

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

In the matter of:

██████████
Petitioner

v

Blue Care Network
Respondent

File No. 148640-001

Issued and entered
this 3rd day of August 2015
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

The Patient's Right to Independent Review Act (MCL 550.1901 *et seq.*) authorizes the Director of Insurance and Financial Services to review denials of coverage for health care services. These external reviews are initiated by policyholders or an authorized representative once a coverage denial has been reviewed by the insurer in its internal grievance process.

On July 1, 2015, ██████████ (Petitioner) filed a request for an external review with the Director of Insurance and Financial Services. The Petitioner receives prescription drug coverage through Blue Care Network (BCN), a health maintenance organization (HMO). His prescription drug benefits are defined in BCN's *Certificate of Coverage for Individuals* and related *Prescription Drug Rider*

The Director notified BCN of the external review request and asked for the information used to make its final adverse determination. BCN provided its initial response on July 2, 2015. On July 9, 2015, after a preliminary review of the material submitted, the Director accepted the request. BCN provided additional documentation on July 15, 2015.

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 July 22, 2015.

II. FACTUAL BACKGROUND

The Petitioner has Hepatitis C, genotype 3a. His doctor recommended treatment with the prescription drug Sovaldi. BCN denied coverage, ruling that the Petitioner did not meet BCN's criteria for the drug.

The Petitioner appealed the denial through BCN's internal grievance process. At the conclusion of that process, BCN on June 2, 2015, issued a final adverse determination upholding the denial. The Petitioner now seeks from the Director a review of the denial.

III. ISSUE

Did BCN properly deny prescription drug coverage for Sovaldi?

IV. ANALYSIS

BCN's Argument

In a letter to the Petitioner dated April 21, 2015, BCBSM offered this explanation of its denial of coverage:

A Blue Care Network medical director or pharmacist reviewed your doctor's appeal request for Sovaldi Tablet. Unfortunately, the appeal request has been denied.

- Coverage for Sovaldi therapy is provided in patients 18 years of age or older with a diagnosis of chronic hepatitis C genotype 3 infection. Based on the information provided, the member was initially diagnosed with hepatitis C in September 2014 with a positive RNA of 1,681 detected in December 2014. A repeat RNA level was not provided in the documentation. At this time, a diagnosis of chronic hepatitis C genotype 3 infection cannot be confirmed.
- The appeal letter did not confirm that the patient has chronic (emphasis on chronic) hepatitis C infection. Only 2 reports, in September and December 2014 of detectable Hep C RNA, and there is no evidence of liver damage provided. Hepatitis C virus is often eliminated by the immune system.

Petitioner's Argument

In a letter dated April 6, 2015 to BCN, the Petitioner's physician's assistant wrote:

[Petitioner] is a [REDACTED] year old male who is diagnosed with chronic Hepatitis C (diagnosis code (70.54) and is genotype 3A....The use of Sovaldi in combination

with Ribavirin provides the first FDA approved all oral therapy for hepatitis C. Sovaldi is much safer than Interferon, offered more effective treatment for the majority of patients involved in a Phase 3 clinical trial.

According to the American Association for the Study of Liver Disease (AASLD), the recommended treatment for Genotype 3 in treatment naïve patients is Sovaldi + Ribavirin for 24 weeks. Sovaldi research has shown 82% to 96% cure rate versus Incivek and Victrelis with only 50% to 70%....The Sovaldi along with Ribavirin are his best treatment option at this time. Ribavirin has already been approved and [Petitioner] is waiting to start therapy until Sovaldi is approved. Without this treatment I fear her condition will continue to decline causing additional and serious medical problems....

In my clinical judgment, Sovaldi along with Ribavirin therapy would provide significant clinical benefit for [Petitioner]. Sovaldi is medically necessary and appropriate to treat [Petitioner] at this stage in his course of care.

Director's Review

The question of whether Sovaldi is medically necessary for the treatment of Petitioner's condition 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 active practice for more than 18 years. The reviewer is familiar with the medical management of patients with the Petitioner's condition. The IRO reviewer's report included the following analysis and conclusion:

The member was diagnosed with hepatitis C in September 2014, which was confirmed in December 2014. However...the information provided [for] review does not establish chronicity of infection...[T]he member had a very low viral load of approximately 1600 IU/ml in December 2014. This value has not been tested again since then. Within the clinical records provided for review, there is no mention of an assessment of hepatic fibrosis.

[T]here was insufficient information provided to determine whether the member would benefit from Sovaldi...[T]he member's viral load is extremely low and chronicity of infection has not been established...[T]here is a reasonable possibility that the member will clear virus without treatment and that waiting several months will not be harmful to him. In addition, advanced fibrosis has not been established...[E]ven if the member's infection were established to be chronic, he may have minimal liver disease and therefore therapy immediately would be unnecessary.

Pursuant to the information set forth above and available documentation...
Sovaldi is not medically necessary for treatment of the member's condition at
this time. [Citations omitted.]

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. The Director finds that the requested drug treatment is not medically necessary.

V. ORDER

The Director upholds BCN's June 2, 2015 final adverse determination. BCN is not required to provide coverage for the prescription drug Sovaldi at this time.

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



Randall S. Gregg
Special Deputy Director