

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. 154184-001

Humana Insurance Company
Respondent

Issued and entered
this 12th day of July 2016
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On June 16, 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 individual health care benefits through Humana Insurance Company. The benefits are defined in Humana's *Individual Medical Policy*. The Director notified Humana of the external review request and asked for the information used to make its final adverse determination. Humana provided its response on June 24, 2016. After a preliminary review of the material submitted, the Director accepted the request on June 23, 2016.

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

II. FACTUAL BACKGROUND

The Petitioner is 41 years old and has a history of ulcerative colitis. She was treated with infliximab. Her physician ordered the Anser IFX diagnostic test to monitor her response to infliximab. The test was performed on August 13, 2014 by Prometheus Laboratories, Inc., a California company that created the test and is the only laboratory that performs the test. Prometheus Laboratories is not in Humana's network of providers. The charge for the test was \$2,500.00

Humana denied coverage indicating the test was experimental/investigational. The

Petitioner appealed the denial through Humana's internal grievance process. At the conclusion of that process Humana issued a final adverse determination dated April 21, 2016, affirming its denial. The Petitioner now seeks the Director's review of that adverse determination.

III. ISSUE

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

IV. ANALYSIS

Humana's Argument

In its final adverse determination, Humana wrote:

At this time, Anser IFX is considered experimental/investigational and not the national standard of care. While this may sometimes be medically appropriate, it is still experimental/investigational. There is a growing body of literature indicating that drug level testing may be beneficial. The largest study was the TAXIT study, which showed that testing drug level for adequacy and checking for antibodies is helpful clinically and cost effective. However, this is still not present in the current practice guidelines or considered the official standard of care. This is seen mostly among experts in the field and in review articles published by these experts. Given that this literature is still in the early stages, it is considered experimental/investigational per national standards. The other treatment options that would have allowed optimizing the member's care include continuing the drug, changing to another anti-tumor necrosis factor drug, or changing drug classes to vedolizumab. The use of antibody and drug level testing is helpful but by no means absolutely necessary to determine how to treat this member.

No national GI societal guidelines include antibody and drug level testing as part of the management algorithm for IBD. The literature surrounding infliximab drug level testing indicates that it is cost effective and can help prevent a loss of response to the drug when a level is checked. Multiple experts in the field advocate for testing for drug level and antibodies, especially when there is concern for a loss of response to the drug. However, this is still not included in any national guideline. Additionally, there are no large randomized trials to adequately answer the question of whether or not this test truly helps.

Petitioner's Argument

In a letter dated June 7, 2016, the Petitioner's authorized representative wrote:

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, as well as the additional, published and peer reviewed literature listed below, clearly demonstrates that this technology cannot be considered unproven, experimental, nor not medically necessary. These, as well as many other publications provide support that the use of the data provided by this assay can be utilized by a clinician as an "an effective management tool."

Director's Review

Humana's *Individual Medical Policy*, on page 36, excludes coverage for services that are experimental or investigational. The policy, on page 69, includes a detailed definition of experimental/investigational medical services.

The question of whether the Anser IFX test was experimental or investigational for 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 reviewer is a physician in active practice who is board certified in gastroenterology and is familiar with the medical management of patients with the member's condition. The IRO report included the following analysis and recommendation:

The member has been on maintenance infliximab with a good response. The member developed skin lesions, diffuse joint pains and fatigue. Initially, there was concern that the etiology of the member's skin and joint complaints were due to the presence of antibodies to infliximab through a drug-induced lupus-like reaction. The member underwent the Anser IFX test on 8/13/14, which demonstrated detectable serum infliximab with undetectable antibodies. Ultimately, the member was treated with Plaquenil with a good response.

[I]n this case, the member appeared to be having an antibody mediated system disorder, which could include the development of a collage vascular disease, a manifestation of extra-intestinal inflammatory bowel disease or the presence of antibodies to infliximab....[I]n order to sort out this complex problem, the measurement of infliximab antibodies was reasonable....[I]nfliximab antibodies were negative and the member was started on therapy for collagen vascular disease with good response....[T]he use of the Anser IFX test was medically necessary in this specific case.

Pursuant to the information set forth above and available documentation...the Anser IFX test performed on 8/13/14 was not 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. The Director can discern no reason why the IRO's recommendation should be rejected in this case.

The Director finds that the Anser IFX test is not experimental or investigational as part of the treatment of the Petitioner's condition and is therefore a benefit under the terms of Humana's *Individual Medical Policy*.

V. ORDER

The Director reverses Humana's final adverse determination of April 21, 2016.

Humana shall immediately provide coverage for the Petitioner's August 13, 2014 Anser IFX test provided. See MCL 550.1911(17). Further, Humana shall, within seven days of providing coverage, furnish the Director with proof it has implemented this order.

To enforce this order, the Petitioner may report any complaint regarding its implementation to the Department of Insurance and Financial Services, Health Care Appeals Section, at this toll free number: (877) 999-6422.

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