

**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. 152092-001**

**Health Alliance Plan of Michigan**  
**Respondent**

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**Issued and entered**  
**this 9<sup>th</sup> day of March 2016**  
**by Randall S. Gregg**  
**Special Deputy Director**

**ORDER**

**I. BACKGROUND**

On February 5, 2016, ██████████, authorized representative of ██████████ (Petitioner), filed a request with the Director of Insurance and Financial Services for an expedited external review under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.*

The Petitioner receives prescription drug coverage from Health Alliance Plan of Michigan (HAP), a health maintenance organization. The Petitioner's health benefits are defined in HAP's *HMO Subscriber Contract*.

The Director notified HAP of the external review request and asked for the information it used to make its final adverse determination. HAP provided its response on February 11, 2016. On February 12, 2016, after a preliminary review of the material submitted, the Director accepted the request.

Because the case involves medical issues, it was assigned to an independent medical review organization. The IRO provided its analysis and recommendation to the Director on February 26, 2016.

**II. FACTUAL BACKGROUND**

The Petitioner is fifty-five years old and has hepatitis C, genotype 1a. Her physician prescribed the drug Harvoni and requested that HAP authorize coverage for the drug. Harvoni is listed on HAP's drug formulary which requires that it be purchased from a HAP-designated pharmacy with HAP's prior authorization. HAP denied the request saying, the Petitioner did not meet its criteria for coverage of this medication.

The Petitioner appealed the denial through HAP's internal grievance process. At the conclusion of that process, HAP issued a final adverse determination dated January 8, 2016, upholding the denial. The Petitioner now seeks from the Director a review of the denial.

### III. ISSUE

Did HAP properly deny coverage for the prescription drug Harvoni?

### IV. ANALYSIS

#### Respondent's Argument

In its final adverse determination, HAP wrote:

After considering all available evidence, previous decisions, and your medication history, we upheld the denial for Harvoni. Your medical records indicate that you currently do not have Cirrhosis and are without a high level of Fibrosis or inflammation. The appeal letter is requesting an exception to the criteria, based on the rationale that there is a possibility of an occurrence of extrahepatic manifestations that can lead to Kidney Disease from the Hepatitis C Virus (HCV). This may lead to a need for a second kidney transplant. Per the Hepatitis C criteria for the use of Harvoni, coverage is provided if there is clinical data to support HCV disease through medical record documentation of active and serious extrahepatic manifestations of HCV, with one or more of the following: 1) Type 2 or 3 essential mixed Cryoglobulinemia with end-organ manifestations, 2) Glomerular Disease – Nephrotic Syndrome or Membranoproliferative Glomerulonephritis. Based on the medical records and documentation provided, there is not any clinical data to support the statement that you are currently experiencing any serious or active Extrahepatic Manifestations (as stated above). In addition, your liver assessment indicates a Metavir score below F3. Your liver biopsy dated June 25, 2015 demonstrates minimal Periportal Fibrosis (Ishak stage 0-1) consistent with Metavir F0-F1. Therefore, for these reasons, the criteria have not been met at this time and the denial is upheld.

#### Petitioner's Argument

In a February 4, 2016, letter filed with the request for an external view, the Petitioner's physician stated:

[Petitioner] was diagnosed with chronic hepatitis C infection many years ago and received therapy with peg-interferon and ribavirin for about 7-8 months in 2008. Because of anemia and worsening renal function treatment had to be discontinued. Her genotype is 1a.

[Petitioner] received a kidney transplant from a hepatitis C positive donor on 11/21/2015 with the idea of eradicating her hepatitis C virus post-transplant.

We are now ready to treat her hepatitis C however, her health insurance denied coverage of Harvoni. She needs to be treated with Harvoni for 12 weeks. Using Viekira pak in combination with Ribavirin (since she is genotype 1a), is not a good option because of the

strong interaction with the immunosuppressant medications that she is on, and the fact that she is anemic.

I understand that her health insurance company has denied the coverage of Harvoni because she does not have advanced hepatic fibrosis or extra-hepatic manifestations. However, based on existing data in patients post-kidney transplant, which indicates that there is an increased risk for de novo glomerulonephritis, chronic allograft rejection, increased risk for extrahepatic manifestations and faster progression of hepatic fibrosis, I believe that it is very important that we treat her sooner rather than later.

I respectfully request that her case is reviewed for consideration of HCV therapy with Harvoni for 12 weeks.

### Director's Review

HAP covers prescription drugs when they are medically necessary and/or approved by HAP. HAP denied authorization, ruling the Petitioner does not meet the criteria for coverage cited in its final adverse determination.

The question of whether HAP's criteria for coverage of Harvoni are in compliance with current medical standards of care was 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 who is board certified in gastroenterology and has been in practice for more than 15 years. The IRO reviewer's report included the following analysis and conclusion.

The member's viral load is approximately 2.3 million IU/ml. The member was previously treated with an interferon containing regimen, but was a non-responder. The patient is status post renal transplant from a hepatitis C positive donor. A recent ultrasound showed an unremarkable liver without signs of portal hypertension. A liver biopsy in 2015 was consistent with F0-F1 disease.

The joint guidelines of the American Association for the Study of Liver Disease/Infectious Disease Society of America (AASLD/IDSA) for direct acting antiviral therapy recommend that it should be prioritized for those who would be most likely to benefit in the near-term. (<http://hcvguidelines.org/full-report>.) [T]he highest priority patients include those who are at highest risk of substantial morbidity and mortality from untreated hepatitis C infection, specifically those with advanced fibrosis or compensated fibrosis, transplant recipients and those with severe extrahepatic manifestations of hepatitis C virus...[T]he Health Plan's policy is not consistent with national guidelines...[T]he member is at very high risk for rapid progression of her liver disease without treatment.

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

(<http://www.uptodate.com/contents/patient-evaluation-and-selection-for-antiviral-therapy-for-chronic-hepatitis-c-virus-infection>. (accessed 2/19/16))

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. In addition, the IRO's recommendation is not contrary to any provision of the Petitioner's coverage. MCL 550.1911(15).

The Director, discerning no reason why the IRO's recommendation should be rejected in the present case, finds 1) that HAP's standards for determining coverage for Harvoni are not consistent with national guidelines, 2) the prescription drug Harvoni is medically necessary for treatment of the Petitioner's condition, and 3) Harvoni is a covered benefit under HAP's *HMO Subscriber Contract*.

#### V. ORDER

The Director reverses HAP's January 8, 2016 final adverse determination. HAP shall immediately provide coverage for the prescription drug Harvoni. 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 sixty 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



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Randall S. Gregg  
Special Deputy Director