

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. 145462-001

United Healthcare Insurance Company
Respondent

Issued and entered
this 22nd day of January 2015
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On December 18, 2014, ██████████, authorized representative of ██████████ (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 prescription drug benefits from a group plan underwritten by United Healthcare Insurance Company (UHC). The prescription drug benefits are defined in UHC's *Outpatient Prescription Drug* certificate of coverage and rider.

The Director notified UHC of the external review request and asked for the information used to make its final adverse determination. After a preliminary review of the material submitted, the Director accepted the request on December 30, 2014.

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 January 13, 2015.

II. FACTUAL BACKGROUND

The Petitioner has chronic hepatitis C with liver disease. His physician prescribed a drug treatment regimen of two prescription drugs: Sovaldi and Olysio. UHC denied coverage. The Petitioner appealed the denial of coverage through UHC's internal grievance process. UHC

affirmed its coverage denial in a final adverse determination issued December 13, 2014. The Petitioner now seeks a review of UHC's decisions from the Director.

III. ISSUE

Did UHC correctly deny coverage for the proposed prescription drug regimen of Sovaldi and Olysio?

IV. ANALYSIS

Petitioner's Argument

In a letter to UHC, the Petitioner's physician wrote:

I am requesting reconsideration of your denial of Olysio (simeprevir) plus Sovaldi (sofosbuvir) for my patient...[who] has Chronic Hep C, Compensated Liver Disease, naive to treatment...[He] has F2 Fibrosis as confirmed by Fibrosure and is considered of HIGH PRIORITY for treatment per the [American Association for the Study of Liver Diseases]. Patient is interferon in-eligible due to a history of Depression.

Olysio+Sovaldi has shown efficacy for HCV genotype 1 patients that are treatment naive or previous null responders...including patients with cirrhosis.

* * *

In summary, Olysio+Sovaldi is the only available treatment combination that is an interferon-free regimen with demonstrated efficacy in genotype 1 HCV. I am requesting that Olysio+Sovaldi be approved for my patient, based on his liver disease and contraindications to an interferon-based regimen.

Respondent's Argument

In its final adverse determination, UHC stated that it had correctly denied coverage because the Petitioner's prescription drug rider excludes coverage for medications that are experimental, investigational or unproven. UHC also stated that its appeals committee made the following determination:

Your doctor sent us information that shows you have Hepatitis C with liver disease. There is not enough information submitted by your doctor so far to show that you meet your Health Plan's criteria for coverage of this treatment. Specifically your doctor must submit: 1) imaging documentation that you have Stage 3 or 4 liver fibrosis; 2) a documented reason why you cannot take Peginterferon and; 3) documentation that you do not have decompensated liver disease (Child-Pugh Class B or C). Also, your doctor must supply documentation that you are not using alcohol or illegal drugs.

Director's Review

UHC's standards for approval of Sovaldi and Olysio and the medical necessity of the treatment regimen with those drugs were the issues 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 for more than 15 years who is board certified in internal medicine and gastroenterology, and is familiar with the medical management of patients with the Petitioner's condition. The IRO reviewer's report included the following analysis and recommendation:

[T]his case involves a 42 year-old male has a history of Hepatitis C, genotype 1a. At issue in this appeal is whether Sovaldi and Olysio are medically necessary for treatment of the member's condition.

The member was considered for treatment 4 years ago, but due to depression was not considered to be a good candidate for interferon. Laboratory results include elevated aminotransferase enzymes and normal platelets. The member's viral load is approximately 10 million IU/ml. His Fibrosure score was in the F2 range at 0.48. His necroinflammatory score was in the severe level. The member is HIV negative.

[T]he combination of Olysio plus Sovaldi has been Food and Drug Administration approved. [T]his combination for treatment of Hepatitis C genotype 1 is not considered experimental or off label. The Health Plan's criteria require equal to or greater than F3 level of fibrosis, which is not consistent with standard guidelines for treatment of Hepatitis C. (Joint Panel from the American Association of the Study of Liver Disease and the Infectious Diseases Society of America. January 2014. www.hcvguidelines.org)...F2 disease with severe inflammation is very significant liver disease and warrants treatment.

Pursuant to the information set forth above and available documentation...Sovaldi and Olysio are 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

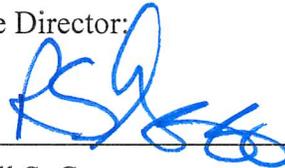
The Director reverses United Healthcare Insurance Company's December 13, 2014 final adverse determination. United Healthcare Insurance Company shall immediately provide coverage for the requested prescription drug regimen and shall, within seven days of providing coverage, furnish the Director with proof it implemented this order.

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.

Annette E. Flood
Director

For the Director:



Randall S. Gregg
Special Deputy Director