

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. 153292-001

Total Health Care, Inc.

Respondent

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

ORDER

I. BACKGROUND

On May 18, 2016, ██████████, authorized representative of ██████████ (Petitioner), filed a request with the Director of Insurance and Financial Services for an external review under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.*

The Petitioner receives health care benefits, including prescription drug coverage, through Total Health Care, Inc. (THC), a health maintenance organization. The Petitioner's benefits are defined in THC's *Point of Service (POS) Certificate of Coverage*. The Director notified THC of the external review request and asked for the information used to make its final adverse determination. THC provided its response on May 24, 2016. The Director accepted the Petitioner's request on May 25, 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 June 13, 2016.

II. FACTUAL BACKGROUND

The Petitioner is sixty years old and has hepatitis C, genotype 1a. He is being treated at the ██████████ in Troy, Michigan. His physician prescribed the drug Harvoni to treat his condition. THC denied coverage for the drug.

Petitioner's authorized representative appealed the denial through THC's internal grievance process. At the conclusion of that process, on May 12, 2016, THC issued a final adverse determination affirming its denial. The Petitioner now seeks the Director's review of that adverse determination.

III. ISSUE

Did THC properly deny coverage for the prescription drug Harvoni?

IV. ANALYSIS

Respondent's Argument

In its final adverse determination, THC explained its denial of coverage to the Petitioner:

Harvoni is not a covered benefit under your plan as it is not listed as a covered medication on the Total Health Care USA formulary. According to your Member Handbook on page 13, Your Total Health Care USA covered benefits may include prescription drug coverage. This benefit provides prescription drugs covered on the Plan's Formulary. The formulary is a list of covered drugs ... In addition, your Certificate of Coverage on page 26 indicates coverage provided is based on the Plan Approved Drug List with required dispensing from an Affiliated Pharmacy or Plan Mail Order Pharmacy. Drugs may be added or removed from the Approved Drug List throughout the Plan Year.

Petitioner's Argument

With her request for external review, the Petitioner's authorized representative, an employee of the [REDACTED], submitted medical records to demonstrate that Harvoni is medically necessary for the Petitioner.

Director's Review

Harvoni is not on THC's approved drug list. However, under Michigan law, health maintenance organizations that offer prescription drugs and limit that benefit to drugs included in a formulary are required to provide for exceptions from the formulary limitation when a nonformulary drug is a medically necessary and appropriate alternative. Section 3406o of the Michigan Insurance Code, MCL 500.3406o, provides:

An insurer that delivers, issues for delivery, or renews in this state an expense-incurred hospital, medical, or surgical policy or certificate that provides coverage for prescription drugs and limits those benefits to drugs included in a formulary shall do all of the following:

* * *

(c) Provide for exceptions from the formulary limitation when a nonformulary alternative is a medically necessary and appropriate alternative. This subdivision does not prevent an insurer from establishing prior authorization requirements or another process for consideration of coverage or higher cost-sharing for nonformulary alternatives. Notice as to whether or not an exception under this subdivision has been granted shall be given by the insurer within 24 hours after receiving all information necessary to determine whether the exception should be granted.

To determine whether Harvoni is a medically necessary and appropriate alternative to treat the Petitioner's condition, the Director presented the issue 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 reviewer is a physician in active practice for more than ten years and is board certified in gastroenterology. The IRO report included the following analysis and conclusion:

The member's viral load is approximately 1.8 million IU/ml. On HCV Fibrosure, the member had a score predictive of F4 fibrosis. The member has evidence of portal hypertension with significant thrombocytopenia. The member has no specific extra-hepatic manifestations of hepatitis C, does not use illicit drugs and rarely uses alcohol.

[T]here is no doubt that Harvoni is far superior to PEG-Interferon plus Ribavirin in the treatment of genotype 1 hepatitis C. PEG-Interferon plus Ribavirin is no longer recommended for treatment of hepatitis C by the American Association for the Study of Liver Diseases (AASLD) ... [T]he member has cirrhosis, indicating that without cure, he will progress to liver failure ... PEG-Interferon based regimens are less effective in the setting of cirrhosis.

Pursuant to the information set forth above and available documentation. Harvoni is medically necessary for treatment of the member's condition. (<http://www.hcvguidelines.org/full-report/initial-treatment-hcv-infection>. (accessed 6/10/16) <http://www.uptodate.com/contents/treatment-regimens-for-chronic-hepatitis-c-virus-genotype-1>. (accessed 6/10/16).)

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 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 a medically necessary and appropriate alternative to THC's formulary drugs in the treatment of the Petitioner's condition. For that reason, Harvoni is a covered benefit

V. ORDER

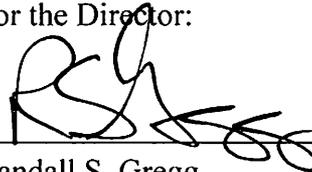
The Director reverses Total Health Care's May 12, 2016 final adverse determination. Total Health Care shall immediately provide the Petitioner with prescription drug coverage for Harvoni, and shall, within seven days of providing coverage, furnish the Director with proof that it has implemented this 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