

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. 153603-001

Blue Cross Blue Shield of Michigan  
Respondent

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Issued and entered  
this 13<sup>th</sup> day of June 2016  
by Randall S. Gregg  
Special Deputy Director

**ORDER**

**I. PROCEDURAL BACKGROUND**

On May █, 2016, Dr. ██████████, 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.* After a preliminary review of the material submitted, the Director accepted the request on May 17, 2016.

The Petitioner receives prescription drug benefits through a plan underwritten by Blue Cross Blue Shield of Michigan (BCBSM). The benefits are defined in BCBSM's *Preferred Rx Program Certificate LG* and a related rider describing copayments, specialty pharmacy requirements, and other cost management features.

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 May 20, 2016. The Petitioner's representative provided additional information on June 1, 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 June 3, 2016.

**II. FACTUAL BACKGROUND**

The Petitioner is 67 years old and has been diagnosed with hyperlipidemia (too many lipids – fats – in the blood). His primary care physician prescribed the drug Repatha. BCBSM denied coverage, ruling that the Petitioner does not meet its criteria for coverage.

The Petitioner appealed the denial through BCBSM's internal grievance process. At the conclusion of that process, BCBSM affirmed its decision in a final adverse determination issued April 5, 2016. The Petitioner now seeks a review of that adverse determination from the Director.

### III. ISSUE

Did BCBSM correctly deny coverage for the prescription drug Repatha to treat the Petitioner?

### IV. Analysis

#### BCBSM's Argument

In the April 5, 2016, final adverse determination BCBSM described its coverage criteria for approval of Repatha and the ways in which, it believes, the Petitioner failed to satisfy the criteria:

1) Our criteria for coverage of the requested medication requires a record (chart notes) of a diagnosis of homozygous familial hypercholesterolemia, heterozygous familial hypercholesterolemia, or clinical atherosclerotic cardiovascular disease. We have no record (chart notes) of either diagnosis.

AND

2) Our criteria for coverage of the requested medication requires that the prescriber is a cardiologist, endocrinologist, or a board certified lipidologist. We have no record that this criteria has been met.

AND

3) Our criteria for coverage of the requested medication require a record (lab report within the last 3 months) of uncontrolled LDL. We have no record (lab report within the last 3 months) of uncontrolled LDL.

AND

4) Our criteria for coverage of the requested medication require a record (chart notes) of adherence with maximally tolerated concurrent treatment with a high intensity statin, ezetimibe, AND a bile acid sequestrant. Pharmacy claims data does not support adherence with all of the required medications.

AND

5) Our criteria for coverage of the requested medication for "statin intolerance" require that you try 3 different statins, in the absence of drug interactions. We have no record (chart notes) of trials with 3 different statins, in the absence of drug interactions....

The requested medication (Repatha) is only FDA approved for use in COMBINATION with a statin; it is not FDA approved as mono-therapy. Please note: A trial with a long-acting non-daily statin may be an option for you, which may be easier to tolerate.

AND

6) Our criteria for coverage of the requested medication require a record (chart notes) of lifestyle modification (heart healthy diet, regular exercise, tobacco avoidance). We have no record of this criteria being met.

Therefore, preauthorization could not be approved; you will be liable for the charges if this prescription is filled.

### Petitioner's Argument

In a letter dated April 20, 2016, filed with the request for external review, the Petitioner's doctor wrote:

This letter is regarding [the Petitioner's] insurance denial of Repatha for the grounds that I am not a Cardiologist, Endocrinologist or a Lipidologist.

I have been [the Petitioner's] physician since 5-7-2013. I have diagnosed him with Hyperlipidemia, Hypertension, Morbid Obesity, Lumbar Disc Degeneration, Rheumatoid Arthritis, Hypothyroidism, and he is S/P DVT with IVC filter placement.

The Patient has tried 4 Statins with side effects and the inability to tolerate the drugs. His insurance states that his Pharmacy claims do not support adherence with other Statins. While I was not his physician at the time, most physicians give their patients samples to try the drugs prior to ordering them when they have a history of adverse reactions. It is unfair to base a denial of a medication due to this criteria.

His 10 year risk of ASCVD is estimated at 20% and current guidelines recommend a high dose statin to reduce the risk. Do I have to be a Cardiologist to follow current recommendations? I am trying to keep him from having his first ASCV event. His insurance criteria requires he has already had an event. The whole idea behind a Statin is prevention. Prevention is more cost effective and provides a better life for the patient. So far, the drug company has been providing samples of Repatha for [the Petitioner], but this is not a long term solution.

### Director's Review

The use of Repatha to treat the Petitioner's medical condition 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 certified by the American Board of Internal Medicine with a subspecialty in infectious disease. The reviewer is an associate professor of medicine at a university based school of medicine and is published in peer reviewed medical literature.

The IRO reviewer concluded that BCBSM's criteria for approving coverage for Repatha is the appropriate standard. The IRO also concluded that the Petitioner did not meet those standards. The IRO report states:

#### **Clinical Rationale for the Decision:**

The references below show the efficacy and safety of Repatha, but the editorial recommends careful selection of patients using Repatha until further long-term trials are completed to confirm the effectiveness and lack of side effects. In addition, Food and Drug Administration (FDA) approval requires the use of Repatha in conjunction with a statin. The use of Repatha as monotherapy is not approved by the FDA.

The enrollee has hyperlipidemia and has failed statins due to lack of effect and/or side effects as per the provider. Alternative treatments are available in place of Repatha and consideration of the use of these therapies should be considered prior to the use of Repatha. Therefore, for the reasons noted above, the prescription drug Repatha is not medically necessary for this enrollee.

**References:**

1. Sabatine MS, Giugliano RP, Wiviott SD, et al. Efficacy and safety of evolocumab in reducing lipids and cardiovascular events. *N Engl J Med.* 2015;372(16): 1500-9.
2. Sullivan D, Olsson AG, Scott R, et al. Effect of a monoclonal antibody to PCSK9 on low-density lipoprotein cholesterol levels in statin-intolerant patients: the GAUSS randomized trial. *JAMA.* 2012;308(23):2497-506.
3. Stone NJ, Lloyd-Jones DM. Lowering LDL Cholesterol Is Good, but How and in Whom? *NEJM* 2015;372: 1564-65.

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 that analysis should be rejected in the present case. In addition, the IRO's recommendation is not contrary to any provision of the Petitioner's coverage. MCL 550.1911(15). Therefore, the Director adopts the IRO analysis and finds that Repatha is not medically necessary to treat the Petitioner.

**V. ORDER**

The Director upholds BCBSM's April 5, 2016 final adverse determination. BCBSM is not required to provide coverage for Repatha to treat 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 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:

  
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Randall S. Gregg  
Special Deputy Director