

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. 150803-001-SF

County of Oakland
and
Navitus Health Solutions
Respondents

Issued and entered
this 14th day of December 2015
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On November 9, 2015, ██████████, authorized representative of ██████████ (Petitioner), filed a request for external review with the Department of Insurance and Financial Services. The request for review concerns a denial of prescription drug coverage issued by Navitus Health Solutions, the administrator of the Petitioner's health benefit plan which is sponsored by Oakland County.

The request for external review was filed under Public Act No. 495 of 2006 (Act 495), MCL 550.1951 *et seq.* Act 495 requires the Director to provide external reviews to a person covered by a self-funded health plan that is established or maintained by a state or local unit of government. The Director's review is performed "as though that person were a covered person under the Patient's Right to Independent Review Act." (MCL 550.1952) The Petitioner's health benefit plan is such a governmental self-funded plan.

On November 17, 2015, after a preliminary review of the information submitted, the Director accepted the Petitioner's request. The Director notified Navitus of the appeal and asked it to provide the information used to make its final adverse determination. Navitus furnished its response on November 19, 2015.

This case involves medical issues so the Director assigned it to an independent review organization which provided its analysis and recommendation to the Director on December 1, 2015.

II. FACTUAL BACKGROUND

The Petitioner has hepatitis C. Her doctor prescribed treatment with the drugs Daklinza and Sovaldi. Navitus denied coverage.

The Petitioner appealed the denials through the Navitus internal grievance process. At the conclusion of that process, on October 16, 2015, Navitus issued two final adverse determinations (one for each requested drug) affirming its denial of coverage. The Petitioner now seeks the Director's review of the final adverse determinations.

III. ISSUE

Was the Navitus denial of prescription drug coverage for Daklinza and Sovaldi appropriate?

IV. ANALYSIS

Navitus' Argument

In its final adverse determinations to the Petitioner, Navitus wrote:

Denial of Daklinza

This request has not been approved because this medication is a non-formulary medication and not covered based on the Pharmacy and Therapeutics (P&T) Committee guidelines for the coverage of non-formulary medications. Please refer to the formulary for specific information on what is covered. Additionally, Daklinza is only FDA-indicated for genotype 3, therefore treatment would be considered experimental and is excluded from coverage. Possible formulary alternatives include the following: Harvoni (prior authorization required).

Denial of Sovaldi

Based on the Pharmacy and Therapeutics (P&T) Committee prior authorization criteria for Solvaldi (genotype 2,3 and 4), this drug is covered for members who meet the following criteria: 1) Prescribed by a Gastroenterologist, Hepatologist, Infectious Disease or Transplant Specialist, and 2) Patient is diagnosed with chronic HCV including genotype and current HCV-RNA titer and date (must be within past 3 months), and 3) Patient has liver fibrosis (Metavir Score F2 or greater), documentation required, and 4) Patient is treatment naïve or if patient has been previously treated, documentation of the treatment response, regimen, duration, and reason for failure is required. In addition, your doctor has requested Daklinza, which is only FDA-approved for the treatment of Chronic Hepatitis C,

genotype 3 in combination with Sovaldi.

Based on the information we have received, you do not meet number 3 the prior authorization criteria because the documentation from your doctor indicates that you have a Metavir (fibrosis score of F0-F1 which is below the threshold for coverage.

Petitioner's Argument

The Petitioner's physician, in a letter dated October 9, 2015, wrote:

I am requesting reconsideration of your denial for the use of once daily Daklinza (daclatasvir) in combination with once daily Sovaldi⁴ (sofosbuvir) for 12 weeks for my patient, [Petitioner], who suffers from chronic hepatitis C (HCV) genotype 1A. The decision to utilize Daklinza and Sovaldi for 12 weeks is based on the results of a clinical trial conducted by Mark Sulkowski et al, for persons co-infected with HCV genotypes 1, 2 and 3. The study revealed a 98% sustained viral response 12 weeks post treatment (SVR12) for persons with genotype 1. This regimen is consistent with the joint recommendations of the American Association for the Study of Liver Diseases (AASLD) and Infectious Disease Society of America (IDSA). These guidelines, updated August 24, 2015, have become the gold standard for the treatment of persons with HCV. The full report of the AASLD/IDSA recommendations is available at www.hcvguidelines.org. This recommendation is also consistent with the EASL (European Association for the Study of the Liver) Recommendations on Treatment of Hepatitis C 2015 published in the Journal of Hepatology 2015.

The use of Daklinza in combination with Sovaldi is applicable to [Petitioner] as she is treatment naive and is ineligible for an interferon or ribavirin based regimen as she has bipolar disorder which can be greatly exacerbated by these medications. Daklinza in combination with Sovaldi has **a higher sustained viral response, was well tolerated** during clinical trial and has a **smaller pill burden** than FDA approved treatment regimens for genotype 1 HCV.

Even though [Petitioner] does not have F3 or F4 liver disease, she is **more likely to achieve SVR12** than persons with F3-F4 disease. Plus, significant medical costs can be avoided by treating [her] before the advancement of her liver disease. The safety and efficacy of Harvoni was established in clinical trial, thus reducing the cost needed to treat adverse events while [Petitioner] is on HCV treatment.

Therefore, treatment with Daklinza in combination with Sovaldi for 12 weeks IS a necessary therapy for [Petitioner's] medical condition, as it prevents disease progression to cirrhosis, hepatocellular carcinoma or even liver failure. These sequelae can necessitate liver transplant. In 2014, the cost of a liver transplant was estimated to be \$739,100 far exceeding the cost of treatment with the prescribed regimen.

Of further interest, compared to data findings from the National Multiple Cause of Death Study during 2006-2010, mortality rate of persons with HCV is 12 times higher than the national average. Plus, the average age at death was 15 years younger than the "all cause death age." With this in mind, it is my clinical opinion and assessment [Petitioner] will benefit from this regimen. I trust the

information presented, along with my medical recommendations, will establish the medical necessity for payment of this claim. [References omitted.]

Director's Review

The questions of whether the proposed drug combination of Sovaldi and Daklinza are medically necessary or are experimental in the treatment of the Petitioner's condition were presented to an independent review organization (IRO) for analysis and a recommendation 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 gastroenterology, has been in active practice for more than 15 years and is familiar with the medical management of patients with the Petitioner's condition. The IRO report included the following analysis and recommendation:

The member has a low viral load of 251K IU/ml. According to Fibrospect testing, the member is predicted to have F0-F1 fibrosis.

Daklinza in combination with Sovaldi can be an acceptable treatment for hepatitis C, genotype 1. However...the health plan's formulary drug is Harvoni, which is a very appropriate choice for this member...[T]here are no contraindications to therapy with Harvoni evident in the information provided for review. The member has a very low viral load and is treatment naïve with minimal fibrosis...[T]he Health Plan's medical criteria and coverage determination regarding Sovaldi for treatment of this member's condition was consistent with accepted standards of practice. [Citations omitted.]

Pursuant to the information set forth above and available documentation... Daklinza in combination with Sovaldi is experimental for 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 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 review 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. 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 finds that the prescription drug Daklinza in combination with Sovaldi is experimental for treatment of the Petitioner's condition and is therefore not a covered benefit under her benefit plan.

V. ORDER

The Director upholds Navitus's final adverse determinations dated October 16, 2015. Navitus is not required to approve coverage for the drugs Daklinza and Sovaldi for treatment of the Petitioner's condition.

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 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

A handwritten signature in black ink, appearing to read 'R. S. Gregg', is written over a horizontal line.

Randall S. Gregg
Special Deputy Director