

STATE OF MICHIGAN
DEPARTMENT OF ENERGY, LABOR & ECONOMIC GROWTH
OFFICE OF FINANCIAL AND INSURANCE REGULATION
Before the Commissioner of Financial and Insurance Regulation

In the matter of

XXXXX

Petitioner

File No. 113153-001

v

US Health and Life Insurance Company
Respondent

Issued and entered
this 5th day of January 2011
by Ken Ross
Commissioner

ORDER

I
PROCEDURAL BACKGROUND

On July 6, 2010, XXXXX (Petitioner), filed a request for external review with the Commissioner of Financial and Insurance Regulation under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.* The Commissioner reviewed the information that was submitted and accepted the request on July 13, 2010.

The Commissioner notified US Health and Life Insurance Company (USHL) of the external review and requested the information used in making its adverse determination. USHL provided the requested information on July 20, 2010.

The case involves medical issues so the Commissioner assigned the matter to an independent review organization which completed its review and sent its recommendation to the Commissioner on July 27, 2010.

II
FACTUAL BACKGROUND

The Petitioner has group health insurance under a USHL certificate of group insurance issued to the XXXXX Health Trust.

Petitioner is sixty-seven years old and was diagnosed in 2009 with pancreatic cancer. Although he received treatment, the cancer metastasized to his liver. After receiving treatment at the XXXXX and being evaluated at XXXXX Cancer Institute and XXXXX Hospital, Petitioner decided to seek treatment at the XXXXX Cancer Treatment Centers of America (CTCA).

Between November 4, 2009, and February 6, 2010, CTCA administered eight courses of hepatic artery infusional (HAI) chemotherapy. When USHL received claims for the chemotherapy USHL denied coverage, asserting that the chemotherapy treatment was experimental and further asserting that Petitioner and CTCA had not received the required authorization from USHL.

The Petitioner appealed the denial through USHL's internal grievance process. USHL maintained its denial and issued a final adverse determination on May 12, 2010.

The Petitioner is appealing chemotherapy treatment he received from CTCA from November 4, 2009, through the present. However, USHL's final adverse determination only addresses the chemotherapy administered between November 4, 2009, and February 6, 2010. The Commissioner may only provide external reviews of claims denial for which a covered person has completed the insurer's internal grievance process. Since the Petitioner has not completed that process for any treatment after February 6, 2010, this Order will address only the November 4, 2009, through February 6, 2010, dates of service only.

III ISSUES

There are two issues raised in this appeal:

1. Did the Petitioner and his provider receive prior authorization for his outpatient chemotherapy?
2. Did the chemotherapy the Petitioner received constitute experimental treatment?

IV ANALYSIS

Petitioner's Argument

Petitioner says representatives at CTCA informed him that treatment was available for his condition. Petitioner says that before receiving treatment a CTCA representative told him that USHL had granted authorization to administer the chemotherapy treatment in question.

XXXXX, a precertification supervisor with CTCA, provided the dates and names of the USHL representatives she spoke with during her attempt to obtain preauthorization for Petitioner's outpatient services at their facility. Ms. XXXXX maintains she was told on two separate occasions that no preauthorization was necessary for outpatient services, including chemotherapy.

Petitioner says the chemotherapy treatment he received at CTCA has been miraculous; he feels positively great after receiving the chemotherapy treatment. Petitioner's suggested remedy is for USHL to provide coverage for the chemotherapy treatment he received at CTCA.

Respondent's Argument

In its May 12, 2010, final adverse determination, USHL stated that it considered the treatment Petitioner received to be experimental/investigational:

According to our independent medical review the use of HAI [hepatic artery infusion] in metastatic pancreatic cancer is not the standard of care and is not an accepted practice for the management of this disease. This treatment regimen would be considered to be in the investigational stage of development, is not of general use by oncology community, and is not [of] demonstrated value in the treatment of this patient's disease. The treatment with FUDR, cisplatin, and mitomycin by HAI would be considered experimental/investigational for this patient with metastatic pancreatic cancer.

USHL maintains that, because it was experimental/investigational, the chemotherapy treatment Petitioner received is not eligible for benefit coverage.

Regarding the prior authorization issue, USHL states that it did not authorize the chemotherapy in question. USHL agrees that it received a general inquiry about coverage provisions in Petitioner's certificate of coverage but did not authorize the treatment Petitioner received. USHL says it did give authorization for treatment on four prior occasions between June and August 2010 but that was for care with other providers, not with CTCA.

Commissioner's Analysis

1. Preauthorization

A factual dispute exists as to whether USHL authorized Petitioner's chemotherapy at CTCA. The PRIRA process under which this review is conducted does not include a hearing process in which the Commissioner can hear the testimony of witnesses and make findings of fact to resolve such a dispute. The PRIRA process is limited to determining whether an insurer has correctly applied the terms of its health insurance policy and whether it has correctly handled any medical issues presented. Since PRIRA lacks a hearing procedure, the Commissioner, in conducting this review, may not consider external information such as telephone conversations with the company or, as in this instance, any description of oral communication between USHL, the Petitioner, or CTCA representatives. The Commissioner may not reverse the USHL claims decision on the basis of oral accounts offered by the individuals involved in this appeal. Issues of that type may be addressed appropriately in civil litigation which the Petitioner has the right to undertake. See section 15 of the PRIRA, MCL 550.1915.

2. Experimental/investigational treatment

Determining whether the treatment provided by CTCA is experimental or investigational requires analysis by an independent medical review organization. See section 11(6) of the PRIRA, MCL 550.1911(6). This review will also consider the definitions of experimental or investigational care and medical necessity in the insurer's certificate of coverage.

USHL provides benefit coverage for medical services when it meets the criteria listed in the certificate of coverage. The "General Definitions" section of the USHL certificate of coverage defines Experimental Treatment and Medically Necessary:

3.35 Experimental Treatment shall mean a service, supply, or treatment that is deemed experimental or investigational by any technological assessment body established by any state or federal government, or meets one or more of these conditions:

- a. It is within the research, investigational or experimental stage;

- b. It involves the use of a drug or substance that has not been approved by the United States Food and Drug Administration by the issuance of a New Drug Application or other formal approval, or has been labeled "Caution: Limited by Federal Law to Investigational Use";
- c. It is not of general use by qualified Physicians; or
- d. It is not of demonstrated value for the diagnosis or treatment of the disability or condition for which it is prescribed.

* * *

3.58 Medically Necessary means that a specific service or supply is:

- a. Reasonably required for the treatment or management of the medical condition;
- b. Commonly and customarily recognized by Physicians as appropriate in the treatment or management of the medical condition; and
- c. Other than educational or experimental in nature.

The question of whether the treatment Petitioner received was experimental/investigational was presented to an independent medical review organization whose reviewer is a physician in active practice certified by the American Board of Internal Medicine with a subspecialty in medical oncology. The reviewer is an assistant professor at a university school of medicine and a member of the American Medical Association, the American College of Physicians, the American Association for the Advancement of Science, the Gerontological Society of America, and the International Society for Geriatric Oncology. In addition, the reviewer is a principal investigator of clinical trials, extensively published in peer reviewed literature, and the recipient of numerous research grants. The reviewer's analysis included the following facts and findings:

The [USHL] definition of "experimental treatment" lists four (4) criteria, any one of which if satisfied is sufficient to consider a treatment investigational:

- a. It is within the research, investigational or experimental stage.

There are no clinical trials of hepatic artery infusion (HAI) to treat liver metastases from pancreatic cancer. For one reason, this indication does not have a strong, rational, support. Aggressive local treatments (like HAI) are usually only considered when patients have disease that is solely in the liver. This clinical situation is rare in liver cancer. Note that [the Petitioner] had disease in the pancreas, lymph nodes by the pancreas, and liver. The HAI treatment only treated the disease in the *liver*. The treatment would not treat the disease in the lymph nodes and the pancreas. [The Petitioner] was not a good candidate for treatment

with HAI chemotherapy, even given the investigational nature of this treatment.

In general, HAI remains the subject of multiple, open, phase I and II clinical trials. . . .

- b. It involves the use of a drug or substance that has not been approved by the United States Food and Drug Administration by the issuance of a New Drug Application or other formal approval, or has been labeled "Caution: Limited by Federal Law to Investigational Use".

All drugs used in the treatments provided are approved by the FDA. Cisplatin and mitomycin are not approved for administration by hepatic artery infusion; this is an off-label use. FUDR is only approved for intra-arterial administration. It is not approved for intra-arterial administration with cisplatin and mitomycin.

- c. It is not of general use by qualified physicians.

The use of hepatic artery infusion as a treatment of metastatic pancreatic cancer is not in general use in the medical community.

* * *

None of the expert recommendations suggest the use of HAI in the treatment of hepatic metastases, and these treatments are not in general use.

- d. It is not of demonstrated value for the diagnosis or treatment of the disability or condition for which it is prescribed.

HAI is not considered of demonstrated value in the treatment of liver metastases from pancreatic cancer. There have been no phase III trials of HAI compared to systemic therapy as a treatment of liver metastases from pancreatic cancer. There have been limited pilot studies of HAI for this clinical setting. . . . These studies have not proved to be promising.

HAI has been studied more as a treatment for liver metastases from colorectal cancer. In this setting, which has been more extensively studied, HAI is not believed to be of proven benefit.

* * *

Since [the] last meta-analysis, HAI as a treatment for liver metastases has generally fallen out of favor in the oncology community; therefore, the use of Cisplatin and Mitomycin with FUDR/Leucovorin for metastatic pancreatic cancer must be considered experimental at this time.

Recommendation:

It is the recommendation of this reviewer that the denial of coverage issued by US Health and Life Insurance Company for the use of Cisplatin and Mitomycin with FUDR/Leucovorin be upheld.

The Commissioner is not required in all instances to accept the IRO's recommendation. However, a recommendation from the IRO is afforded deference by the Commissioner. In a decision to uphold or reverse an adverse determination, the Commissioner must cite "the principal reason or reasons why the Commissioner 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 Commissioner can discern no reason why the IRO's recommendation should be rejected in the present case.

The Commissioner finds that USHL's denial of coverage for chemotherapy treatment received at CTCA from November 4, 2009, through February 6, 2010, was consistent with the terms of the certificate.

V
ORDER

USHL's May 12, 2010, final adverse determination is upheld. USHL is not required to provide coverage for the chemotherapy treatment Petitioner received at XXXXX from November 4, 2009, through February 6, 2010.

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 sixty 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 Commissioner of Financial and Insurance Regulation, Health Plans Division, Post Office Box 30220, Lansing, MI 48909-7720.