

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. 149465-001

United Healthcare Insurance Company

Respondent

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Issued and entered  
this 21<sup>st</sup> day of September 2015  
by Randall S. Gregg  
Special Deputy Director

**ORDER**

**I. PROCEDURAL BACKGROUND**

On August 21, 2015, the authorized representatives 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 health care and prescription drug benefits from a group plan underwritten by United Healthcare Insurance Company (UHC). The prescription drug benefits are defined in UHC's *Choice Plus* certificate of coverage and *Outpatient Prescription Drug Rider*.

The Director notified UHC of the external review request and asked for the information used to make its final adverse determination. UHC furnished the requested information on August 24 2015. On August 28, 2015, UHC provided additional information. After a preliminary review of the material submitted, the Director accepted the request on August 28, 2015.

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 September 11, 2015.

**II. FACTUAL BACKGROUND**

The Petitioner has hepatitis C. His physician prescribed a 24 week treatment regimen of the prescription drugs Sovaldi and ribavirin. UHC was requested to provide coverage for the

drugs. UHC denied coverage for Solvaldi. (Ribavirin is a covered drug that does not require prior authorization.) The Petitioner appealed the denial of coverage through UHC's internal grievance process. UHC affirmed its coverage denial in a final adverse determination issued July 14, 2015. The Petitioner now seeks a review of UHC's decisions from the Director.

### III. ISSUE

Did UHC correctly deny coverage for Sovaldi in the proposed prescription drug regimen for treatment of Petitioner's hepatitis C?

### IV. ANALYSIS

#### Petitioner's Argument

In a letter of appeal to UHC dated June 12, 2015, the Petitioner's physician wrote:

[Petitioner] has genotype 3 Hepatitis C virus (HCV) that is accompanied by elevations in his AST and ALT....These findings are documented in the attached patient records.

[Petitioner] had a liver biopsy conducted 9/15/2014 which showed periportal fibrosis (stage 2 of 4). Although these findings did not indicate the presence of cirrhosis at that time, it is unknown the rate at which his disease could progress. Given the fact that he is male (a non-modifiable risk factor associated with accelerated fibrosis progression) I feel that it would be prudent to treat his disease now, rather than deferring treatment until his disease advances. Van der Meer, AJ, et al. AASLD 2013, Abstract 143 demonstrated that patients who progress to advanced fibrosis and advanced cirrhosis have a significant increase in the risk of developing hepatocellular carcinoma (HCC) even after an SVR has been achieved. Therefore, treatment for [Petitioner] can be considered medically necessary to prevent further, irreversible advancement of liver damage, increased risk of HCC, and potential progression to liver failure that is associated with untreated chronic HCV infection.

Your plan also requires documentation that the patient is ineligible for treatment with peginterferon-alfa. The current American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA)

"Recommendations for Testing, Managing, and Treating Hepatitis C" recommend the combination of Sovaldi plus ribavirin for 24 weeks the first-line treatment regimen for patients with genotype 3 infection. As such, I am not sure why your plan would require patients to pursue treatment with peginterferon-alfa, especially given the unfavorable side effect profile.

### Respondent's Argument

In its final adverse determination, UHC stated that it denied coverage because Sovaldi "is not a covered drug under your plan." UHC also stated that Sovaldi could be approved for coverage if the Petitioner met an extensive list of criteria. According to UHC, the Petitioner did not meet those criteria.

### Director's Review

The issues of the medical necessity of Sovaldi and the criteria UHC applied to determine coverage were evaluated by 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 reviewer is a physician who is board certified in internal medicine and gastroenterology, has been in active practice for more than 15 years, 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]he Health Plan's criteria for coverage of Solvadi differ from the recommendations put forth by UpToDate<sup>1</sup> as well as national societies....[D]irect antiviral therapy for patients with hepatitis C should be prioritized for those who would be most likely to benefit in the near-term, as recommended by the joint guidelines from the Study of Liver Diseases and the Infectious Diseases Society of America. <http://www.uptodate.com/contents/patient-evaluation-and-selection-for-antiviral-therapy-for-chronic-hepatitis-c-virus-infection>. (Accessed 9/8/15). Recommendations for Testing, Managing, and Treating Hepatitis C. Joint panel from the American Association of the Study of Liver Diseases and the Infectious Diseases Society of America. January 2014 <http://www.hcvguidelines.org/>. (Accessed 9/8/15)...[T]he highest priority patients include those who are at highest risk of substantial morbidity and mortality from untreated hepatitis C infection, namely those with advanced fibrosis or compensated fibrosis and those with severe extrahepatic manifestations of infection....[H]igh priority patients include those at high risk for fibrosis progression, such as patients with substantial fibrosis, including Metavir stage F2....[T]he member would be considered a high priority patient as he has a significant probability of experiencing liver-related morbidity over the next 10 to 20 years without eradication of the hepatitis C virus. Pursuant to the information set forth above and available documentation...Sovaldi is medically necessary for treatment of the member's condition.

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1. UpToDate is an online resource that provides physician-authored materials to assist medical professionals in making clinical decisions.

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 certificate of coverage. See MCL 550.1911(15). The Director can discern no reason why the analysis should be rejected in the present case.

The Director finds that UHC's criteria for determining coverage for Sovaldi do not reflect current medical standards. Further, the Director finds that Sovaldi is medically necessary in the prescription drug regimen proposed for treatment of Petitioner's condition.

#### V. ORDER

The Director reverses United Healthcare Insurance Company's July 14, 2015, final adverse determination. United Healthcare Insurance Company shall immediately provide coverage for the requested prescription drug Sovaldi 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.

Patrick M. McPharlin  
Director

For the Director:



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Randall S. Gregg  
Special Deputy Director