

**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. 154317-001

Priority Health

Respondent

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Issued and entered  
this 3<sup>rd</sup> day of August 2016  
by Randall S. Gregg  
Special Deputy Director

**ORDER**

**I. PROCEDURAL BACKGROUND**

On June 24, 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 Director notified Priority Health of the external review request and asked for the information used to make its final adverse determination. Priority Health provided its initial response on June 28, 2016. After a preliminary review of the material submitted, the Director accepted the request on July 1, 2015.

The case involves a medical issue so it was assigned to an independent review organization which submitted its analysis to the Director on July 22, 2015.

**II. FACTUAL BACKGROUND**

The Petitioner, who is eleven years old, has ulcerative colitis. She has received treatment for her condition with adalimumab and infliximab. Her physician ordered the Anser ADA and Anser IFX diagnostic tests to monitor her response to the drugs. The Anser ADA and the Anser IFX tests were performed by Prometheus Laboratories, Inc.,

on February 24 and May 20, 2015, respectively. Prometheus Laboratories is a California company that created the tests and is the only laboratory that performs the tests. Prometheus Laboratories is not in Priority Health's network of providers. The amount charged for each test was \$2,500.00.

Priority Health denied coverage ruling that the tests were "experimental/investigational/ unproven." The Petitioner appealed the denials through Priority Health's internal grievance process. At the conclusion of that process, Priority Health issued final adverse determinations dated May 3, 2016 and May 19, 2016 affirming its denials. The Petitioner now seeks the Director's review of the adverse determinations.

### III. ISSUE

Are the Anser ADA and Anser IFX tests experimental, investigational, or unproven in the medical management of the Petitioner's condition?

### IV. ANALYSIS

#### BCN's Argument

In its May 3, 2016 final adverse determination for the Anser ADA test, Priority Health wrote:

[R]equested coverage will not be provided in accordance with Medical Policy No 91117-R10 Experimental/Investigational/Unproven Care/Benefit Exceptions and Priority Health Medical Policy No. 91583-R3 Markers for Digestive Disorders. Specifically, Anser ADA Diagnostic Test is considered experimental/ investigational/unproven care and therefore, not a covered benefit.

In its May 19, 2016 final adverse determination for the Anser IFX test, Priority Health wrote:

[R]equested coverage will not be provided. Specifically, Anser IFX Diagnostic Test is considered experimental/investigational/unproven care and therefore, not a covered benefit in accordance with Priority Health Medical Policy 91583-R3 Markers for Digestive Disorders, and Medical Policy 91117-R9 Experimental/ Investigational/Unproven Care/Benefit Exceptions.

### Petitioner's Argument

In the Petitioner's 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

The question of whether the Anser ADA and the Anser IFX tests were experimental or investigational for the medical management of 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 pediatrics with subspecialty certification in pediatric gastroenterology. The reviewer is a clinical assistant professor at a university-based medical college and is published in peer reviewed medical literature. The IRO report included the following analysis and recommendation:

It is the determination of this reviewer that the Anser assay tests provided on May 20, 2015 and February 24, 2015 were experimental/investigational for the treatment of the enrollee's condition.

#### **Clinical Rationale for the Decision:**

The use of anti-tumor necrosis factor (TNF) medications is standard of care for the management of inflammatory bowel disease, specifically ulcerative colitis. The use of this approach is well supported in the medical literature. However, the routine use of the Anser IFX/ADA diagnostic tests is not considered standard of care for the management of inflammatory bowel disease. Although

antibodies can develop during the course of the use of infliximab and adalimumab, the decision to continue, discontinue, or change the dose of therapy remains a clinical one based on observation of the patient and their response to the therapy as provided. Whether to continue or discontinue therapy is determined by the patient's clinical status and not based on antibody assays. A diminished or suboptimal response to this therapy can be managed in several ways: shortening the interval between doses, increasing the dose, switching to a different anti-TNF agent, or switching to a non-anti-TNF agent. If benefit is not seen, then the therapy is discontinued, regardless of whether there is the presence of an antibody.

Furthermore, if there is the presence of an antibody but the patient is tolerating the therapy and benefitting from the therapy, there is no indication to discontinue the treatment based solely on a laboratory study result, such as the Anser IFX diagnostic test. As such, the balance of the scientific literature does not demonstrate that the expected benefits of the Anser IFX diagnostic test are more likely to be beneficial to this enrollee than the available approach for the management of inflammatory bowel disease with biologic therapy. The Food and Drug Administration (FDA) has not approved the use of the Anser IFX/ ADA assays for the treatment and management of inflammatory bowel disease.

[Description of cited medical studies omitted.]

As noted above in the review of the available literature, there is no consensus on the use of this assay or its results; there is no agreement on the levels to be considered meaningful for this assay; and there is no literature to support the use of the Anser IFX assay as having a positive effect on healthcare outcomes at this time. There are no guidelines or national bodies that support its use. Therefore, measurement of antibodies to infliximab in a patient receiving treatment with infliximab, either alone or as a combination test which includes the measurement of serum infliximab levels, is not medically necessary.

Based on the documentation submitted for review, the enrollee suffered from inflammatory bowel disease and had been receiving Humira and subsequently Remicaide. Based on the documentation submitted for review and current medical literature, the use of the Anser assay tests in this type of clinical condition as performed on these two dates is considered experimental/investigational for this enrollee.

**Recommendation:**

It is the recommendation of this reviewer that the denial issued by Priority Health...be upheld.

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 ADA and the Anser IFX tests are experimental or investigational in the treatment of the Petitioner's condition and are therefore, not benefits under the terms of the Petitioner's certificate of coverage.

**V. ORDER**

The Director upholds Priority Health's final adverse determinations of May 3, 2016 and May 19, 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:



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Randall S. Gregg  
Special Deputy Director