

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. 154333-001

Priority Health,

Respondent.

Issued and entered
this 27th day of July 2016
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

██████████ (Petitioner) was denied coverage for a diagnostic test by her health plan, Priority Health, a health maintenance organization.

On June 24, 2016 ██████████, 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 has individual health care coverage through Priority Health, a health maintenance organization. The Director immediately notified Priority Health of the external review request and asked for the information it used to make its final adverse determination. Priority Health provided its initial response on July 5, 2016, and after a preliminary review of the material submitted, the Director accepted the request.

The case involves a medical issue so it was assigned to an independent review organization which submitted its recommendation to the Director on July 19, 2015.

II. FACTUAL BACKGROUND

The Petitioner's health care benefits are defined in Priority Health's *MyPriority HMO Agreement* (the contract).

The Petitioner has Crohn's disease and has treated her condition with adalimumab. Her physician ordered the Anser ADA diagnostic test to monitor her response to adalimumab.

The test was performed on November 23, 2015 by Prometheus Laboratories, Inc., a California company that created the test and is the only laboratory that performs the test. Prometheus is not in Priority Health's network of providers. The charge for the test was \$2,500.00.

Priority Health denied coverage, saying the test was experimental, investigational, or unproven. The Petitioner appealed the denial through Priority Health's internal grievance process. At the conclusion of that process, Priority Health issued a final adverse determination dated April 19, 2016 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, investigational, or unproven for the treatment of the Petitioner's condition?

IV. ANALYSIS

Priority Health's Argument

In its final adverse determination, Priority Health wrote:

... Prometheus Laboratory is requesting coverage, on [the Petitioner's] behalf, for the Anser ADA test performed August 4, 2015, by Prometheus Laboratory.

* * *

Decision:

Uphold denial - requested coverage will not be provided. Specifically, Anser ADA Diagnostic Test is considered experimental / investigational / unproven care and therefore, not a covered benefit in accordance with Priority Health Medical Policy No. 91583-R3 Markers for Digestive Disorders, Medical Policy No 91117-R10 Experimental / Investigational / Unproven Care/Benefit Exceptions. Hayes search & summary entitled "Anser ADA (Prometheus Laboratories Inc.) for Monitoring Adalimumab Treatment of inflammatory Bowel Disease, dated July 30, 2015, and MyPriority Agreement.

Petitioner's Argument

In a June 13, 2016 letter that was submitted with the external review request, the Petitioner's authorized representative said:

Anti-TNF agents, such as Humira (adalimumab), have demonstrated efficacy for induction and maintenance of remission in patients with moderate to severe CD or UC 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 [her] with Adalimumab for her IBD. 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).

An increasing number of studies have assessed the relationship between Adalimumab levels and the presence of ATA's with outcomes in patients with IBD ...

* * *

In summary, there 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 the inflammation is not TNF-driven

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 her physician believed could play a critical role in assessing and managing her response to Humira. [References omitted]

Director's Review

The certificate covers diagnostic tests. However, the certificate (p. 37) has this exclusion:

Non-Covered Services

Any drug, device, treatment or procedure that is experimental, investigational or unproven ...

The question of whether the Anser ADA test is experimental, investigational, or unproven for the medical management 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 and gastroenterology, is familiar with the medical management of patients with the member's condition, and is in active practice. The IRO report included the following analysis and recommendation:

Recommended Decision:

The MAXIMUS physician consultant determined that the Anser ADA testing performed on 11/23/15 was experimental / investigational for diagnosis and treatment of the member's condition.

Rationale:

* * *

The member was maintained for Humira for her ileal Crohn's disease. The member's last Humira dose prior to the services at issue in this appeal was on 11/13/15. According to the record from the member's 11/9/15 visit to her gastroenterologist "her Crohn's has been stable; hasn't worsened. Doing very well, in remission on biologics." The member's treating provider ordered the Prometheus Anser ADA test in November 2015 for an unclear indication. The results of this testing showed detectable and therapeutic serum adalimumab at 18.4 ug/mL and undetectable antibodies to adalimumab at less than 1.7 U/mL.

The Prometheus Anser IFX test is quantitative measure of serum infliximab (IFX) and anti-IFX antibodies and that Anser ADA test assesses serum adalimumab (ADA) and anti-ADA antibodies. These are proprietary studies performed only by Prometheus Laboratories. The tests are not Food and Drug Administration (FDA) approved. The MAXIMUS physician consultant also indicated that some evidence exists that low serum levels of infliximab and adalimumab and/or the presence of antibodies to infliximab or adalimumab may play a role in primary or secondary response failures.

The physician consultant noted that antidrug antibodies develop in a substantial number of patients and may be responsible for acute drug infusion reactions as well as delayed hypersensitivity reactions. The consultant indicated that in a large percent of patients who develop antibodies, such antibodies may disappear after continued treatment. The physician consultant explained that the reasons for therapeutic failure remain unclear. Some evidence exists that low serum levels of infliximab or adalimumab or the presence of IFX or ADA antibodies have an adverse effect on the clinical outcome of a patient's response to treatment. The physician consultant explained that however, while there have been testimonials, there are few well controlled clinical trials to confirm that use of the Anser testing leads to improved patient outcomes or quality of life as opposed to the standard methods of treatment.

As in the case of other anti-TNF therapy, "in patients with IBD who lose response to infliximab, clinical improvement may occur upon intensification of infliximab therapy, irrespective of infliximab serum concentrations or presence of antibodies to infliximab." The consultant explained that as such, the clinical utility of measuring drug antibody concentrations has not been established and it has not been established how patient management would change based on test results.

The physician consultant indicated that limited retrospective evidence describes changes in management after measurement of anti-drug antibodies, but does not compare these management changes to those made in the absence of anti-drug antibody measurement. The consultant explained that it has not yet been established whether the use of threshold levels aid in the discrimination of treatment response and the optimal timing of when to measure antibody levels has also not been established.

Pursuant to the information set forth above and available documentation, the MAXIMUS physician consultant determined that the Anser ADA testing performed on 11/23/15 was experimental / investigational for 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. The Director, discerning no reason why the IRO's recommendation should be rejected, finds that the Anser ADA test is experimental or investigational in the treatment of the Petitioner's condition and is therefore not a benefit under the terms of the certificate.

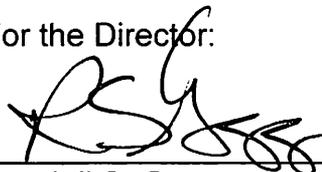
V. ORDER

The Director upholds Priority Health's final adverse determination.

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