, the MAXIMUS physician consultant explained that the use of the test is problematic clinically. The physician consultant indicated that antibodies can be transient and may not be biologically significant in any given patient. That is, many patients with the presence of antibodies continue to respond and only through serial measurement can antibodies be determined to be transient. The consultant also indicated that the target level of adalimumab necessary to achieve clinical benefit remains unknown. The physician consultant explained that this point is relevant to the member's case as it is not clear how measuring drug levels would provide assurance that Humira could be dose-reduced. The consultant also explained that

there are no randomized prospective clinical trials demonstrating that treatment guided by trough adalimumab levels is superior to optimal clinical care.

Pursuant to the information set forth above and available documentation, the MAXIMUS physician consultant determined the Anser ADA testing performed on 4/15/14 was experimental/investigational for diagnosis and treatment of the member's conditions. [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 or investigational for the treatment of the Petitioner's condition and is therefore not a benefit under the terms of the certificate.

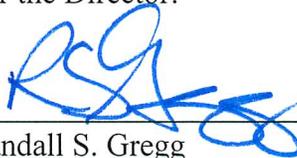
V. ORDER

The Director upholds BCBSM's final adverse determination of December 29, 2014.

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:



Randall S. Gregg
Special Deputy Director