

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. 150421-001

United Healthcare Insurance Company
Respondent

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

ORDER

I. PROCEDURAL BACKGROUND

On October 20, 2015, ██████████ (Petitioner) filed a request for external review with the Director of Insurance and Financial Services under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.* The Petitioner receives health care and prescription drug benefits from a group plan underwritten by United Healthcare Insurance Company (United). The prescription drug benefits are defined in United's *Choice Plus* certificate of coverage and *Outpatient Prescription Drug Rider*.

The Director notified United of the external review request and asked for the information used to make its final adverse determination. United furnished the requested information on October 21, 2015. After a preliminary review of the material submitted, the Director accepted the request on October 27, 2015.

Because the case involves medical issues, it was assigned to an independent medical review organization which provided its analysis and recommendation to the Director on November 10, 2015.

II. FACTUAL BACKGROUND

The Petitioner has hepatitis C. Her physician prescribed the drug Harvoni. United denied coverage. The Petitioner appealed the denial of coverage through United's internal grievance process. United affirmed its coverage denial in a final adverse determination issued September 4, 2015. The Petitioner now seeks a review of United's coverage denial from the Director.

III. ISSUE

Did United correctly deny coverage for the prescription drug Harvoni?

IV. ANALYSIS

Respondent's Argument

In its final adverse determination, United stated that it had correctly denied coverage because the Petitioner does not meet its criteria for coverage of the prescription drug:

Our decision is based on Food and Drug Administration (FDA) supported uses or uses that we have found to be medically necessary. For coverage the criteria requires:

Medical records (e.g., chart notes, laboratory values) showing stage 3 or 4 liver fibrosis or cirrhosis, OR a serious complications of HCV outside of your liver; OR you have human immunodeficiency virus (HIV), OR you are taking immunosuppressant therapy following organ transplantation;

AND

If you have a history of drug abuse, you have had a urine drug screen collected within 30 days before beginning Harvoni that shows no use of illicit drugs.

The information provided does not meet these criteria. Your benefit plan and your Drug Policy do not cover drugs when their use is determined not to be medically necessary.

Petitioner's Argument

In her request for an external review, the Petitioner wrote:

I was diagnosed with Hepatitis C virus infection in 2003. There is a cure for the Hepatitis now and my doctor suggested the medication Harvoni for the treatment. My doctor filed an appeal with the insurance company and they denied the appeal. I have been suffering with this illness for the past 12 years. Now there's a cure and I don't think I should have to wait until I'm in the 3 or 4 stage of liver cirrhosis to receive treatment.

In a letter to United dated August 13, 2015, the Petitioner's physician wrote:

I am writing to ask for an appeal on behalf of my patient, [Petitioner], who was denied Harvoni for treatment of Chronic Hepatitis C virus infection. The denial stated that Harvoni does not meet the health plan's criteria for approval.

[Petitioner] is a 55 year old female who was diagnosed with Chronic Hepatitis C, genotype 1b, non-cirrhotic and a viral load of 74,039 IU/ml. [Petitioner] has never been treated for Hepatitis C and currently is a good treatment candidate. Harvoni was chosen for treatment because studies have proved that there is a 94-99% cure rate with only 8 weeks of the FDA approved therapy. There are also low rates of relapse after treatment with Harvoni based regimen. The tolerability of this regimen has been found to be better, with fewer adverse events and discontinuations. In addition, it is first line recommendation for Hepatitis C treatment AASLD guideline.

In conclusion, please reconsider the denial of Harvoni....A regimen that includes Harvoni has a greater chance of Sustained Viral Response and little chance of relapse after treatment, and is easier to tolerate, therefore giving us a higher chance of curing Hepatitis C for this patient.

Director's Review

The Director requested that an independent review organization (IRO) evaluate the medical issues presented in this appeal as required by the Patient's Right to Independent Review Act See MCL 550.1911(6). The IRO reviewer is a physician in active practice for more than 15 years who is board certified in gastroenterology, is familiar with the medical management of patients with the Petitioner's condition. The IRO reviewer's report included the following analysis:

According to the American Association for the Study of Liver Disease/Infectious Disease Society of America (AASLD/IDSA) guidelines, treatment is recommended for all patients with chronic hepatitis C virus (HCV) infection, except for those with short life expectancies of less than 12 months due to comorbid conditions. [Citation omitted.] [T]his recommendation was given a rating of Class I, Level A....[T]he Health Plan's policy is not consistent with national guidelines. These national guidelines recommend that clinicians should treat HCV infected patients with antiviral therapy with the goal of achieving a sustained virologic response, preferably early in the course of their chronic hepatitis C infection before the development of severe liver disease and other complications....[R]ecent reports suggest that initiating therapy in patients with lower stage fibrosis may extend the benefit of sustained virologic response. In a long-term follow-up study, 820 patients with Metavir stage F0 or F1 fibrosis confirmed by biopsy were followed for 20 years and the 15 year survival rate was statistically significantly better for those who experienced a sustained virologic response than for those whose treatment failed or those who remained untreated....[T]his study argues for consideration of earlier initiation of treatment....[S]everal other modeling studies suggest a greater mortality benefit if

treatment is initiated at stages prior to F2. [Citations omitted.]

Pursuant to the information set forth above and available documentation...
Harvoni is medically necessary for treatment of the member's condition.

The Director is not required to accept the IRO's recommendation. *Ross v Blue Care Network of Michigan*, 480 Mich 153 (2008). However, the IRO's 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 the present case.

V. ORDER

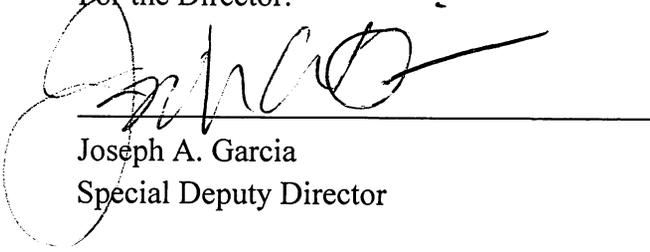
The Director reverses United Healthcare Insurance Company's final adverse determination of September 4, 2015. United Healthcare Insurance Company shall immediately provide coverage for the requested prescription drug regimen and shall, within seven days of providing coverage, furnish the Director with proof it implemented this order. See MCL 550.1911(17).

To enforce this order, the Petitioner may report any complaint regarding the implementation to the Department of Insurance and Financial Services, Health Care Appeals Sections, at this toll free telephone number: (877) 999-6442.

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 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