

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

In the matter of:

██████████
Petitioner

v

Blue Cross Blue Shield of Michigan
Respondent

File No. 153552-001

Issued and entered
this 6th day of June 2016
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On May 5, 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.* After a preliminary review of the material submitted, the Director accepted the request on May 12, 2016.

The Petitioner receives prescription drug benefits through a plan underwritten by Blue Cross Blue Shield of Michigan (BCBSM). The benefits are defined in BCBSM's *Preferred Rx Program Certificate LG*.

The Director notified BCBSM of the external review request and asked for the information it used to make its final adverse determination. BCBSM provided its response on May 17, 2016. To address the medical issue in the case, the Director assigned it to an independent medical review organization which provided its analysis and recommendation on May 24, 2016.

II. FACTUAL BACKGROUND

The Petitioner is 59 years old and has hepatitis C. His doctor prescribed treatment with the prescription drugs Daklinza and Sovaldi. BCBSM denied coverage, ruling that the Petitioner does not meet its eligibility criteria for the drugs.

The Petitioner appealed the denial through BCBSM's internal grievance process. At the conclusion of that process, BCBSM affirmed its decision in a final adverse determination dated April 15, 2016. The Petitioner now seeks the Director's review of that adverse determination.

III. ISSUE

Did BCBSM correctly deny coverage for the prescription drugs Daklinza and Sovaldi?

IV. ANALYSIS

BCBSM's Argument

In its final adverse determination BCBSM stated that the Petitioner's request for coverage was evaluated by a clinical pharmacist who wrote with respect to each drug:

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 requires 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. According to our record, your therapy includes Sovaldi and Daklinza for 12 weeks. However, we have no record of you being interferon ineligible. The American Association for the Study of Liver Disease defines interferon ineligible as a platelet count less than 90,000/microliter. We have no record your platelet count is above 90,000/microliter with a platelet count in December 2015 of 111,000/microliter and a platelet count in August 2015 of 114,000/microliter and are therefore eligible for Sovaldi, ribavirin and peg-interferon for 12 weeks.

Petitioner's Argument

In the request for external review, the Petitioner wrote "I have Hepatitis C. Need to take Daklinza and Sovaldi medication to take care of my problems."

Director's Review

BCBSM's *Preferred Rx Program Certificate LG* (page 32) provides coverage for select specialty pharmaceuticals if they are preauthorized by BCBSM. In the Petitioner's case, BCBSM denied authorization, ruling that the Petitioner did not meet its coverage criteria. BCBSM's criteria for Dalinksa and Sovaldi are detailed in its April 2016 *Prior Authorization and Step Therapy Guidelines*:

Dalinkza

Coverage will only be given for chronic hepatitis C genotype 3 infection without cirrhosis and only in combination with Sovaldi.

Sovaldi

Criteria for coverage require diagnosis of chronic hepatitis C genotypes 1, 2, 3, 4 in patient 18 years or older and compensated liver disease (including cirrhosis).

Must be used in combination with peg-interferon alfa, ribavirin, or Olysia (simeprevir) per the 2014 American Association for the Study of Liver Disease (AASLD) Hepatitis C guidelines.

The medical necessity of Petitioner's treatment with Daklinza and Sovaldi was 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 in active practice for more than twelve years who is board certified in internal medicine and gastroenterology. The reviewer is familiar with the medical management of patients with the Petitioner's condition. The IRO report included the following analysis and recommendation:

[T]his case involves a 59 year-old male with chronic viral hepatitis C (HCV), genotype 3. The member is treatment naïve with a viral load of 1,833,349 IU/ml as of 9/17/15. The member's treating provider has recommended a 12 week course of Sovaldi + Daklinza. The Health Plan's preferred treatment option for the member's specific genotype and circumstance (non interferon-ineligible) is peg-interferon + ribavirin + Sovaldi. At issue in this appeal is whether treatment with Daklinza and Sovaldi is medically necessary for treatment of the member's condition.

The member is not co-infected with HIV. The member denies alcohol excess or illicit drug use. An ultrasound performed in 2015 showed a choledochal cyst and choelithiasis. Liver biopsy on 12/4/15 yielded a fibrosis stage of Metavir F1. The member's treating provider contended however that his fibrosis stage may be higher given his marked transaminitis, low albumin/globulin ratio (0.8), chronic thrombocytopenia (platelets 111K on 12/4/15), and resulting APRI score of 3.433 and Fib-4 score of 4.71. There is no accompanying coagulopathy (INR 1.0) or hypoalbuminemia (3.4). Extrahepatic manifestations of hepatitis C virus are not supported by available records.

American Association for the Study of Liver Diseases/Infectious Diseases Society of American (AASLD/IDSA) recommendations for treatment of patients with this member's condition have shifted to the two following equally recommended treatment options:

Daily daclatasvir (60 mg*) plus sofosbuvir (400 mg) for 12 weeks is a Recommended regimen for treatment-naïve patients with HCV genotype 3 infection who do not have cirrhosis. Rating: Class I, Level A

and

Daily sofosbuvir (400 mg) and weight-based RBV plus weekly PEG-IFN for 12 weeks is a recommended regimen for treatment-naïve patients with HCV genotype 3 infection who do not have cirrhosis and who are eligible to receive PEG-IFN. Rating: Class I, Level A.

These recommendations state that

Daclatasvir with sofosbuvir for 12 weeks was approved by the FDA for treatment of HCV genotype 3 infection. The recommendation is based on ALLY-3, a phase III study of the once-daily NS5A inhibitor daclatasvir plus sofosbuvir for 12 weeks; the study included 101 treatment-naïve patients and demonstrated an SVR12 rate of 90%. In treatment-naïve patients without cirrhosis (Metavir F0-F3), 97% achieved SVR12, and in treatment-naïve patients with cirrhosis (Metavir F4), 58% achieved SVR12.

However, pertinent to the Health Plan's preferred regimen, AASLD/IDSA further opines:

The triple-arm, controlled BOSTON study (Foster, 2015) randomly assigned treatment-naïve and -experienced patients with HCV genotype 3 infection to either sofosbuvir or RBV for 16 weeks (n=196) or 24 weeks (n=199) or sofosbuvir plus PEG-IFN/RBV for 12 weeks (n=197). The SVR12 rate among treatment-naïve patients was 77% (70/91), 88% (83/94), and 95% (89/94) for each arm, respectively. The greater SVR12 in the IFN-containing arm was noted regardless of evidence of cirrhosis with SVR12 rates of 83% (58/70) versus 57% (12/21), 90% (65/72) versus 82% (18/22), and 96% (68/71) versus 91% (21/23), for those in each arm without versus with cirrhosis, respectively. Although the regimen of sofosbuvir plus PEG-IFN/RBV has greater adverse event rates and requires an increase in monitoring, the shortened 12 weeks of treatment coupled with superior results makes this the recommended regimen for IFN-eligible patients, until superior IFN-free options are defined....

[T]he member is not absolutely contraindicated to this combination therapy.

[A]ccordingly, the Health Plan's preferred option of peg-interferon + ribavirin + Sovaldi is non-inferior, equally efficacious, and as highly recommended by AASLD/IDSA guidelines as the Daklinza + Sovaldi regimen at issue....[W]hile the latter may have greater convenience for Appellant due to its all-oral administration, it does not meet the definition of "medically necessary" under the Michigan insurance code regarding formulary exceptions.

The member's liver biopsy does not support advanced fibrosis. However...the medical necessity of HCV treatment as per AASLD/IDSA recommendations, and the medical appropriateness of antiviral therapy for the member, exists irrespective of fibrosis score. AASLD/IDSA guidelines underscore this position with the following statement: "Evidence clearly supports treatment in all HCV-infected persons, except those with limited life expectancy (less than 12 months)."...[T]he member's available medical records support that his life expectancy exceeds this limit....[I]f the member can be treated with the Health Plan's preferred combination of peg-interferon + ribavirin + Sovaldi x 12 weeks, then the denial of Sovaldi + Daklinza should be upheld.

Pursuant to the information set forth above and available documentation... treatment with Daklinza and Sovaldi is not medically necessary for treatment of the member's condition. [References 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. In addition, the IRO's recommendation is not contrary to any provision of the Petitioner's coverage. MCL 550.1911(15). The Director can discern no reason why that analysis should be rejected in the present case. Therefore, the Director adopts the IRO analysis and finds that treatment with Daklinza and Sovaldi is not medically necessary for the Petitioner.

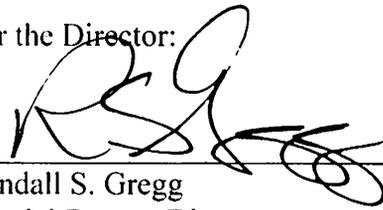
V. ORDER

The Director upholds BCBSM's April 15, 2016 final adverse determination. BCBSM is not required to provide coverage for Daklinza and Sovaldi as part of the Petitioner's treatment.

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:



Randall S. Gregg
Special Deputy Director