

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. 151867-001

Time Insurance Company,

Respondent.

Issued and entered
this 2nd day of March 2016
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

██████████ (Petitioner) was denied coverage for a diagnostic test by her health insurer, Time Insurance Company (Time).

On January 25, 2016, ██████████, the Petitioner's authorized representative, filed a request with the Director of Insurance and Financial Services for an external review of Time's denial under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.*

The Petitioner is covered under an individual medical plan that is underwritten by 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 January 26, 2016. After a preliminary review of the material submitted, the Director accepted the external review request on February 1, 2016.

The case involves medical issues so it was assigned to an independent review organization which submitted its recommendation on February 15, 2016.

II. FACTUAL BACKGROUND

The Petitioner's health care benefits are defined in a policy called *Preferred Provider Individual Major Medical Coverage With Child Dental and Vision Benefits* (the policy).

The Petitioner has pancolitis, a severe form of ulcerative colitis that involves the entire large intestine (colon). She has been treated with the drug Remicade (infliximab) and her physician ordered the Anser IFX diagnostic test to monitor her response to the drug. The test was performed on April 3, 2015, by Prometheus Laboratories, Inc., a non-participating provider. The charge was \$2,500.00.

Assurant Health 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 December 22, 2015, affirming its denial. The Petitioner now seeks a review of that final adverse determination from the Director.

III. ISSUE

Was the Anser IFX test experimental or investigational for the treatment of the Petitioner's condition?

IV. ANALYSIS

Petitioner's Argument

In a January 16, 2016, letter included with the external review request, the Petitioner's authorized representative said:

The patient was denied coverage for the PROMETHEUS Anser IFX diagnostic test performed on 04/03/2015 due to the service being Experimental / Investigational. . . .

We respectfully dispute all of the criteria that were used to deny Anser IFX testing for this patient. In our previous appeals we provided five peer-reviewed publications that address the importance of measuring levels of infliximab as well as antibodies to infliximab (ATI). There is an ever increasing body of evidence that demonstrates the impact that increasing levels of ATI can have on a patient's response to infliximab. Those publications . . . clearly demonstrate that this technology cannot be considered unproven, experimental, nor not medically necessary. [M]any other publications provide support that the use of the data provided by this assay can be utilized by a clinician as "an effective management tool".

* * *

It should also be noted that this test was developed and its performance characteristics determined by Prometheus Laboratories Inc. Please note, that as a lab developed test (LDT) neither pre-market clearance nor pre-market approval under

the Federal Food, Drug and Cosmetic Act (FFDCA) is required for this test to be lawfully marketed at this time.

Based upon the totality of all the documentation . . . and the additional information listed above, we are asking that the denial for the Anser IFX test be overturned and the claim processed utilizing the patient's in-network benefits.

Time's Argument

In its final adverse determination, Assurant Health explained its denial to the Petitioner's authorized representative:

. . . All file information and available records were reviewed by an independent physician who is Board Certified in Internal Medicine / Gastroenterology. 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:

The clinical policy bulletin states that the Prometheus Anser IFX is investigational as its clinical value has not been established. There is insufficient literature regarding the effectiveness of Prometheus Anser IFX on health outcomes. 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, the Prometheus Anser IFX is considered investigational per plan language.

CLINICAL SUMMARY:

This is a [REDACTED] year old female with Ulcerative colitis treated with Remicade. She has lost a clinical response. MD requested Prometheus Anser IFX to help determine if loss of response might be due to low infliximab levels or to the presence of infliximab antibodies.

Director's Review

The certificate (pp. 37, 41) says:

We will not pay benefits for any of the following:

* * *

36. Charges Incurred for Experimental or Investigational Services, except for Routine Patient Costs in an Approved Clinical Trial.

The term “Experimental or Investigational Services” is defined in the policy (pp. 73-74):

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 IFX test is experimental or investigational when used to treat or diagnose 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 gastroenterology, has been in active clinical practice for more than 15 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 Prometheus Anser IFX test performed on 4/3/15 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 [REDACTED] year-old female who has a history of eosinophilic esophagitis and ulcerative colitis. At issue in this appeal is whether Prometheus Anser IFX test performed on 4/3/15 was experimental / investigational for diagnosis and treatment of the member’s condition.

The member has pancolitis. In the past, the member has been treated Remicade, Delzicol and Uceris, as well as course of prednisone. The record from an office visit on 4/6/15 reported that the member was doing reasonably well with 2 loose bowel movements per day, but no rectal urgency or bleeding. The Anser IFX test performed on 4/3/15 demonstrated detectable levels of both serum infliximab and antibodies to infliximab.

The MAXIMUS physician consultant explained that monitoring of patients on infliximab with measurement of infliximab levels and antibodies to infliximab continues to be an area of intense investigation. In general, infliximab levels correlate inversely with disease activity. The physician consultant indicated that the target level of infliximab necessary to achieve clinical benefit remains unknown. The target value has been investigated in one study and is likely between 3 and 7 ng/ml. However, the consultant explained that there are no controlled data that have identified the optimal drug level and this issue remains speculative. The physician consultant also explained that the issues of how a patient is doing on the drug, whether the patient is responding, whether the patient is losing response and whether the patient is having severe adverse side effects, such as infusion reactions, are more important than the drug level. The consultant noted that to attempt to answer this question in a patient failing therapy, one can construct a hypothetical 2 x 2 table categorizing drug levels as high or low and antibody levels as high or low. The physician 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 Prometheus Anser IFX test performed on 4/3/15 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 the IRO's recommendation should be rejected in this case, finds that the Anser IFX test is experimental or investigational for the treatment of the Petitioner's condition and is therefore not a benefit under the terms of the terms of the Petitioner's coverage.

V. ORDER

The Director upholds Time Insurance Company's final adverse determination of December 22, 2015.

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