

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. 154499-001

Blue Cross Blue Shield of Michigan
Respondent

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

ORDER

I. PROCEDURAL BACKGROUND

██████████ (Petitioner) was denied coverage for a prescription drug by her health insurer, Blue Cross Blue Shield of Michigan (BCBSM). On July 7, 2016, the Petitioner filed a request with the Director of Insurance and Financial Services for an external review of that denial 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 July 14, 2016.

The Petitioner receives prescription drug benefits through a plan underwritten by BCBSM. The benefits are described 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 responded on July 22, 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 July 28, 2016.

II. FACTUAL BACKGROUND

The Petitioner is 44 years old. She was diagnosed in February 2013 with relapsing remitting multiple sclerosis. She has been treated, unsuccessfully, with the prescription drugs Avonex and Copaxone. Her physician asked BCBSM to provide

coverage for the specialty drug Tysabri (natalizumab). BCBSM denied the request.

The Petitioner appealed the denial through BCBSM's internal grievance process. BCBSM affirmed its decision in a final adverse determination dated June 29, 2016. The Petitioner now seeks the Director's review of that final adverse determination.

III. ISSUE

Did BCBSM correctly deny prescription drug coverage for Tysabri?

IV. ANALYSIS

BCBSM's Argument

In its final adverse determination, BCBSM's representative stated that the Petitioner's appeal had been reviewed by a clinical pharmacist who wrote:

The Medical Policy for Tysabri, in patients with relapsing remitting multiple sclerosis (RRMS), requires you to have tried and failed at least one injectable agent (examples: Avonex, Betaseron, Copaxone, Extavia, and Rebif) AND at least one oral agent (examples: Aubagio, Gilenya, and Tecfidera). We have record you have tried at least one injectable agent; however, we have no record that you tried and failed treatment with at least one oral agent from the list above.

Petitioner's Argument

On the request for external review form, the Petitioner wrote:

BCBSM has denied me medication prescribed and ordered by my doctor. I have met all criteria per BCBSM guidelines. I am a MS patient and need this medication (Tysabri) and wish to have the medication paid for by BCBSM.

Director's Review

Tysabri is a prescription drug listed on BCBSM drug formulary. In order to be covered, the drug must be approved by BCBSM according to standards listed in BCBSM's "Medication Use Policy for Tysabri (natalizumab)."

The Director assigned an independent review organization (IRO) to evaluate BCBSM's Tysabri policy and to determine whether Tysabri is medically necessary in the Petitioner's treatment. Evaluation of medical issues by an IRO is required by section 11(6) of the Patient's Right to Independent Review Act, MCL 550.1911(6).

The IRO reviewer in this case is a physician in active practice who is certified by the American Board of Psychiatry and Neurology with a subspecialty in clinical neurophysiology. The reviewer is a member of the American Academy of Neurology and the American Epilepsy Society and is published in peer reviewed medical literature. The IRO report included the following analysis in response to questions presented by the Director.

Has the enrollee met the plan's criteria for coverage for Tysabri?

No. The enrollee has not met the plan's criteria for coverage of Tysabri. The plan's criteria for Tysabri coverage specify that the patient should try and fail at least an injectable and an oral disease modifying drug prior to the coverage being approved.

Are the plan's coverage criteria for Tysabri consistent with the current medical standard of care for treatment of the enrollee's condition?

No. The plan's coverage criteria for Tysabri is not consistent with the current medical standard of care for the treatment of the enrollee's condition. The current standard of care for patients with RRMS is detailed below.

Clinical Rationale for the Decision:

The standard of care for the treatment of MS in a patient with the enrollee's clinical circumstances includes starting Tysabri in patients who do not have significant contraindications to this medication. Tysabri could increase the risk of PML and therefore is not indicated in patients who are JC virus antibody positive or have had immunosuppressant therapies previously with medications such as methotrexate or azathioprine. All other patients failing to respond to first line disease modifying therapies, either oral or injectable, or who have a heavy MS lesion burden should be able to benefit from the superior efficacy of Tysabri in preventing MS relapses and reducing disability.

[Description of published medical studies omitted.]

The enrollee is suffering from RRMS with cerebral and cervical cord lesions. She has been treated with Avonex and more recently Copaxone and this failed to control her disease. Tysabri has been recommended since the enrollee has been having relapses while taking these drugs appropriately and according to her neurologist's notes, she has been having worsening MRI abnormalities as well. Therefore, based on the documentation submitted for review and current medical literature, the medication Tysabri is medically necessary for the treatment of this enrollee.

Recommendation:

It is the recommendation of this reviewer that the denial issued by Blue Cross Blue Shield of Michigan for Tysabri be overturned.

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, discerning no reason why the IRO's recommendation should be rejected, adopts the recommendation and finds that Tysabri is the appropriate medical treatment and is medically necessary for the Petitioner.

V. ORDER

The Director reverses BCBSM's final adverse determination. BCBSM shall immediately provide coverage of Tysabri for the Petitioner. See MCL 550.1911(17). Further, BCBSM shall, within seven days of authorizing coverage, furnish the Director with proof it has implemented this order.

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