

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. 150545-001

Blue Cross Blue Shield of Michigan
Respondent

Issued and entered
this 2nd day of December 2015
by Randall S. Gregg
Special Deputy Director

ORDER

I. BACKGROUND

On October 26, 2015, ██████████ (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 Director accepted the request on November 2, 2015. 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 November 9, 2015.

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

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 November 16, 2015.

II. FACTUAL BACKGROUND

The Petitioner is █ years old and has a history of relapsing remitting multiple sclerosis (RRMS). The Petitioner's physician prescribed the Plegridy Pen Injector for treatment of his condition. BCBSM denied approval for this drug since it is not a covered benefit under his certificate.

The Petitioner appealed the denial through BCBSM's internal grievance process. At the conclusion of that process, BCBSM issued a final adverse determination dated October 5, 2015, upholding the denial. The Petitioner now seeks from the Director a review of the denial.

III. ISSUE

Did BCBSM properly deny prescription drug coverage for the Plegridy Pen Injector?

IV. ANALYSIS

Respondent's Argument

In its final adverse determination, BCBSM wrote:

You are covered under the *Preferred Rx Program Certificate SG*. As explained in **Section 3: Prescription Drugs Not Covered**, on page 18 of the certificate, it states the following:

- We do not pay for anything other than covered drugs and services

A Clinical Pharmacist, PhP, reviewed your claim, your appeal, and your health care plan benefits for [BCBSM] and determined the following:

The requested medication is excluded from coverage under your Custom Select drug plan. Covered alternatives include: generic Copaxone 20mg, Copaxone 40 mg, Rebif, Extavia, Tecfidors (which requires prior authorization from BCBSM), Gilenya (which requires prior authorization from BCBSM), and Aubagio (which requires prior authorization from BCBSM).

Petitioner's Argument

In a letter filed with the request for an external review the Petitioner wrote:

[My doctor] thought that Plegridy to treat relapsing MS would prove to be a favorable option of treatment for me; he had to submit an appeal to [BCBSM], on my behalf, for a request for prior authorization for the Plegridy Pen Injector. I recently received notice that the appeal was denied as it was determined that the medication is excluded from coverage under my BCBSM prescription plan.

On the Plegridy.com site, it states "*Great News! Many of the top insurance providers are now covering PLEGRIDY (peginterferon beta-1a). You can expect to continue to see insurance providers adding PLEGRIDY to their plans over the coming months.*" In addition, the site does list, Blue Cross Blue Shield of Michigan and Blue Care Network of Michigan as insurance providers that cover Plegridy....

I do understand that there are many different types of plans and formularies within the Blue family of products. However, it would make sense that if it is covered by Blue Cross and Blue Shield of Michigan, that it should be covered for my BCBSM plan as well.

I would appreciate the consideration of an external review regarding coverage for this medication as it would require a reduced amount of injections, less anxiety and allow me to experience fewer relapses. These changes would improve the quality of my life.

Director's Review

BCBSM denied coverage for the Plegridy Pen Injector because it was not listed as a covered drug on BCBSM's Custom Select Drug List. However, under these circumstances, section 3406o of the Michigan Insurance Code, MCL 500.3406o, requires that insurers provide coverage for a nonformulary alternative when it is a medically necessary and appropriate alternative. The question of whether Plegridy Pen Injector is medically necessary for the treatment of Petitioner's condition as presented by the Director to an independent review organization (IRO) for analysis of this medical question 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 certified by the American Board of Psychiatry and Neurology with a subspecialty in clinical neurophysiology. The IRO reviewer's report included the following analysis and conclusion:

Patients with RRMS are currently treated with a disease modifying drug to reduce the frequency of relapse and long-term disability. Many options are available and they include injectable medications, such as Rebif, Avonex, and Copaxone, and oral medications, such as Tecfidera and Gilenya.

* * *

The Plegridy Pen Injector provides Peginterferon beta-1a, which is one of the new disease modifying drugs approved by the Food and Drug Administration (FDA) in 2014 for the treatment of RRMS. Peginterferon beta-1a is a drug that belongs to the same interferon class as several medications that have been approved by the FDA for the treatment of people with relapsing forms of MS, including Avonex. It is a "pegylated" form of interferon beta-1a, meaning that polyethylene glycol is attached to the interferon molecules, which enables them to maintain biologic effects in the body for longer periods of time and allows for less frequent dosing. Plegridy is given by subcutaneous injections once every two weeks. Per the enrollee's undated letter in the documentation submitted for review, the reduced number of injections with Plegridy will result in less anxiety for him and improved quality of life. However, many other disease modifying medications are currently FDA approved for the management of RRMS. Several of these are oral medications, such as Techfidera, Gilenya and Aubagio, which would not cause needle phobia and anxiety.

The enrollee is a [REDACTED] year old [REDACTED] who has been on Avonex therapy since July 2013. The enrollee has had a recent relapse resulting in thoracic paresthesias and Plegridy has been prescribed. The clinical notes submitted for review provided no explanation for the medication change, and the only disease modifying medication tried by the enrollee was Avonex. No side effects due to Avonex are mentioned. The enrollee's neurologist lists Avonex as "not helpful" in his request for approval of Plegridy.

There are no studies indicating a superior efficacy of Peginterferon beta-1a (Plegridy) over interferon beta-1a (Avonex). In the ADVANCE clinical trial, Plegridy administered every two weeks was found to be superior to placebo in reducing the MS relapse rate, but no

direct comparison exists between Plegridy and Avonex or any other MS modifying medications. Therefore, based on the documentation submitted for review and current medical literature, the Plegridy Pen Injector is not medically necessary for this enrollee.

Recommendation:

It is the recommendation of this reviewer that the denial issued by Blue Cross Blue Shield of Michigan for the Plegridy Pen Injector be upheld.

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 the IRO's recommendation should be rejected in the present case.

The Director finds that the Plegridy Pen Injector is not medically necessary in the treatment of the Petitioner's condition.

V. ORDER

The Director upholds BCBSM's October 5, 2015 final adverse determination. BCBSM is not required to provide the Petitioner with coverage for the Plegridy Pen Injector.

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