

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

In the matter of:

██████████
Petitioner

V

Health Alliance Plan of Michigan
Respondent

File No. 154409-001

Issued and entered
this 8th day of August 2016
by Randall S. Gregg
Special Deputy Director

ORDER

I. BACKGROUND

On July 1, 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 prescription drug coverage from Health Alliance Plan of Michigan (HAP), a health maintenance organization. The Director notified HAP of the external review request and asked for the information used to make its final adverse determination. HAP provided its response on July 7, 2015. On July 11, 2016, after a preliminary review of the material submitted, the Director accepted the request.

Because the case involves medical issues, it was assigned to an independent medical review organization which provided its analysis and recommendation on July 26, 2016.

II. FACTUAL BACKGROUND

The Petitioner is 45 years old and has chronic hepatitis C virus, genotype 3. His physician recommended treatment with a combination of the prescription drugs Daklinza and Sovaldi and requested that HAP provide coverage for their use. HAP denied the request.

The Petitioner appealed the denial through HAP's internal grievance process. At the conclusion of that process, HAP issued its final adverse determination upholding the denial. The Petitioner now seeks the Director's review of the final determination.

III. ISSUE

Did HAP properly deny prescription drug coverage for Daklinza and Sovaldi?

IV. ANALYSIS

Respondent's Argument

In its final adverse determination to the Petitioner, HAP stated:

After considering all available evidence, previous decisions and your medication history, the recommendation is to uphold the denial for the Hepatitis C Virus (HCV) treatment regimen consisting of Daklinza and Sovaldi for 12 weeks. Daklinza is not included on your formulary and is considered a non-formulary drug; therefore, the Hepatitis C treatment regimen consisting of Daklinza and Sovaldi is non-formulary.

Additionally, based on medical information submitted to HAP, your Fibrosure score (a tool used to assess the degree of inflammation and fibrosis of the liver) is below F3; specifically, the liver assessment demonstrates F0 fibrosis. Therefore, general criteria for use of any Hepatitis C Virus treatment regimen have not been met. For these two reasons, the original denial for the Hepatitis C Virus treatment regimen consisting of Daklinza and Sovaldi is upheld.

Petitioner's Argument

In a June 27, 2016 letter filed with the request for an external review, the Petitioner's doctor stated:

I am writing in response to the denial of Daklinza/Sovaldi to treat [the Petitioner], for his chronic hepatitis C GT 3 virus. It was stated in the letter that my patient would not be considered for treatment due to his liver disease not being advanced to the stage of F3 or higher on fibrosis scale as well as the medication not being on formulary.

Early detection and treatment of hepatitis C is my main focus as a practitioner of gastroenterology. Making my patient suffer through debilitating effects of this disease, both mentally and physically, for the reason that they are not sick enough is not valid reason for non-payment of Daklinza and Sovaldi. I urge you to reconsider the coverage for [Petitioner] as he suffers from a Necroinflammatory activity score of 0.71. This is equal to grade A3/severe activity.

The mental instability associated with hepatitis C causes depression and leads to social anxiety affecting quality of life. Please reconsider treatment with Daklinza and Sovaldi for [Petitioner] at this time as it is medically necessary and appropriate. Considering use of a less efficacious regimen can increase the risk of further complications, transplantation and/or death (including suicide).

Director's Review

HAP's denial of coverage for the Petitioner's Daklinza/Sovaldi treatment 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 in active practice who is board certified in internal medicine with a subspecialty in gastroenterology. The IRO reviewer's report included the following analysis and recommendation:

The landscape of treatment for hepatitis C virus (HCV) infection has evolved substantially since the introduction of highly effective HCV protease inhibitor therapies in 2011. The pace of change is expected to increase rapidly, as numerous new drugs with different mechanisms of action will likely become available over the next few years. To provide healthcare professionals with timely guidance as new therapies are available and integrated into HCV regimens, the American Association for the Study of Liver Diseases (AASLD) and Infectious Diseases Society of America (IDSA), in collaboration with the International Antiviral Society-USA (IAS-USA), developed a web-based process for the rapid formulation and dissemination of evidence-based expert-developed recommendations for hepatitis C management. In keeping with the spirit of the AASLD/IDSA, guidelines provided is a "living document" that is updated and services as the national standard by which patients with hepatitis C are provided treatment options.

In the most recent iteration pertinent to enrollee's circumstances (e.g. genotype 3 treatment-naïve without cirrhosis), AASLD/IDSA offers the following equal and highly recommended regimens:

- Daily daclatasvir (60 milligrams [mg] plus sofosbuvir (400 mg) for twelve weeks is a recommended regimen for treatment-naïve patients with HCV genotype 3 infection who do not have cirrhosis. Rating: Class I, Level A
- Daily fixed-dose combination of sofosbuvir (400 mg)/velpatasvir (100 mg) for twelve weeks is a recommended regimen for treatment-naïve patients with HCV genotype 3 infection who do not have cirrhosis. Rating: Class I, Level A

With specific reference to the treatment under review, AASLD/IDSA opines, "Daclatasvir with sofosbuvir for 12 weeks was approved by the [Food and Drug Administration] 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 [sustained virological response] rate of 90%. In treatment-naïve patients without cirrhosis (Metavir F0-F3), 97% achieved SVR 12, and in treatment-naïve patients with cirrhosis (Metavir F4), 58% achieved SVR12.”

The medical necessity of Daklinza in combination with Sovaldi is not diminished by health plan fibrosis thresholds nor now obsoleted AASLD/IDSA language that otherwise permitted treatment prioritization of “those patients with advanced fibrosis (Metavir F3), those with compensated cirrhosis (Metavir F4), liver transplant recipients, and patients with severe extrahepatic hepatitis C”. The documentation submitted for review does not support advanced fibrosis in this enrollee. However, the medical necessity of HCV treatment as per current AASLD/IDSA recommendations, and the medical appropriateness of therapy as proposed for this enrollee, exists irrespective of fibrosis score. AASLD/IDSA guidelines, updated October 22, 2015, 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).” The enrollee’s records support that his life expectancy exceeds this limit.

[B]ased on the documentation submitted for review, national guidelines and current medical literature, the regimen of Daklinza and Sovaldi is medically necessary for the treatment of the enrollee’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. The Director can discern no reason why the IRO’s recommendation should be rejected in the present case. The Director finds that Daklinza and Sovaldi are the current standard of treatment for patients with the Petitioner’s condition. HAP has offered no explanation for its exclusion of Daklinza from its drug formulary. This is significant in light of the IRO’s statement that the drug is a part of the currently preferred treatment for the Petitioner’s disease. If Daklinza is not presently listed on HAP’s formulary, it is a medically necessary nonformulary alternative. Coverage for such an alternative is mandated under section 3406o of the Michigan Insurance Code, MCL 500.3406o, which 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.

The requested course of treatment is medically necessary and, therefore, is a covered benefit under the benefit plan.

V. ORDER

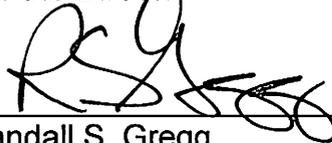
The Director reverses HAP's final adverse determination. HAP shall immediately provide coverage for the prescription drugs Daklinza and Sovaldi. See MCL 550.1911(17). HAP shall, within seven days of providing coverage, furnish the Director with proof it has implemented this order.

To enforce this order, the Petitioner may report any complaint regarding the implementation to the Department of Insurance and Financial Services, Health Care Appeals 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 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