

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. 145619-001

██████████

Plan Sponsor,

and

Blue Cross Blue Shield of Michigan, Plan Administrator,

Respondents.

Issued and entered
this 5th day of February 2015
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On January 5, 2015, ██████████, authorized representative of ██████████ (Petitioner),¹ filed a request with the Director of Insurance and Financial Services for an external review under Public Act No. 495 of 2006 (Act 495), MCL 550.1951 *et seq.* On January 12, 2015, after a preliminary review of the information submitted, the Director accepted the request.

The Petitioner receives health care benefits through a group plan sponsored by the ██████████ (the plan), a self-funded government health plan subject to Act 495. Blue Cross Blue Shield of Michigan (BCBSM) administers the plan. 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 January 20, 2015.

Section 2(2) of Act 495, MCL 550.1952(2), authorizes the Director to conduct this external review as though the Petitioner were a covered person under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.*

The case involves medical issues so it was assigned to an independent review organization which provided its recommendation to the Director on January 26, 2015.

¹ The Petitioner is a minor (born ██████████, ██████████ the Petitioner's parent, authorized ██████████ to represent her.

II. FACTUAL BACKGROUND

The Petitioner's health care coverage is governed by the [REDACTED] Health Plan's *Your Benefit Guide New State Health Plan PPO*² (the benefit guide).

The Petitioner has Crohn's disease and was treated with adalimumab. Her physician ordered the Anser ADA test to measure serum adalimumab and anti-adalimumab antibodies. The test was performed on July 27, 2013, by [REDACTED] 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 November 5, 2014, affirming its denial. The Petitioner now seeks a review of that adverse determination from the Director.

III. ISSUE

Is the Anser ADA testing experimental or investigational for the treatment of the Petitioner's condition?

IV. ANALYSIS

BCBSM's Argument

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

A Grievance and Appeals Coordinator for [BCBSM] and board-certified D.O. in Internal Medicine reviewed the claim in question, your appeal, and the member's health care plan benefits. Based on that review, I confirmed that payment cannot be approved for procedure 84999 (unlisted chemistry procedure). This procedure is considered experimental/investigational by the BCBSM/BCN Joint Uniform Medical Policy Committee (JUMP).

* * *

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.

2 For employees hired or rehired on or after April 1, 2010; published 01/01/2013.

To give your request appeal full consideration, the member's medical records were reviewed by our board-certified D. O. in Internal Medicine [who] determined the following:

The member is appealing the denial of payment for procedure code 84999. The provider ordered the measurement of antibodies to drugs used to treat Inflammatory Bowel Disease. According to BCBSM Policy, "Measurement of serum antibodies to Infliximab and Adalimumab," the measurement of antibodies to either Infliximab or Adalimumab in a patient receiving treatment with these drugs is considered experimental/investigational. The use of these tests has not been clinically proven to improve patient clinical outcomes.

. . . I understand that member's family may have felt that this test was medically necessary. However, as mentioned above, our board-certified D.O. in Internal Medicine determined that this service is experimental. Because investigational services are not covered under the terms and conditions of the member's health care plan, we are unable to approve payment for this service. The member remains liable for the non-covered charges for this test.

Petitioner's Argument

On the request for external review form, the Petitioner's authorized representative said:

. . . [The Petitioner's physician] ordered the proven Anser ADA test since it was medically necessary in the management of the child's condition. However, BCBSM has denied coverage for the test and internal appeal are now exhausted.

In a letter to BCBSM dated August 11, 2014, the Petitioner's authorized representative said:

Anti-TFN agents such as Humira (adalimumab) have demonstrated efficacy for induction and maintenance of remission in patients with moderate to severe CD [*Crohn's disease*] and UC [*ulcerated 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 respondents, the response wanes over time. [The Petitioner's doctor] has been treating [her] 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 presence of antibodies to Adalimumab (ATA).

* * *

Advantages of the Anser ADA assay include:

- Detection of all antibody isotypes and subclasses of IgG, and antibodies with low binding affinity, yielding fewer false negative results
- Data demonstrating no significant interference in both assays from common endogenous components of human serum and drug, generating fewer false positive results thereby reducing likelihood of unnecessary changes in management

- Analytical validation of both the ATA and Adalimumab assays with robust performance data (99% specificity and 100% sensitivity for ATI, 97% specificity and 100% sensitivity for ADA)

Director's Review

The benefit guide (p. 48) has this exclusion:

In addition to the exclusions listed with the benefit, the following services are not covered under the NSHP PPO:

* * *

- Services, care, devices or supplies considered experimental or investigative.

“Experimental or investigative” is defined in the certificate (p. 60) as

a service, procedure, treatment, device or supply that has not been scientifically demonstrated to be safe and effective for treatment of the patient's condition. . . .

The question of whether the Anser ADA test is 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 certified by the American Board of Pediatrics with subspecialty certification in pediatric gastroenterology and is in active practice. 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 diagnostic test received on July 27, 2013 was not considered experimental/investigational for the treatment of the enrollee's condition.

Clinical Rationale for the Decision:

The enrollee has classic Crohn's disease as seen in the pediatric age group. Treatment has been in accordance with established guidelines. Mercaptopurine was an appropriate first line drug. When she did not tolerate it, biologic therapy was used. Both Infliximab and Adalimumab are appropriate choices.

When faced with a child who has Crohn's disease and who is not responding or losing responsiveness to biologic therapy there are limited choices. One can switch to another biologic agent in this case, likely Infliximab. The doses of the biologic can be increased or the duration between treatments shortened. Another immunosuppressive agent such as methotrexate can be added. Before there was ability to measure serum levels and presence of antibodies, this was done on an ad hoc basis. Measure of serum levels helps guide a more rational approach.

Kamaris K et al demonstrate that patients with serum concentrations of adalimumab greater than 5 mcg/ml has better outcomes and were able to stay on the drug longer. Low trough levels were often associated with the development of antibodies.

Yanai H et al demonstrated that favorable clinical outcome is consequence of sustained therapeutic drug levels. The current literature supports dose adjustments. In the absence of direct measurement of drug levels and anti-drug antibodies, clinical judgment is necessary to determine the clinical approach.

In July of 2013, there was increasing evidence that the response to adalimumab was correlated to trough levels. One of the factors affecting drug levels and the effectiveness of therapy was the presence or absence of antibodies. Knowing the levels are adequate enables the provider to make appropriate changes in therapy. Therefore, in this clinical scenario, the Anser ADA diagnostic testing is medically necessary in the treatment of this enrollee.

Recommendation:

It is the recommendation of this reviewer that the denial issued by [BCBSM] for the Anser ADA diagnostic test received on July 27, 2013 be overturned.

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 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 not experimental or investigational for the treatment of the Petitioner's condition and is therefore a benefit.

V. ORDER

The Director reverses BCBSM's final adverse determination of November 5, 2014. Pursuant to section 11(17) of the Patient's Right to Independent Review Act, MCL 550.1911(17), BCBSM shall immediately approve coverage for the Petitioner's Anser ADA test on July 27, 2013, and shall, within seven days, furnish the Director with proof it has complied with this Order.

To enforce this Order, the Petitioner may report any complaint regarding its implementation to the Department of Insurance and Financial Services, Health Care Appeals, at the toll free number: (877) 999-6442.

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:

A handwritten signature in black ink, appearing to read 'RSG', is written over a horizontal line.

Randall S. Gregg
Special Deputy Director