

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. 149451-001

Priority Health,

Respondent.

Issued and entered
this 17th day of September 2015
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

██████████ (Petitioner) was denied coverage for a diagnostic test by his health care plan, Priority Health, a health maintenance organization.

On August 20, 2015, ██████████ the Petitioner's authorized representative, filed a request with the Director of Insurance and Financial Services for an external review of that denial under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.*

The Director immediately notified Priority Health of the external review request and asked for the information it used to make its final adverse determination. Priority Health furnished the information on August 24, 2015. On August 27, 2015, after a preliminary review of the information submitted, the Director accepted the request.

To address the medical issue presented, the Director assigned the case to an independent medical review organization which provided its analysis and recommendation on September 10, 2015.

II. FACTUAL BACKGROUND

The Petitioner's health care benefits are defined in Priority Health's *MyPriority HMO Agreement* (the contract).

The Petitioner has Crohn's disease and was treated with the prescription drug Remicade (infliximab). His physician ordered the Anser IFX diagnostic test to monitor his response to Remicade. The test was performed on November 5, 2014, by Prometheus Laboratories, Inc., a non-participating provider.

Priority Health denied coverage, saying the test was experimental or investigational and unproven for treatment of Petitioner's condition and therefore not a covered benefit. 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 June 18, 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 or unproven for the treatment of the Petitioner's condition?

IV. ANALYSIS

Petitioner's Argument

In an August 11, 2015, letter included with the external review request, the Petitioner's authorized representative said:

The [Petitioner] was denied coverage for the PROMETHEUS Anser IFX diagnostic test performed on 11/05/2014 due to the service being Experimental / Investigational service. We have exhausted the internal appeals process disputing this decision. . . .

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 . . . clearly demonstrate 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 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 . . . is required for this test to be lawfully marketed at this time.

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

Priority Health's Argument

In its final adverse determination, Priority Health informed the Petitioner of its decision:

Uphold denial – requested coverage will not be provided. Specifically, the Appeal Committee determined that there were no unique, clinical circumstances in this individual case, to justify an exception to allow coverage.

. . . [The] Anser IFX Diagnostic Test is considered experimental, investigational and unproven care in accordance with Medical Policy No. 91117-R7 Experimental/Investigational/Unproven Care/Benefit Exceptions and Priority Health Medical Policy No. 91583-R3 Markers for Digestive Disorders.

Priority Health also relied on a Hayes, Inc., brief, "Use of Anti-Infliximab Antibody Levels to Monitor Infliximab Treatment in Patients with Inflammatory Bowel Disease (IBD)," which said:

Although the available evidence is abundant, the overall quality is low and does not conclusively establish the utility of assaying ATIs for management of patients with IBD with regard to long-term health outcomes such as need for repeated endoscopies or colectomy or quality of life.

Hayes Rating: D2

Hayes Ratings Definitions states:

D 2 - Insufficient evidence. There is insufficient published evidence to assess the safety and / or impact on health outcomes or patient management.

Director's Review

The contract (p. 37) has this exclusion:

Non-Covered Services

Any drug, device, treatment or procedure that is experimental, investigational or unproven. A drug, device, treatment or procedure is experimental, investigational or unproven if one or more of the following applies:

- (a) The drug or device has not been approved by the Food and Drug Administration (FDA) and, therefore, cannot be lawfully marketed in the United States.

- (b) An institutional review board or other body oversees the administration of the drug, device, treatment or procedure or approves or reviews research concerning safety, toxicity or efficacy.
- (c) The patient informed consent documents describe the drug, device, treatment or procedure as experimental or investigational or in other terms that indicate the service is being evaluated for its safety, toxicity or efficacy.
- (d) Reliable Evidence shows that the drug, device, treatment or procedure is:
 - (i.) The subject of on-going Phase I or Phase II clinical trials; or
 - (ii.) The subject of research, experimental study, or the investigational arm of on-going Phase III clinical trials; or
 - (iii.) Otherwise under study to determine its toxicity, safety, or efficacy as compared with a standard means of treatment or diagnosis; or
 - (iv.) Believed by a majority of experts to require further studies or clinical trials to determine the toxicity, safety, or efficacy of the drug, device, treatment or procedure as compared with a standard means of treatment or diagnosis.

"Reliable Evidence" includes any of the following:

- Published reports and articles in authoritative medical and scientific literature, or technology assessment and cost effectiveness analysis; or
- A written protocol or protocols used by the treating facility or the protocol(s) of another facility studying the same or a similar drug, device, treatment or procedure; or
- Patient informed consent documents used by the treating facility or by another facility studying the same or a similar drug, device, treatment or procedure.

The question of whether the Anser IFX test was experimental or investigational or unproven in the treatment of 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 certified by the American Board of Internal Medicine, subspecialty in gastroenterology; is published in the peer reviewed medical literature; and is in active clinical practice. The IRO report included the following analysis and recommendation:

Reviewer's Decision and Principal Reasons for the Decision:

It is the determination of this reviewer that the Anser IFX diagnostic test performed on November 5, 2014 was considered experimental / investigational for the treatment of the enrollee's condition.

Clinical Rationale for the Decision:

Although a preliminary evaluation by Yanai and Hanauer states that the combination of antibodies to infliximab (ATI) and infliximab (IFX) serum level measurement can have an impact in the care of patients, it is further stated that this hypothesis requires prospective evaluation. (4)As noted in a review of the subject of the usefulness of monitoring both ATI's and serum infliximab levels, "Serum IFX concentrations are related to response in luminal or fistulizing Crohn's disease, as well as in ulcerative colitis. Those patients receiving maintenance IFX who had detectable trough concentrations of IFX had a higher rate of clinical remission, a lower serum C-reactive protein, and a higher rate of endoscopic improvement, *irrespective of ATI status or concomitant immunosuppression.*" (*Emphasis added*).

As noted in a study specifically aimed at determining the clinical utility of the measurement of these parameters, "In patients with IBD who lose response to infliximab, clinical improvement may occur upon intensification of infliximab therapy, irrespective of infliximab serum concentration or presence of ATI."

The Anser IFX panel consists of two (2) separate serological levels: antibodies to infliximab, and serum infliximab levels. The adjustment of the medication dose follows the current standard of care. The measurement of serum infliximab levels has been suggested as a cost-effective followup to the adjustment of infliximab dosing, without measurement of antibodies to infliximab. However, it is not the standard of care at this time.

The serological testing for serum infliximab level, and antibodies to infliximab, is a proprietary test panel. The results were internally validated and the testing does not require United States Food and Drug Administration (FDA) approval for use as intended.

The currently available evidence has not demonstrated that the use of this test panel is superior to the current standard approach. It has been suggested that further study is required to prospectively demonstrate its utility. For the reasons noted above, the Anser IFX serological panel remains experimental and/or investigational for the enrollee's condition.

Recommendation:

It is the recommendation of this reviewer that the denial issued by Priority Health for the Anser IFX diagnostic test performed on November 5, 2014 be upheld.

[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, investigation, or unproved and therefore not a benefit under the terms of the contract.

V. ORDER

The Director upholds Priority Health’s final adverse determination of June 18, 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