

STATE OF MICHIGAN
DEPARTMENT OF INSURANCE AND FINANCIAL SERVICES
Before the Director of Insurance and Financial Services

In the matter of:

██████████,
Petitioner,

v

Alliance Health and Life Insurance Company,
Respondent.

File No. 154156-001

Issued and entered
this 19th day of July 2016
by Randall S. Gregg
Special Deputy Director

ORDER

I. BACKGROUND

██████████ (Petitioner) was denied coverage for a prescription drug by her health insurer, respondent Alliance Health and Life Insurance Company (AHL).

On June 15, 2016, ██████████ the Petitioner's authorized representative, filed a request with the Director of Insurance and Financial Services for an external review of that denial under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.* On June 22, 2016, after a preliminary review of the information submitted, the Director accepted the request.

The Petitioner receives health care benefits, including prescription drug coverage, through a group health plan underwritten by AHL. The Director immediately notified AHL of the external review request and asked for the information it used to make its final adverse determination. AHL responded on July 6, 2016.

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 July 14, 2016.

II. FACTUAL BACKGROUND

The Petitioner's health care benefits are defined in AHL's *Preferred Provider Organization Group Health Insurance Policy* (the policy).

The Petitioner has hepatitis C, genotype 1a. Her physician prescribed the drug Harvoni to treat her condition and asked AHL to cover it. AHL denied the request.

The Petitioner appealed the denial through AHL's internal grievance process. At the conclusion of that process, AHL issued a final adverse determination dated June 8, 2016, affirming its denial. The Petitioner now seeks the Director's review of that adverse determination.

III. ISSUE

Did AHL properly deny prescription drug coverage for Harvoni?

IV. ANALYSIS

Respondent's Argument

In its final adverse determination following an expedited internal appeal, AHL explained its denial of coverage to the Petitioner:

Level 1 Internal Adverse Benefit Determination: New Information has not been submitted for this first level appeal; therefore, after considering all available evidence, previous decisions and your medication history, the recommendation is to uphold the original denial for Harvoni. Based on information submitted to HAP, the Metavir score (a tool used to assess the degree of inflammation and fibrosis of the liver) is below F3 and/or the Fibroscan reading is below 9.5 kPa. Your Fibroscan reading is 5.0 kPa - this score is not consistent with advanced fibrosis. Therefore, criteria for Use of Hepatitis C treatment Regimens have not been met and the original denial for Harvoni is upheld.

As part of our investigation, your request was reviewed by one of our licensed pharmacists, in our Pharmacy Care Management department, who was not involved in the initial denial.

We reviewed the following documents and statements to make this decision:

- HAP Criteria for Use of Hepatitis C Virus (HCV) Treatment Regimens Document

Petitioner's Argument

In a June 13, 2016 letter included with the external review request, the Petitioner's physician and nurse practitioner explained the request for Harvoni:

[The Petitioner] is genotype 1a, and a current viral load of 252,000 as of 4-16-2016. On March 24, 2016, she had a fibroscan completed which gave

a score of 4.3 kPa, which also showed liver stiffness. [She] is in the beginning early stages of liver damage. Providing coverage for treatment is a preventable measure to reduce the spread of infection, to her family, and others in the community. In addition provide her the chance to live her life, reduce depression, fatigue, and continued damage. Based on your denial, [Petitioner] does not meet criteria because she is not F3 or F4 metavir score. Please be advised that this letter serves as a complaint of discrimination against my patient.

According to the Harvoni guidelines, anyone diagnosed with Hepatitis C, with a genotype of, 1,2,4,6, including sub types of 1a and 1b, whom are treatment naive with a viral load less than 6 million, qualifies for treatment.

Your letter of denial indicated that she does not qualify for treatment, when in fact she does meet the criteria for being treated with Harvoni for 8 weeks of therapy, and cured of Hepatitis C.

Please be informed that not allowing my patient for a chance to be cured of this infectious virus increases her risk of becoming co infected, weakened immune system, pneumonia, fatigue. In addition her liver enzyme does show an increase since October of 2015, which is another concern, AST- 73, ALT-142.

In a Harvoni study 647 patients with genotype 1 Hep C treatment and without cirrhosis, 96% (208 out of 216) of those patients who received Harvoni once daily for 12 weeks were cured. And of those patients with lower levels of virus (less than 6 million IU/ml) who received Harvoni once daily for 8 weeks, 97% (119 out of 123) were cured. I am asking you to overturn your decision to approve Harvoni because it is imperative that my patient begin treatment of Harvoni at this time.

Director's Review

Harvoni is on AHL's approved drug list (its "Commercial Formulary") but it requires prior authorization before it will be covered. HAP's criteria for prior authorization are found in its Pharmacy Care Management policy "Criteria for Use of Hepatitis C Virus (HCV) Treatment Regimens." HAP denied Petitioner's request for prior authorization because she did not meet its medical necessity criteria, i.e., her "Metavir score . . . is below F3 and/or the Fibroscan reading is below 9.5 kPa."

The questions of 1) whether AHL's criteria for approval of Harvoni are consistent with the current standard of care, and 2) if Harvoni is medically necessary to treat the Petitioner, were 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 gastroenterology, has been in active practice for more than ten years, and is familiar with the medical management of patients with

the Petitioner's condition. The IRO report included the following analysis and recommendation:

Recommended Decision:

The MAXIMUS physician consultant determined that Harvoni is medically necessary for treatment of the member's condition.

Rationale:

* * *

The member's viral load is less than 1 million IU/ml. The member is treatment naïve. The member denies a history of drug use and rarely drinks alcohol. The member is in overall good physical health and has a long life expectance. The member underwent transient elastography and the results were consistent with minimal to no fibrosis. Harvoni therapy has been requested by the member's treating provider. The Health Plan denied this request on the basis that its criteria require a minimum of F3 fibrosis or higher for coverage of this medication.

According to the combined American Association for the Study of Liver Diseases / Infectious Disease Society of American (AASLD/IDSA) guidelines, treatment is recommended for all patients with chronic hepatitis C infections, except those with a short life expectance due to comorbid conditions. This recommendation was given a rating of Class I, Level A. The MAXIMUS physician consultant indicated that the Health Plan's policy is not consistent with national guidelines. The guidelines recommend that clinicians should treat hepatitis C virus-infected patients with antiviral therapy with the goal of achieving a sustained viral response, preferably early in the course of their chronic hepatitis C virus infection before the development of severe liver disease and other complications. The physician consultant explained that reports suggest that initiating therapy in patients with lower stage fibrosis may extend the benefits of a sustained viral response. In a long-term follow-up study, 820 patients with Metavir stage F0 or F1 fibrosis confirmed by biopsy were followed for up to 20 years and the 15 year survival rate was statistically significantly better for those who experienced an sustained viral response than for those whose treatment failed or those who remained untreated. The consultant explained that this study argues for consideration of earlier initiation of treatment.

Pursuant to the information set forth above and available documentation, the MAXIMUS physician consultant determined that Harvoni is medically necessary for treatment of the member's condition. [References omitted]

The IRO determined that, according to current national guidelines, Harvoni is medically necessary for the Petitioner.

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 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. In addition, the IRO's recommendation is not contrary to any provision of the Petitioner's certificate of coverage. MCL 550.1911(15). The Director accepts the IRO's recommendation and finds the prescription drug Harvoni is medically necessary to treat the Petitioner's condition and is a covered benefit under the terms of the policy.

V. ORDER

The Director reverses AHL's June 8, 2016, final adverse determination.

AHL shall immediately cover the prescription drug Harvoni for the Petitioner, and shall, within seven days of providing coverage, furnish the Director with proof that it has 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 Section, 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 sixty days from the date of this Order in the circuit court for the Michigan 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