

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. 150296-001

Blue Cross Blue Shield of Michigan,
Respondent.

Issued and entered
this 12th day of November 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 Cross Blue Shield of Michigan (BCBSM).

On October 12, 2015, the Petitioner filed a request with the Director of Insurance and Financial Services for an external review of BCBSM's denial under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.* On October 19, 2015, after a preliminary review of the information submitted, the Director accepted the request.

The Petitioner receives health care benefits through a group plan that is underwritten by 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 furnished the information on October 22, 2015.

The case involves medical issues so it was assigned to an independent review organization which submitted its recommendation on November 2, 2015.

II. FACTUAL BACKGROUND

The Petitioner's health care benefits are defined in the *Simply Blue Group Benefit Certificate*¹ (the certificate).

¹ BCBSM form no. 778E, approved 8/14.

The Petitioner has Crohn's disease and was treated with the prescription drug Humira (adalimumab). Her physician ordered the Anser ADA diagnostic test to monitor her response to Humira. The test was performed on December 5, 2014, by Prometheus Laboratories, Inc., a non-participating provider. The charge was \$2,500.00.

BCBSM denied coverage, saying the test was experimental or investigational 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 August 27, 2015, affirming its denial. The Petitioner now seeks a review of that final 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

Petitioner's Argument

On the external review request form the Petitioner said:

My doctor ordered lab test to see if I had developed antibodies to my medication (Humira). I had been in the hospital and there was a very inflamed area in my intestine. I had the test done because he thought the medication wasn't working. Nobody told me it was \$2,500 or possibly not covered. I was assured it was a lab test to see if my medication was still effective and that it was routinely done. I would like it to be covered by my insurance.

An October 6, 2015, letter from a representative of the laboratory that performed the test was included with the external review request:

. . . On 8/27/2015 . . . BCBS MI denied the PROMETHEUS Anser ADA diagnostic test performed on 12/5/2014 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 physician] has been treating [the Petitioner with adalimumab for her IBD [*irritable 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 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 her response to Humira.

BCBSM's Argument

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

This letter is in response to the appeal . . . and will inform you of the outcome of your managerial-level conference conducted on August 10, 2015. The purpose of the conference was to discuss the denial of payment for [Anser ADA testing]. After a thorough review, I confirmed that the claim processed correctly. [The Petitioner] remains responsible for non-covered charges of \$2,500.00.

Prometheus Laboratories Inc., submitted a claim to [BCBSM] for procedure code 84999 (unlisted chemistry procedure), for the Prometheus Anser ADA testing. The BCBSM/BCN Joint Uniform Medical Policy Committee (JUMP) has determined that the service is considered investigational.

* * *

To ensure all consideration, your appeal was reviewed by a board-certified M.D. in Family Medicine who determined:

[The Petitioner's] doctor ordered Anser ADA testing because she has Crohn's disease, for which she is taking Humira (Adalimumab). According to the [BCBSM] medical policy titled "Measurement of Serum Antibodies to Infliximab and Adalimumab," 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 that includes the serum infliximab or adalimumab levels, is considered experimental/investigational. The use of these tests has not been clinically proven to improve patient clinical outcomes. Deny 84999.

Director's Review

The certificate (p. 137) says,

Services That Are Not Payable

We do not pay for experimental treatment (including experimental drugs or devices) or services related to experimental treatment, except as explained . . . below. In addition, we do not pay for administrative costs related to experimental treatment or for research management.

"Experimental treatment" is defined in the certificate (p. 155) as:

Treatment 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 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 physician reviewer is board certified in internal medicine with a subspecialty in gastroenterology and is in active clinical practice. The IRO report included the following analysis and recommendation:

Reviewer's Decision and Principal Reasons for the Decision:

It is the determination of this reviewer that the Anser ADA test on December 5, 2014, was experimental/investigational for the treatment of the enrollee's condition.

Clinical Rationale for the Decision:

* * *

The Anser ADA panel consists of two (2) separate serological levels: antibodies to adalimumab, and serum adalimumab levels. This enrollee has been noted to have had loss of therapeutic effect of the adalimumab injections. As noted above, the measurement of serum adalimumab levels has been suggested as a cost-effective follow-up to the adjustment of adalimumab dosing, without measurement of antibodies to adalimumab. The use of this test panel is not part of the routine management as noted in the specialty society guidelines for the treatment of inflammatory bowel disease.

The Anser test panel does not require Food and Drug Administration (FDA) approval for the use in this enrollee's condition.

The medical evidence does not demonstrate that the expected benefits of the use of this test panel are more likely to be beneficial than standard management of this enrollee. The Anser ADA serological testing panel has not been part of the applicable professional standards, and has not yet been shown to materially improve health outcomes. As noted above, the current literature states that this test panel (serum adalimumab level and measurement of antibodies to adalimumab) requires further study to demonstrate its clinical role. For the reasons noted above, the requested services (Anser ADA serological panel) is considered experimental/investigational for this enrollee.

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 August 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