

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. 149112-001

Blue Cross Blue Shield of Michigan
Respondent

Issued and entered
this 21st day of August 2015
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On July 31, 2015, ██████████ authorized representative of his patient ██████████ (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 August 7, 2015.

The Petitioner receives health care benefits under a group plan underwritten by Blue Cross Blue Shield of Michigan (BCBSM). The Director notified BCBSM of the external review request and requested the information used to make its final adverse determination. BCBSM provided its response on August 12, 2015.

To address the medical issues presented in this appeal, the Director assigned the case to an independent medical review organization which provided its analysis and recommendation on August 19, 2015.

II. FACTUAL BACKGROUND

The Petitioner's prescription drug benefits are defined in BCBSM's *Simply Blue HSA*

*Group Benefits Certificate Without Prescription Drugs LG.*¹

The Petitioner has Crohn's disease. His doctor prescribed Cimzia and requested that BCBSM provide coverage for the drug. The request was submitted to BCBSM on its prior authorization request form as required in the *Simply Blue* certificate of coverage. BCBSM denied the request.

The Petitioner appealed the denial through BCBSM's internal grievance process. At the conclusion of that process, BCBSM affirmed its denial in a final adverse determination dated July 10, 2015. The Petitioner now seeks a review of that final adverse determination from the Director.

III. ISSUE

Did BCBSM correctly deny coverage for Cimzia to treat Petitioner's Crohn's disease?

IV. ANALYSIS

Petitioner's Argument

In a letter dated June 30, 2015, submitted for the external review, the Petitioner's authorized representative wrote:

[Petitioner] has been followed in our office for Crohn's disease of the terminal ileum. He has a known terminal ileal stricture and has been hospitalized for small bowel obstruction. The patient was recently started on Cimzia and actually is doing quite well with this and a mesalamine product. I understand that it is your policy that either Remicade or Humira be the first line of defense; however, in light of the patient's response to the medication, I hate to stop him on this since he is doing so well.

BCBSM's Argument

In its final adverse determination, BCBSM's representative wrote:

Cimzia is a specialty pharmaceutical that requires prior authorization. For this reason, a Clinical Pharmacist, RPH reviewed the appeal and the notes from your Conference and determined the following:

1. Despite its title, the *Simply Blue* certificate does provide prescription drug coverage which is described on pages 75-77 of the certificate.

The Medical Policy for Cimzia, in patients with Crohn's Disease (CD), requires you to have tried and failed Humira and Remicade. While we have record that you are diagnosed with CD, we have no record that you have tried and failed Humira and Remicade.

Therefore, prior authorization could not be approved....

Director's Review

The *Simply Blue* certificate (pages 76-77) requires prior authorization for specialty drugs:

- Prior authorization is required for select specialty pharmaceuticals administered in locations as determined by BCBSM, including but not limited to the following: office, clinic or home. The prior authorization requirement affects all in-state and out-of-state services. The prescribing physician should contact BCBSM and follow BCBSM's utilization management processes in order to obtain prior authorization of the specialty pharmaceuticals. We will notify the prescribing physician whether the request has been granted after receiving all the information needed to evaluate the request. Only FDA-approved medications are eligible for prior authorization and of those drugs, only the specialty pharmaceuticals that meet BCBSM's medical policy criteria for treatment of the condition will be preauthorized.
 - If prior authorization is requested, but is not approved by BCBSM, you have the right to appeal under applicable law. If the prior authorization is not approved via the appeal, you will be responsible for the full cost of the specialty pharmaceuticals.

BCBSM also has a medical policy for Cimzia describing its uses and the criteria for coverage. The policy was effective February 12, 2015. The policy states that Cimzia is a covered drug when used for "acute treatment of an exacerbation of Crohn's disease" when one of four listed criteria are met. These standards are not addressed in BCBSM's final adverse determination. BCBSM only states that an individual must "have tried and failed Humira and Remicade" before Cimzia will be covered. This explicit requirement does not appear in the medical policy.

The medical policy lists three treatment options for treating Crohn's disease: glucocorticoids, immunosuppressants, and biologic agents. Humira and Remicade are biologic agents. The policy states that Cimzia is indicated "for reducing signs and symptoms of Crohn's disease and maintaining clinical response in adult patients with moderately to severely active

disease who have had an inadequate response to conventional therapy.” The policy does not specify treatments that are “conventional therapy.”

BCBSM does have an “authorization request form” to be submitted when coverage for Cimzia is requested. The form contains two questions about medication with which the Petitioner has previously been treated. The Petitioner’s doctor indicated on the form that the Petitioner had previously been treated with the drug Pentasa, an anti-inflammatory drug used to treat mild to moderate Crohn’s disease.

While the Petitioner appears not to have been treated with Humira or Remicade, he has been unsuccessfully treated with another drug, Pentasa, which is a conventional treatment for Crohn’s disease.

The propriety of the use of Cimzia for the treatment of Crohn’s disease was presented to 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 who is certified by the American Board of Internal Medicine with a subspecialty certification in gastroenterology. The reviewer is a clinical assistant professor of a university-based medical college and is published in peer reviewed medical literature. The IRO reviewer’s report included the following analysis and recommendation:

The use of Cimzia is well-supported in Crohn’s disease. The United States Food and Drug Administration (FDA) has approved this medication for use in the enrollee’s clinical condition. There is no medical literature that recommends or requires the use of Remicade or Humira prior to consideration of Cimzia in the management of Crohn’s disease. For the reasons noted above, Cimzia is appropriate for treatment of Crohn’s disease and is medically necessary for this enrollee. [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 recommendation is not contrary to any provision of the Petitioner’s certificate of 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 Cimzia is a medically necessary and appropriate treatment for the Petitioner's condition.

V. ORDER

The Director reverses BCBSM's final adverse determination of July 10, 2015. BCBSM shall immediately provide the Petitioner with prescription drug coverage for Cimzia. See MCL 550.1911(17). BCBSM shall, within seven days of providing coverage, furnish the Director proof it has implemented this order.

To enforce this order, the Petitioner may report any complaint regarding its implementation the Department of Insurance and Financial Services, Health Plans Division, toll free 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 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:



Randall S. Gregg
Special Deputy Director