

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. 147851-001

Time Insurance Company,

Respondent.

_____ /

Issued and entered
this 9th day of June 2015
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On May 12, 2015, ██████████ (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 has health coverage through an individual plan that is underwritten by Time Insurance Company (Time). The Director immediately notified Time of the external review request and asked for the information it used to make its final adverse determination. The information was submitted by Assurant Health, which administers the plan, on May 13, 2015. After a preliminary review of the material submitted, the Director accepted the request on May 19, 2015.

Because medical issues are involved, the Director assigned the case to an independent review organization which provided its analysis and recommendations on June 2, 2015.

II. FACTUAL BACKGROUND

The Petitioner's health care benefits are described in a medical certificate of insurance (the certificate) issued by Time.

The Petitioner was diagnosed with ovarian cancer. On May 1, 2014, Precision Therapeutics, Inc., performed the ChemoFx Assay (CPT code 89240), a proprietary test used to guide effective chemotherapy in the treatment of cancer patients.

Time denied coverage for the ChemoFx test on the basis that is experimental or investigational. The Petitioner appealed the denial through Time's internal grievance process. At the conclusion of that process, Time affirmed its decision in a final adverse determination dated April 28, 2015. The Petitioner now seeks a review of that final adverse determination from the Director.

III. ISSUE

Did Time correctly deny coverage for the ChemoFx Assay?

IV. ANALYSIS

Petitioner's Argument

In her request for external review, the Petitioner said that she had met her deductible at the time she had the ChemoFx test and she seeks a reversal of the final adverse determination.

Respondent's Argument

In its final adverse determination, Time informed the Petitioner:

This letter is in response to a request for an Appeal Panel review of the adverse decision concerning the [ChemoFx Assay]. All file information and available records were reviewed by an independent physician who is Board Certified in Gynecologic Oncology. Based on this review, and the information you presented during your teleconference with the Panel, the Appeal Panel maintained the determination that the ChemoFx Assay for date of service May 1, 2014 was experimental/ investigational.

* * *

. . . In vitro assays of chemosensitivity or resistance, such as the ChemoFx assay . . . are laboratory tests that have been developed as a method to select the optimal chemotherapy regimen (sensitivity assays) or identify those agents least likely to be effective (resistance assays). However, the utility of these assays have not been prospectively validated, and cost benefits have not been clearly demonstrated.

The American Society of Clinical Oncology has concluded that the evidence is insufficient to justify the routine use of any of these assays outside of the clinical trial setting and that oncologists should make chemotherapy treatment recommen-

dations on the basis of published clinical trial reports while taking into account an individual patient's treatment preferences.

The ChemoFx assay is considered E/I [*experimental/investigational*] as there is no data from well controlled randomized trials that shows that it is effective or that it improves overall survival or health outcomes in women with ovarian cancer. That is, there is no data to show that health outcomes or overall survival are better in women with ovarian cancer who are treated based on the assay results versus standard of care chemotherapy protocols. The assay would be appropriate to use in the setting of a Phase II or III clinical trial that would require institutional review board protocol.

As per the American Society of Clinical Oncology (ASCO) and the National Comprehensive Cancer Network (NCCN) the assay is not to be used as a standard of care given that it lacks efficacy and should be used only in the setting of a clinical trial. Both organizations have noted that this assay lacks efficacy data and that it is appropriate only in the setting of a clinical trial. . . .

* * *

The letter from [your physician] was considered along with the medical records and does not change the decision regarding (CPT 89240) ChemoFx Assay for date of service May 1, 2014. [Your physician's] letter does not change the prior decision since there are no data to show that this test improves outcomes or overall survival in women with ovarian cancer.

Therefore, the request for ChemoFx Assay remains E/I per the submitted clinical policy bulletin and the contract language.

Director's Review

The certificate (p. 40) covers laboratory services. But the certificate also has this exclusion (pp. 53, 57):

We will not pay benefits for any of the following:

* * *

37. Charges Incurred for Experimental or Investigational Services.

The term "experimental or investigational services" is defined in the certificate (p.17-18):

Treatment, services, supplies or equipment which, at the time the charges are Incurred, We determine are:

1. Not proven to be of benefit for diagnosis or treatment of a Sickness or an Injury; or

2. Not generally used or recognized by the medical community as safe, effective and appropriate for diagnosis or treatment of a Sickness or an Injury; or
3. In the research or investigational stage, provided or performed in a special setting for research purposes or under a controlled environment or clinical protocol; or
4. Obsolete or ineffective for the treatment of a Sickness or an Injury; or
5. Medications used for non-FDA approved indications and/or dosage regimens.

To answer the question of whether the ChemoFx assay is experimental or investigational for the treatment of the Petitioner's condition, the matter was presented to an independent review organization (IRO) as required by section 11(6) of the Patient's Right to Independent Review Act, MCL 550.1911(6).

The IRO physician reviewer is board certified in obstetrics and gynecology and gynecologic oncology and has been in active practice for more than twelve years. The IRO report included the following analysis and recommendation:

Recommended Decision:

The MAXIMUS physician consultant determined that the ChemoFx assay test performed on 5/1/14 was experimental/investigational for diagnosis and treatment of the member's condition.

Rationale:

* * *

The results of the consultant's review indicate that this case involves a 47 year-old female who has a history of ovarian cancer. At issue in this appeal is whether the ChemoFx assay test performed on 5/1/14 was experimental/investigational for diagnosis and treatment of the member's condition.

The MAXIMUS physician consultant indicated that the ChemoFx chemosensitivity assay has been studied extensively in epithelial ovarian cancer. Both clinical and cost effectiveness have been reported. One study predicted an improvement in progress free survival on the order of 2 to 3 fold over non-guided therapy. An additional advantage in overall survival was noted in a subsequent study. A 2009 presentation at the annual Society of Gynecologic Oncologists (SGO) Meeting also noted a clinical cost advantage of using the assay to guide therapy over non-guided therapy, which later received peer reviewed publication.

However, the physician consultant explained that all of these studies were retrospective in nature and are thus criticized for their clinical utility in accepted standards of care. The physician consultant indicated that a more recent prospective study was conducted and the results were presented at the 2013 SGO Meeting validating favorable outcome data using prospective sampling. This

study was published in rapid fashion. However, the consultant explained that as this study is not a randomized prospective trial of primary ovarian cancer patients, like the member in this case, it would not be able to support the use of this chemosensitivity assay in the initial treatment planning for chemotherapy. The physician consultant also explained that standard first line chemotherapy with Platinum and Taxol would be predicted as superior to any other regimen and therefore, the chemosensitivity assay would not be considered medically necessary in this case. [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 and the Director can discern no reason why the IRO's recommendation should be rejected in this case.

The Director finds that Time was correct when it denied coverage for the ChemoFx Assay as experimental and investigational.

V. ORDER

The Director upholds Time Insurance Company's April 28, 2015, final adverse determination.

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 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 Director of Insurance and Financial Services, Health Care Appeals Section, Post Office Box 30220, Lansing, MI 48909-7720.

Patrick M. McPharlin
Director

For the Director



Randall S. Gregg
Special Deputy Director