

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. 151830-001

Health Alliance Plan HMO
Respondent

Issued and entered
this 23rd day of February 2016
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On January 21, 2016, ██████████ (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 through an individual plan underwritten by Health Alliance Plan (HAP), a health maintenance organization. The prescription drug benefits are described in HAP's *Outpatient Prescription Drug Benefit Rider (Rider E027)*.

The Director notified HAP of the external review request and asked for the information used to make its final adverse determination. HAP furnished the requested information on January 25, 2016. After a preliminary review of the material submitted, the Director accepted the request on January 28, 2016.¹

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 February 11, 2016.

1. There was some evidence that the request for external review may have been untimely filed by the Petitioner. However, based on a review of the material submitted by both parties, it appears that HAP did not provide the Petitioner with a final adverse determination and the appeal notices required by the Patient's Right to Independent Review Act. In light of these facts, the Director has accepted this case for review. See MCL 550.1907.

II. FACTUAL BACKGROUND

The Petitioner has hepatitis C. Her physician prescribed the drug Harvoni. HAP denied coverage. The Petitioner now seeks the Director's review of HAP's coverage denial.

III. ISSUE

Did HAP correctly deny coverage for the prescription drug Harvoni?

IV. ANALYSIS

Respondent's Argument

HAP stated in its January 25, 2016, letter to the Department of Insurance and Financial Services that it had denied coverage "because the criterion for the use of Harvoni has not been met." HAP provided a more detailed explanation of its decision in a July 23, 2015, letter to the Petitioner and her doctor:

We have reviewed your request for Harvoni for use in Genotype 1, Hepatitis C. According to Hepatitis C Criteria for Use, cases are reviewed based on necessity and severity of disease. Necessity for treatment is determined by the presence of cirrhosis and the patient's Metavir Score (high fibrosis score 3&4, and A3 disease activity). Metavir is a tool used to assess the degree of inflammation and fibrosis of the liver. Additional criteria taken into account include the type of liver assessment tool used: and prior use of illicit medication or alcohol. According to medical information submitted, you do not meet criteria for coverage.

Specifically, your liver assessment does not demonstrate a Metavir score of F3 (or equivalent) or above, therefore you do not meet criteria for coverage at this time.

Petitioner's Argument

In her request for external review, the Petitioner submitted the following letter from her physician:

[Petitioner] has been under my care from November 2014 to present. [She] was diagnosed with Chronic Hepatitis C back in August 2014. She is treatment naive. Her viral load is 673,396, Geno type 1a or 1b. Also, her Fibro scan shows that her liver stiffness is consistent with moderate to significant fibrosis. With you not approving her medication, you run the risk of her getting severely sick, or possibly getting someone else sick. Which in the long run is costing you more money. Why not help her by fixing/prolonging the problem. This is my third request, my decision is not going to change. With my professional opinion, she is a great candidate for Harvoni 90/400 mg. I am very concerned for her health. I would greatly appreciate if you would approve this/look at this in an urgent matter. Enclosed is all her medical records and chart notes to show all proof of the findings. If you have any questions or concerns, please contact my staff.

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 and is familiar with the medical management of patients with the Petitioner's condition. The IRO reviewer's report included the following analysis:

The member was diagnosed in 2014 and is treatment naïve. The member has a viral load of less than 1 million IU/ml and has genotype 1. The member also has a history of hypertension, gastroesophageal reflux disease, lower gastrointestinal bleeding and colon polyps. The member is negative for other forms of liver disease. An ultrasound of the liver was unremarkable. Transient elastography was consistent with moderate to significant fibrosis.

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. (<http://hcvguidelines.org/full-report>, (accessed on 2/10/16))...[T]his recommendation was given a rating of Class I, Level A...

[T]he Health Plan's policy is not consistent with national guidelines....

[B]ecause of the myriad of benefits associated with successful hepatitis C virus (HCV) treatment, clinicians should treat HCV infected patients with antiviral therapy with the goal of achieving a sustained viral response, preferably early in the course of their chronic HCV 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 benefits of sustained viral response (SVR). 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. (Jezequel C, et al. Survival of patient infected by chronic hepatitis C and F0F1 fibrosis at baseline after 15 year follow-up. 50th Annual Meeting of the European Association for the Study of Liver Disease (EASL). April 22-26, 2015;S598; Vienna, Austria.)...[S]everal other modeling studies suggest a greater mortality benefit if treatment is initiated at stages prior to F3. (Ovrehus ALH, et al. Impact of prioritizing treatment in a high resource setting – minimizing the burden of HCV related disease in 15 years. 50th Annual Meeting of the European Association for the Study of Liver Disease (EASL). April 22-26, 2015;S591; Vienna, Austria. McCombs JS, et al. Can hepatitis C treatment be safely delayed? Evidence from the Veterans Administration Healthcare System. 50th Annual Meeting of the European Association for the Study of Liver Disease (EASL). April 22-26, 2015;S191; Vienna, Austria.)

Pursuant to the information set forth above and available documentation...

Harvoni is medically necessary for treatment of the member's condition.
[Emphasis added.]

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.

The Director finds that HAP's denial of coverage is not based on the appropriate national guidelines for the treatment of the Petitioner's condition. The Director further finds that the requested treatment is medically necessary.

V. ORDER

The Director reverses HAP's denial of coverage. HAP shall immediately provide coverage for the requested prescription drug regimen. See MCL 550.1911(17). HAP 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.

Patrick M. McPharlin
Director

For the Director.



Randall S. Gregg
Special Deputy Director