

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. 151553-001

US Health and Life Insurance Company  
Respondent

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Issued and entered  
this 3rd day of February 2016  
by Randall S. Gregg  
Special Deputy Director

**ORDER**

**I. PROCEDURAL BACKGROUND**

On January 4, 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 a group plan underwritten by US Health and Life Insurance Company (USHL). The prescription drug benefits are defined in USHL's *Coalition of Public Safety Employees Health Trust Group Insurance* certificate of coverage and schedule of benefits. Magellan Rx Management, Inc. administers pharmacy benefits for USHL.

The Director notified USHL of the external review request and asked for the information used to make its final adverse determination. USHL responded to the notification on January 7, 2016, and furnished the requested information on January 11, 2016. After a preliminary review of the material submitted, the Director accepted the request on January 11, 2016. USHL furnished additional information for the review on January 13, 19 and 21, 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 January 20, 2016.

**II. FACTUAL BACKGROUND**

The Petitioner has chronic hepatitis C. Her physician prescribed the drug Harvoni to treat her condition. USHL denied coverage. The Petitioner appealed the denial of coverage through

USHL's internal grievance process. USHL affirmed its coverage denial in an adverse determination issued November 25, 2015. The Petitioner now seeks a review of USHL's coverage denial from the Director.

### III. ISSUE

Did USHL correctly deny coverage for the prescription drug Harvoni?

### IV. ANALYSIS

#### Respondent's Argument

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

Your medication request has been denied as it does not appear to meet medically necessary requirements. Plan rules require clinical parameters (diagnosis, lab values, test results, physical exam findings etc.) be met for medical necessity approval. Information submitted does not indicate required parameter results were met.

The clinical rationale for this decision is:

This request was denied because the patient does not meet disease severity criteria for approval (Fibroscan score greater than 9.5kPa, FIB-4 greater than 3.25 or APRI score greater than 1.5 or Cirrhotic features on imaging). No documentation of alcohol screen (i.e. Alcohol Use Disorders Identification Test (AUDIT C) or CAGE alcohol screen) was submitted. Fibroscan score submitted is 9.3 kPa.

Therefore, Magellan is unable to authorize coverage for the above listed medication.

#### Petitioner's Argument

In a letter to Magellan dated December 10, 2015, the Petitioner's doctor wrote:

[Petitioner] has a history of Colon Cancer and is status post a partial colectomy followed by 21 cycles of chemotherapy. She has severe fibrosis and is in dire need of treatment to prevent the advancement of this disease. [Petitioner] is being denied treatment because her Fibroscan score is 0.2 below what is recommended by your protocol.

Current recommendation by the AASLD [American Association for the Study of Liver Diseases] GUIDELINES recommend treating patients at an earlier state of fibrosis to prevent the progression of the disease. I am requesting 12 weeks of Harvoni for [Petitioner], which is the recommendation for those patients who are treatment naïve with a viral load above 6 million ui/ml.

\* \* \*

Per my assessment, it is necessary to treat the above patient with Harvoni. This treatment will provide a more compliant duration of therapy and increase patient adherence. There are fewer side effects associated with Harvoni compared to previous treatment regimens of Peg-interferon and ribavirin, both of which can cause neutropenia and anemia, respectively, and the need for other supportive therapies to be added. The fixed dose combination of Harvoni provides a very attractive and effective one pill once a day option for treatment of genotype 1 chronic hepatitis C infection. It is the first FDA approved IFN/RBV free regimen. It has shown SVR rates consistently above 90% (versus Sovaldi or IFN). The most recent statement from AASLD states:

*Our recent addition to the Guidelines prepared by a committee of leading liver experts from AASLD and the Infectious Disease Society of America (IDSA) proposed that the sickest patients be treated first, but all patients who receive advice from their doctor to take the newest medications should not be denied. The decision across the board should be in the hands of the clinician and the patient to make the decision. Unfortunately payers across America are denying treatment when a doctor has prescribed it for their patient. We adamantly disagree with this decision.*

Given the patient's history, condition and the published data supporting the use of Harvoni for 12 weeks, and the AASLD's position on treatment, I believe this treatment is warranted, appropriate and medically necessary.

### Director's Review

USHL's standards for approval of Harvoni and the medical necessity of the treatment regimen with the drug 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 who is certified by the American Board of Internal Medicine with a subspecialty in gastroenterology. The reviewer is a clinical assistant professor at a university based medical college and is published in peer reviewed medical literature. The reviewer is familiar with the medical management of patients with the Petitioner's condition. The reviewer's report included the following responses to questions posed by the Director:

**1. Is Harvoni medically necessary for treatment of the enrollee's condition?**

Harvoni is medically necessary for the treatment of this enrollee's condition based on the medical literature. There are few exclusions for Harvoni and none of which apply to this patient.

The American Association for the Study of Liver Diseases (AASLD) states the following regarding hepatitis C chronic infection:

"The goal of treatment of HCV [hepatitis C virus]-infected persons is to reduce all-cause mortality and liver-related health adverse consequences, including end-stage liver disease and hepatocellular carcinoma, by the achievement of virologic cure as evidenced by a sustained virologic response." The AASLD, while advocating using the new hepatitis C medications for the sicker patients, did not in any way preclude treatment for any infected patient. There is no limitation for treatment based on fibrosis score.

Furthermore, the Food and Drug Administration (FDA) approved package insert has no restrictions for the use of Harvoni in patients whatsoever based on a fibrosis score. The fact the enrollee is infected is the main criteria. There is no limitation on patients due to prior treatment regimens or failures or fibrosis score in the literature.

[Discussion of clinical trial omitted.]

The enrollee has an infection with a clear morbidity and mortality rate. There is a medication that can provide a cure for this infection with a greater than 97% certainty. Therefore, providing treatment with Harvoni is clearly beneficial to the health of the enrollee. Withholding treatment would conversely be deleterious to the health of the enrollee. Based on the current standard of care as defined by the AASLD recommendations and the evidence based literature, the requested service is medically necessary.

**2. Has the enrollee met the plan's medical criteria for coverage of the drug Harvoni?**

The enrollee did not meet the old plan criteria, but the enrollee did meet the new plan criteria, which was just submitted on January 19, 2016. The old criteria required that a patient evidence a Fibroscan score of 9.5 kPa or greater, while the new criteria states: Ultrasound based transient elastography (Fibroscan) score  $\geq$  7.1 kPa. This enrollee had a Fibroscan score of 9.3 kPa and as such does meet the new plan criteria. Per the latest plan criteria and the standard of care, the enrollee does meet medical necessity for the requested medication.

[List of old and new criteria omitted.]

**3. Is the plan's medical coverage criteria appropriate and consistent with current accepted standards for use of Harvoni in treating the enrollee's condition?**

The old plan criteria was not consistent with the standard of care. The plan's medical coverage denial, which was based on the old plan criteria, was not consistent with the standards for treatment of hepatitis C as evidenced by the AASLD and additional medical literature as described above. As noted above, the enrollee does meet the new plan criteria for coverage.

**Recommendation:**

It is the recommendation of this reviewer that the denial issued by US Health & Life Insurance for Harvoni be overturned.

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

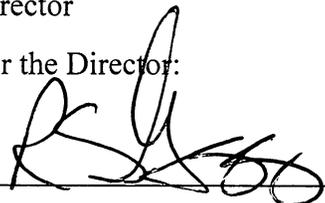
The Director reverses US Health and Life Insurance Company's final adverse determination of November 25, 2015. US Health and Life Insurance Company shall immediately provide coverage for the requested prescription drug regimen and shall, within seven days of providing coverage, furnish the Director with 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:

A handwritten signature in black ink, appearing to read 'R. S. Gregg', is written over a solid horizontal line.

Randall S. Gregg  
Special Deputy Director