

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. 152606-001

Time Insurance Company,
Respondent.

Issued and entered
this 20th day of April 2016
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On March 18, 2016, ██████████ (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 health care benefits under a group medical plan that is underwritten by Time Insurance Company (Time). The Director immediately notified Time of the external review request and asked for the information it used to make its final adverse determination. Assurant Health, which administers the Petitioner's plan for Time, furnished the information on March 21, 2016. After a preliminary review of the material submitted, the Director accepted the external review request on March 25, 2016.

The case involves medical issues so it was assigned to an independent review organization which submitted its recommendation on April 7, 2016.

II. FACTUAL BACKGROUND

The Petitioner has a history of ulcerative colitis. He has been treated with the drug Humira (adalimumab), but lost response to the treatment. His physician ordered the Prometheus Anser ADA diagnostic test to monitor his response to the drug. The test was performed on April 7, 2015, by VHS University Laboratories, a non-participating provider. Time 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 the plan's internal grievance process. At the conclusion of that process Assurant Health issued a final adverse determination dated January 26, 2016, affirming the 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

The Petitioner explained his grievance on the external review request form, he wrote:

Seeking payment by Assurant Health for Humira antibody lab draw on 4-7-15 the Prometheus Anser Ada test. I was not responding to Humira so [my doctor] ordered the antibody test to see if I had built up immunity to the medication. Humira was costing Assurant Health almost \$5000.00 a month so before adding another medication to the expensive Humira [my doctor] wanted to see if Humira was even working.

Time's Argument

In its final adverse determination, Assurant Health explained its denial to the Petitioner:

. . . Based on this review and the review of the Appeal Panel, it was determined that the previous decision has been upheld that the treatment in question was experimental / investigational.

The clinical rationale for the decision is as follows:

Per the Clinical Policy Bulletin (CPB) . . . considers the Anser ADA test for persons being treated with adalimumab experimental and investigational because the effectiveness of this approach has not been established.

While some studies have shown that the test is used to effect clinical management decisions, others have shown that the importance of previous tests were potentially biased by use of different types of assays, different cut-off values for binary classification of test results, and inconsistent timing of measurements. It is

stated that prospective validation of proposed treatment algorithms in larger cohorts is warranted. As reliable evidence concludes that further studies are needed to determine efficacy in effecting health outcomes, there is not sufficient outcomes data available from controlled clinical trials published in the peer-reviewed literature to substantiate its safety and effectiveness, the Prometheus Anser ADA is considered investigational per plan language.

Director's Review

The certificate (pp. 64, 68) excludes coverage for experimental or investigation services:

We will not pay benefits for any of the following:

* * *

41. Charges Incurred for Experimental or Investigational Services.

The term "experimental or investigational services" is defined in part in the certificate (p. 22):

Treatment, services, supplies or equipment which, at the time the charges are Incurred, We determine are:

1. Not proven to be of benefit for diagnosis or treatment of a Sickness or an Injury; or
2. Not generally used or recognized by the medical community as safe, effective and appropriate for diagnosis or treatment of a Sickness or an Injury; or
3. In the research or investigational stage, provided or performed in a special setting for research purposes or under a controlled environment or clinical protocol; or
4. Obsolete or ineffective for the treatment of a Sickness or an Injury; or
5. Medications used for non-FDA approved indications and/or dosage regimens.

The question of whether the Anser ADA test is experimental or investigational when used to treat 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 clinical practice for more than 18 years, and is familiar with the medical management of patients with the Petitioner'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 4/7/15 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 ■ year-old male who has a history of ulcerative colitis. At issue in this appeal is whether the Anser ADA testing performed on 4/7/15 was experimental / investigational for diagnosis and treatment of the member's condition.

Based on the information provided for review, it appears that the member was started on Humira at some point in 2014. The records submitted do not specify whether this treatment was ever effective. In the spring of 2015, the member experienced an exacerbation of symptoms requiring a course of prednisone. While the member was doing poorly, it was empirically decided to increase Humira from weekly dosing to every other week dosing. The member underwent the Anser ADA test on 4/7/15.

Monitoring patients on adalimumab with measurement of adalimumab levels and antibodies to adalimumab levels remains an area of clinical interest. In general, adalimumab levels correlate inversely with disease activity. However, the MAXIMUS physician consultant explained that the target level of adalimumab necessary to achieve clinical benefit remains unknown. The physician consultant also explained that there are no controlled data which have identified the optimal drug level to date. This issue remains speculative. The physician consultant indicated that issues of how a patient is doing on the drug, whether the patient is responding or losing response are more important than drug level. For a patient failing therapy, one can set up a hypothetical 2 x 2 table categorizing drug levels as high or low and antibody levels as high or low. The consultant explained that although this algorithmic approach is appealing, it has not been validated using prospectively controlled data.

Pursuant to the information set forth above and available documentation, the MAXIMUS physician consultant determined that the Anser ADA testing performed on 4/7/15 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 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 Petitioner’s coverage.

V. ORDER

The Director upholds Time Insurance Company’s final adverse determination of January 26, 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