

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. 153665-001

Priority Health,

Respondent.

Issued and entered
this 13th day of June 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 (Priority).

On May 12, 2016, ██████████, the Petitioner's authorized representative, filed a request with the Director of Insurance and Financial Services for an external review of the denial under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.*

The Petitioner receives group health care benefits through Priority, a health maintenance organization. The Director immediately notified Priority of the request and asked for the information it used to make its final adverse determination. Priority responded on May 17, 2016. After a preliminary review of the material submitted, the Director accepted the external review request on May 19, 2016.

The case involves medical issues so it was assigned to an independent review organization, which submitted its recommendation to the Director on June 2, 2016.

II. FACTUAL BACKGROUND

The Petitioner's health care benefits are described in the *Priority Health HMO Certificate of Coverage* (the certificate).

The Petitioner has ulcerative colitis 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 August 4, 2015, by Prometheus Laboratories, Inc., a non-participating provider. The charge was \$2,500.00.

Priority denied coverage, saying the test was investigational or experimental for the Petitioner's condition and therefore not a covered benefit. The Petitioner appealed that denial through Priority's internal grievance process. At the conclusion of that process, Priority issued a final adverse determination dated March 25, 2016, affirming its decision. The Petitioner now seeks a review of that final adverse determination by 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

In a letter dated May 4, 2016, submitted with the external review request, the Petitioner's authorized representative said:

We have requested this external review on behalf of [the Petitioner]. On 03/22/2016 her insurance company Priority Health denied the PROMETHEUS Anser ADA diagnostic test performed on 08/04/2015 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 [*ulcerated colitis*] or both but the response is not universal. More than one third of patients do not respond to induction therapy (primary response) and even among initial responders, the response wanes over time. [The Petitioner's physician] has been treating [her] with Adalimumab for her IBD [*irritable bowel disease*]. She has 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 her physician believed could play a critical role in assessing and managing her response to Humira.

Priority's Argument

In its final adverse determination, Priority told the Petitioner and her authorized representative:

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

Prometheus Labs states: [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 and / or the presence of antibodies to Adalimumab.

* * *

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 91583-R3 Markers for Digestive Disorders, Medical Policy 91117-R9 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 the Certificate of Coverage.

Director's Review

Priority considers the Anser ADA test to be experimental. The certificate, in “Section 6. Covered and Non-covered Services,” has this exclusion (pp. 34 - 35):

Experimental, Investigational or Unproven Services

* * *

Non-Covered Services

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

The question of whether the Anser ADA test was experimental in treating the Petitioner's condition was presented to an independent review organization (IRO) for analysis and a recommendation 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, has been in active practice for more than 18 years, and is familiar with the medical management of patients with the member's condition. The IRO report included the following analysis and recommendation:

Recommended Decision:

The MAXIMUS physician consultant determined that the Anser ADA testing performed on 8/4/15 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 36 year-old female who has a history of Crohn's disease, isolated to the colon. At issue in this appeal is whether the Anser ADA testing performed on 8/4/15 was experimental / investigational for diagnosis and treatment of the member's condition.

The member discontinued Humira and Imuran during a pregnancy in 2014. Humira was resumed, however, the member continued to do poorly after delivery with worsening of diarrhea. The member did not respond well to budesonide. Apriso was not particularly beneficial. In January 2015, the member was given prednisone and a day course of oral antibiotics, Cipro / Flagyl, due to ongoing diarrhea and rectal bleeding. The member apparently did well as the next office visit note provided for review was from August 2015. This office visit note mentions that the member had no abdominal pain, diarrhea or rectal bleeding and states that a recent complete blood count (CBC) and CRP were normal. The Anser ADA test was performed on 8/4/15 and demonstrated detectable levels of serum adalimumab with an absence of antibodies to the drug.

The MAXIMUS physician consultant explained that in January 2015, it would have been reasonable to order the Anser ADA test after the member was restarted on Humira in the setting of interrupted therapy. The physician consultant noted that it appears that the member did not respond right away after restarting therapy and there could have been a theoretical concern for drug antibodies. However, the consultant explained that in August 2015, the member was clinically stable and actually doing quite well. The consultant also explained that routine measurement of drug levels in this setting is not standard of care and would be considered investigational.

Pursuant to the information set forth above and available documentation, the MAXIMUS physician consultant determined that the Anser ADA testing performed on 8/4/15 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. 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 it should be rejected in this case, accepts the IRO's recommendation and 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 certificate.

V. ORDER

The Director upholds Priority Health's final adverse determination of March 25, 2016.

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