

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. 152794-001

Priority Health,
Respondent.

Issued and entered
this 21st day of April 2016
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On March 22, 2016, ██████████, 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.*

The Petitioner receives group health care benefits through Priority Health (Priority), a health maintenance organization. The Director notified Priority of the external review request and asked for the information it used to make its final adverse determination. Priority provided its initial response on March 23, 2016. After a preliminary review of the material submitted, the Director accepted the request on March 29, 2015.

The case involves medical issues so it was assigned to an independent review organization which submitted its recommendation to the Director on April 12, 2016.

II. FACTUAL BACKGROUND

The Petitioner is a █████ year-old female with a history of 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 February 2, 2015, by Prometheus Laboratories, Inc., a non-participating provider.

Priority 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 Priority's internal grievance process. At the conclusion of that process Priority issued a final adverse determination dated February 12, 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 March 14, 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 2/12/2016 her insurance company Priority Health denied the PROMETHEUS Anser ADA diagnostic test performed on 2/02/2015 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 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 more initial responders, the response wanes over time. Ben Dozeman has been treating [the Petitioner] 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).

The PROMETHEUS Anser ADA ASSAY is propriety, fluid-phase mobility shift assay for the simultaneous detection of ATA and Adalimumab. The HMSA methodology offers several advantages, listed below, over solid-phase bridge (ECLIA/ELISA) assays and in published data, demonstrates high sensitivity, precision and accuracy.

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's authorized representative:

Prometheus Labs is requesting coverage, on [the Petitioner's] behalf, for the Anser ADA test performed February 2, 2015 by Prometheus Laboratory, a Non-Participating provider.

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

In its final adverse determination, Priority said the Anser ADA test was considered to be experimental. The certificate Section 5, Non-covered Services it includes "Any drug, device, treatment or procedure that is experimental, investigational or unproven.

The question of whether the Anser ADA test was experimental for 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 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 test performed on 2/5/15 was experimental/investigational for treatment of the member's condition.

Rationale:

The MAXIMUS physician consultant indicated that the record from the member's office visit on 1/7/15, immediately prior to the Anser ADA testing at issue in this appeal, demonstrates both excellent tolerance and response to Humira and the absence of any significant ulcerative colitis flare symptoms while tapering her corticosteroid. The physician consultant explained that generally, except on a rare case-by-case basis, diminished or suboptimal response to adalimumab can be managed in one of several ways including shortening the interval between doses, increasing the dose, switching to a

different anti-tumor necrosis factor agent in patients who continue to have loss of response after receiving an increased dose or switching to a non-anti-tumor necrosis factor agent based on clinical observation.

The consultant indicated that anti-drug 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 also indicated that in a large percent of patients who develop antibodies, such antibodies may disappear after continued treatment. The reasons for therapeutic failures remain unclear. The physician consultant noted that some evidence exists that low serum levels of adalimumab or the presence of antibodies to adalimumab have an adverse effect on the clinical outcome of a patient's response to treatment. However, the consultant explained that while there have been testimonials to this effect, there are few well controlled clinical trials to confirm that the use of Anser ADA testing leads to improved patient outcomes or quality of life compared to the standard method of treatment (Individualized therapy is more cost-effective than dose intensification in patients with Crohn's disease who lose response to anti-tumor necrosis factor treatment: a randomized controlled trial. The consultant also explained that the clinical utility of measuring drug antibody concentration 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 the measurement to anti-drug antibodies, but does not compare their management changes to those made in the absence of anti-drug antibody measurement. The consultant also indicated that it has not yet been established whether use of threshold levels aids in the discrimination of treatment response nor has the optimal timing of when to measure antibody levels been established.

Pursuant to the information set forth above and available documentation, the MAXIMUS physician consultant determined that the Anser ADA testing performed on 2/5/15 was experimental/investigational for diagnosis and treatment of the member's condition.
[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 for the treatment of the Petitioner's condition and is therefore not a benefit under the terms of the certificate.

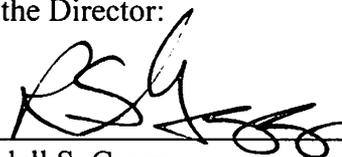
V. ORDER

The Director upholds Priority Health's final adverse determination of February 12, 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