

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. 148372-001-SF

████████████████████ **Plan Sponsor,**

and

Meritain Health, Plan Administrator,

Respondents.

Issued and entered
this 16th day of July 2015
by Joseph A. Garcia
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On June 17, 2015, ██████████, authorized representative of ██████████ (Petitioner), filed a request with the Director of Insurance and Financial Services for an external review under Public Act No. 495 of 2006, (Act 495), MCL 550.1951 *et seq.*

The Petitioner receives health care benefits through a group plan sponsored by the City of ██████████ (the plan), a self-funded governmental health plan as defined in Act 495. Meritain Health administers the plan. The Director immediately notified Meritain of the external review request and asked for the information it used to make the plan's final adverse determination. Meritain submitted the material on June 22, 2015, and on June 24, 2015, after a preliminary review of the information submitted, the Director accepted the Petitioner's request.

Section 2(2) of Act 495, MCL 550.1952(2), authorizes the Director to conduct this external review as though the Petitioner were a covered person under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.*

To address the medical issue in this case, the Director assigned it to an independent medical review organization which provided its analysis and recommendation on July 7, 2015.

II. FACTUAL BACKGROUND

The Petitioner's health care benefits are defined in a document called the *City of [REDACTED] Unified Health Care Plan* (the plan document).

The Petitioner has ulcerative colitis and was treated with the prescription drug Remicade. His physician ordered the Anser IFX diagnostic test to monitor his response to Remicade. The test was performed on June 3, 2014, by Prometheus Laboratories, Inc., a non-participating provider. The charge for the test was \$2,500.00.

Meritain, acting for the plan, denied coverage, saying the test is experimental or investigational when used to manage the Petitioner's condition and is therefore not a covered benefit.

The Petitioner appealed the denial through Meritain's internal grievance process. At the conclusion of that process Meritain issued a final adverse determination dated April 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 medical management of the Petitioner's condition?

IV. ANALYSIS

Meritain's Argument

In its final adverse determination, Meritain explained its decision to the Petitioner:

This letter serves as notice of a final internal adverse benefit determination. The company in charge of legal matters for your benefits plan (also called a "Plan Fiduciary") is City of [REDACTED]. After review of your appeal, and all of the available information, the Plan Fiduciary has decided to uphold the original decision related to this claim. . . . As the contract administrator of your benefits plan, we are writing to you to communicate the Plan's decision regarding your appeal.

* * *

The 1st Level appeal review was completed on 11/24/14 with the City of [REDACTED] upholding the benefit denial for the Prometheus Anser IFX Test as being Experimental and Investigational under the terms of the Plan.

Petitioner's Argument

In a letter dated June 16, 2015, sent with the external review request, 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 demonstrate that this technology cannot be considered unproven, experimental, or 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."

* * *

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.

Director's Review

Diagnostic tests are shown as a benefit in the plan document (p. 60). However, the plan document also has this provision (pp. 63, 64):

Exclusions

Examples of what The Plan does **not** pay:

* * *

24. Expenses for treatment, procedures, devices, drugs or medicines which are determined to be Experimental and/or Investigational will not be considered eligible, except to the extent such expenses are Qualified Clinical Trial Expenses

"Experimental and/or Investigational" is defined in the plan document as

services, supplies, care, and treatment which does not constitute accepted medical practice properly within the range of appropriate medical practice under the standards of the case and by the standards of a reasonably substantial, qualified, responsible, relevant segment of the medical or dental community or government oversight agencies at the time services were rendered.

The question of whether the Anser IFX test was experimental or investigational when used in 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, board certified in gastroenterology, who has been in practice for more than 15 years and is familiar with the medical management of individuals with the Petitioner's condition. The IRO report included the following analysis and recommendation:

The results of the consultant's review indicate that this case involves a then [REDACTED] year-old male who has a history of ulcerative colitis. At issue in this appeal is whether the Prometheus Anser IFX test performed on 6/3/14 was experimental/investigational for treatment of the member's condition.

The member was taking a thiopurine drug. The member was started on Remicade around February of 2014 at 5mg/kg. In June 2014, the member was reported to be slowly improving and gaining weight with a modest amount of diarrhea. The member underwent the Anser IFX assay on 6/3/14, which demonstrated detectable levels of the drug, albeit at a lower level, and undetectable levels of antibody. No dose adjustment in Remicade was made after this testing.

The MAXIMUS physician consultant noted that in this case, it could be argued that a Remicade level was ordered after the indication period in order to assess whether the level was too high or too low. The physician consultant explained that the presence of drug antibody would not be relevant at this early phase in treatment. The result was 1.6 µg/ml, which is detectable but low. No dose adjustment was made. The literature has reported a target therapeutic range of 3-7 µg/ml. However, the member was demonstrating improvement. The physician consultant explained that perhaps, for this member a low level was sufficient or perhaps his tissue level of the drug was higher. Tissue level is not measurable at this time. The consultant indicated that the available data does not demonstrate the clinical utility of measurement of infliximab drug levels at this time.

Pursuant to the information set forth above and available documentation, the MAXIMUS physician consultant determined that the Prometheus Anser IFX test performed on 6/3/14 was experimental/investigational for 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.

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 in the treatment of the Petitioner and is therefore not a benefit.

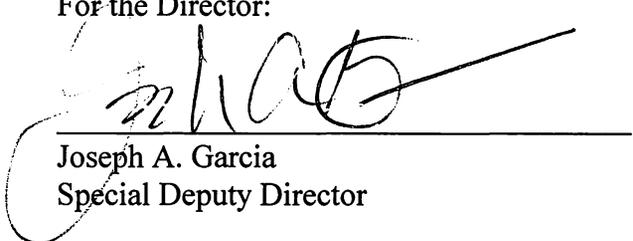
V. ORDER

The Director upholds the plan's final adverse determination of April 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:



Joseph A. Garcia
Special Deputy Director