

STATE OF MICHIGAN
DEPARTMENT OF INSURANCE AND FINANCIAL SERVICES
Before the Director of Insurance and Financial Services

In the matter of:

██████████
Petitioner

v

Priority Health
Respondent

File No. 154013-001

Issued and entered
this 17th day of July 2016
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On June 6, 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, a health maintenance organization. The benefits are defined in Priority Health's HMO certificate of coverage. The Director notified Priority Health of the external review request and asked for the information it used to make its final adverse determination. Priority Health provided its response on June 7, 2016. After a preliminary review of the material submitted, the Director accepted the request on June 13, 2016.

The case involves a medical issue so it was assigned to an independent review organization which submitted its recommendation on June 27, 2016.

II. FACTUAL BACKGROUND

The Petitioner is 19 years old and has Crohn's disease. He was treated with infliximab. To measure the levels of infliximab and antibodies, an Anser-IFX test was ordered by his gastroenterologist and performed by the test's developer, Prometheus Laboratories, Inc., on September 26, 2014.

Priority Health denied coverage for the test indicating it was experimental/investigational. The Petitioner appealed the denial through Priority Health's internal grievance process. At the conclusion of that process Priority Health 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 for the treatment of the Petitioner's condition?

IV. ANALYSIS

Priority Health's Argument

In its final adverse determination, Priority Health wrote:

Anser IFX Diagnostic Test is considered experimental/investigational/unproven care, and therefore not a covered benefit in accordance with Medical Policy No. 91117-RB Experimental/Investigational/Unproven Care/Benefit Exceptions and Priority Health Medical Policy No. 91583-R3 Markers for Digestive Disorders.

The medical policy, "Markers for Digestive Disorders," states:

Testing for any of the following individually or as part of a panel are experimental and investigational to diagnose inflammatory bowel disease, to distinguish ulcerative colitis from Crohn's disease, and for all other indications: ... measurement of serum infliximab (IFX) and antibody to infliximab (ATI) (i.e., PROMETHEUS Anser nIFX.)

Petitioner's Argument

In a letter dated May 31, 2016, accompanying the request for an external review, 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

Priority Health’s certificate of coverage, on page 33, excludes coverage for services that are experimental or investigational. 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 for more than 15 years 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 had multiple surgeries as a result of his disease. The member has been tried on Humira, Remicade and Cimzia with no apparent benefit. In the spring of 2014, the member was doing fairly well, however in the summer and fall of 2014, he had some diarrhea and severe worsening of his joint disease related to inflammatory bowel disease. There was strong consideration given to restarting the member on an immune modulator along with restarting Remicade. There was concern that the member may have pre-formed anti-infliximab antibodies due to prior use and it was determined to look for these prior to restarting Remicade. The Anser IFX testing performed on 9/26/14 demonstrated both undetectable serum infliximab and antibodies to infliximab.

[I]n this particular circumstance, testing for the existence of antibodies to infliximab prior to restarting therapy [is] critical ... [T]here was a high probability with interrupted therapy that these antibodies could be present ... [I]f antibodies were present, they would render giving more Remicade useless ... [T]here was a significant possibility that the member could have experienced life-threatening antibody mediated infusion reactions if antibodies had been present.

Pursuant to the information set forth above and available documentation ... the Anser IFX test performed on 9/26/14 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, discerning no reason why the IRO's recommendation should be rejected in this case, finds that the Anser IFX test is not experimental or investigational for the treatment of the Petitioner's condition and is therefore a benefit under the Priority Health certificate of coverage.

V. ORDER

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

Priority Health shall immediately, provide coverage for the Anser IFX. See MCL 550.1911 (17). Further, Priority Health 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