

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. 152692-001

Blue Cross Blue Shield of Michigan,

Respondent.

Issued and entered
this 18th day of April 2016
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On March 15, 2016, ██████████ (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 prescription drug coverage through a group health plan underwritten by Blue Cross Blue Shield of Michigan (BCBSM). The Director notified BCBSM of the external review request and asked for the information it used to make its final adverse determination. On March 22, 2016, after a preliminary review of the material submitted, the Director accepted the request. BCBSM provided its response on March 28, 2016.

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 April 5, 2016.

II. FACTUAL BACKGROUND

The Petitioner's health care benefits are described in BCBSM's *Simply Blue HSA Group Benefits Certificate with Prescription Drugs LG* (the certificate).

The Petitioner has chronic hepatitis C, genotype 3. Her physician prescribed the drugs Sovaldi and Daklinza to treat her condition. BCBSM denied preauthorization on the basis that she did not meet its criteria for coverage.

The Petitioner appealed the denial through BCBSM's internal grievance process. At the conclusion of that process, BCBSM issued its final adverse determination dated February 19, 2016, upholding its decision. The Petitioner now seeks a review of that final adverse determination from the Director.

III. ISSUE

Did BCBSM correctly deny coverage for Sovaldi and Daklinza?

IV. ANALYSIS

Petitioner's Argument

In a February 16, 2016, letter submitted with the external review request, the Petitioner's physician wrote:

This letter is in response to the denial of medication Daklinza for [the Petitioner]. [Her] therapy would include taking one tablet (60 mg) by mouth once daily. This letter documents the medical necessity for this therapy in the treatment of chronic hepatitis C and provides information about the patient's medical history and treatment.

[The Petitioner] is a ■ year old female who is diagnosed with chronic Hepatitis C (diagnosis code B18.2) and is genotype 3. She is treatment naive and her recent fibro score is 0.53 without cirrhosis. [She] will be taking Daklinza in combination with Sovaldi. Daklinza would only require [her] to take 1 tablet daily; less tablet load leads to increased compliance, which is vital to success in double therapy. Daklinza is FDA approved for Hepatitis C and is also found to be more effective than the formulary options. Putting [the Petitioner], in her current state, on a potentially less effective medication is against my professional judgment. Approving treatment with Daklinza in combination with Sovaldi would increase compliance and lead to lower overall costs. Untreated, Hepatitis C can lead to very serious health problems and [she] cannot afford to take that risk. Daklinza in combination with Sovaldi is her best treatment option at this time. Without this treatment her condition will continue to decline into major liver damage and will affect her quality of life. Please approve Daklinza for [Petitioner] as soon as possible so she can begin treatment immediately without interruption.

Respondent's Argument

In its final adverse determination, BCBSM stated:

... After review, I confirmed that [the Petitioner] does not meet the prior authorization criteria for Sovaldi and Daklinza.

[The Petitioner] is covered under [a] group health care plan. Page 76 of her *Simply Blue HSA Group Benefits Certificate with Prescription Drugs LG* details her coverage regarding prior authorization of prescription drugs and indicates that prior authorization will be decided based on:

- Medical necessity,
- The patient's current medical information, and
- Criteria approved by BCBSM

Note: We may require you to try one or more preferred drugs before we will pay for the brand-name drug.

Additionally, as indicated on page 80, BCBSM does not pay for:

Any drug or device prescribed for uses or in dosages other than those specifically approved by the Federal Food and Drug Administration. This is often referred to as the off-label use of a drug or device. (However, we will pay for such drugs and the reasonable cost of supplies needed to administer them, if the prescribing M.D. or D.O. can substantiate that the drug is recognized for treatment of the condition for which it was prescribed. See criteria under "Covered Drug" in Section 7.) Some chemotherapeutic drugs may be subject to prior authorization review.

A Clinical Pharmacist, RPh, reviewed the submitted documentation for Sovaldi and Daklinza and determined:

The coverage guidelines for your Custom Drug List benefit require criteria be met before coverage can be authorized.

Our criteria for coverage of this medication require patients who are Hepatitis C Genotype 3, treatment naive, without cirrhosis, and are interferon eligible, to be treated with Sovaldi, ribavirin, and peg-interferon for 12 weeks. However, we have no record of you being interferon ineligible and are therefore eligible for Sovaldi, ribavirin and peginterferon for 12 weeks.

As [the Petitioner] does not meet the criteria for authorization of Sovaldi or Daklinza, authorization cannot be granted. If she chooses to obtain the prescription drugs, she will be liable for the non-covered charges.

Director's Review

The question of whether BCBSM's criteria for the use of Daklinza and Sovaldi meet the current standard 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 physician reviewer is board certified in internal medicine and gastroenterology, has been in active clinical practice for more than 12 years, and is familiar with the medical

management of patients with the member's condition. The IRO report included the following analysis and recommendation:

Recommended Decision:

The MAXIMUS physician consultant determined that Sovaldi and Daklinza are medically necessary treatment of the member's condition.

Rationale:

* * *

The member's viral load is very [load] at less than 10,000 IU/ml. The member is treatment naïve. The member has a remote history of intravenous drug abuse, but [no] longer uses drugs or alcohol. A liver ultrasound was normal. The member has no other forms of liver disease. There are no specific extra-hepatic manifestations of hepatitis C. The member has underlying depression. The member's treating provider has requested coverage for Daklinza in combination with Sovaldi for 12 weeks. This request was denied by the Health Plan, which has a step-therapy algorithm and requires patients who are not ineligible to be treated with a peg-interferon based regimen that includes Sovaldi and ribavirin.

The MAXIMUS physician consultant indicated that the Health Plan's criteria for coverage of Sovaldi and Daklinza are not consistent with current standards of care. The physician consultant explained that the current standard of care is not to use Sovaldi plus Daklinza as a second line agent in patients eligible for interferon. The consultant also explained that rather, Sovaldi plus Daklinza is used a first line therapy, even if the patient is eligible for interferon.

The physician consultant indicated that the preferred regimen for genotype 3 infected patients without cirrhosis is daclatasvir plus sofosbuvir for 12 weeks. In an open-label study that include 120 genotype 3 infected patients without cirrhosis, the regimen resulted in a sustained viral response rate of 98% among the treatment-naïve and 92% percent among the treatment-experienced. The consultant explained that the member has underlying depression as detailed in her medical records and therefore, is not a candidate for interferon regimen. Guidelines for treatment of hepatitis C virus state that daily daclatasvir (60mg) plus sofosbuvir (400mg) for 12 weeks is a recommended regimen for treatment-naïve patients with hepatitis C virus genotype 3 infection who do not have cirrhosis. This recommendation has a Class 1, Level A rating. [References omitted]

Pursuant to the information set forth above and available documentation, the MAXIMUS physician consultant determined that Sovaldi and Daklinza are medically necessary treatment of the member's condition.

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 this case, finds that the prescription drugs Sovaldi and Daklinza are medically necessary to treat the Petitioner’s condition and therefore are a covered benefit under the terms of the certificate.

V. ORDER

The Director reverses BCBSM’s February 19, 2016 final adverse determination. BCBSM shall immediately cover the prescription drugs Sovaldi and Daklinza for the Petitioner. MCL 550.1911(17). BCBSM 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 its 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 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