

**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. 146662-001**

**Blue Cross Blue Shield of Michigan**

**Respondent**

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**Issued and entered**  
**this 2<sup>nd</sup> day of April 2015**  
**by Joseph A. Garcia**  
**Special Deputy Director**

**ORDER**

**I. PROCEDURAL BACKGROUND**

On March 5, 2015, ██████████, MD, 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 March 12, 2015.

The Petitioner receives prescription drug benefits through a group plan underwritten by Blue Cross Blue Shield of Michigan (BCBSM). The Director immediately 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 March 12, 2015.

To address the medical issues in the case, the Director assigned it to an independent medical review organization which provided its analysis and recommendation on March 26, 2015.

**II. FACTUAL BACKGROUND**

The prescription drug benefits are defined in BCBSM's *Simply Blue HSA Group Benefits Certificate with Prescription Drugs SG*<sup>1</sup> (the certificate).

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<sup>1</sup> BCBSM form no. 913F, effective 2015.

██████████, the Petitioner's rheumatologist, asked BCBSM to authorize coverage for the infused prescription drug Simponi Aria to treat the Petitioner's "chronic inflammatory arthritis most likely related to chronic Hepatitis C, arthritis with features of both Rheumatoid Arthritis (RA) and Psoriatic Arthritis." 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 February 18, 2015. The Petitioner now seeks a review of that adverse determination from the Director.

### III. ISSUE

Did BCBSM correctly deny authorization for the prescription drug Simponi Aria?

### IV. ANALYSIS

#### Petitioner's Argument

In a letter to BCBSM dated February 13, 2015, ██████████ explained his reasons for requesting coverage of Simponi Aria:

[The Petitioner] has had incomplete response with prior therapies but nonetheless she had significant exam improvement while on prior TNF inhibitor therapy. For these reasons and her limited ability to take other medications due to chronic liver disease, I have prescribed Simponi Aria in an attempt to better control her inflammatory disease.

Although Simponi Aria is a different mode of delivery, it is the same agent as the subcutaneous form of Simponi which is approved for the treatment of both Psoriatic arthritis as well as RA. As noted, she had already shown positive effect from TNF inhibition in the past, but with an incomplete response. Therefore, changing the mode of delivery makes sense to help improve [her] response and tolerance and is indeed medically necessary. This agent . . . should not be denied to this patient simply because of a coding difference of her arthritis type, as a different form of arthritis is not a rationale for treatment decisions when the drug class is known to be both safe and effective in this condition.

#### BCBSM's Argument

In its final adverse determination, BCBSM's representative told the Petitioner:

. . . After review, I confirmed that you do not meet the criteria necessary for coverage and the prior authorization remains denied.

You are covered under the [certificate] which details the prior authorization for Specialty Pharmaceuticals on page 84 to 85. The certificate states that preauthorization is required for select specialty pharmaceuticals administered in locations as determined by BCBSM, including but not limited to the following: office, clinic or home. Only FDA-approved medications are eligible for preauthorization and of those drugs, only the specialty pharmaceuticals that meet BCBSM's medical policy criteria for treatment of the condition will be preauthorized.

\* \* \*

The clinical pharmacist that reviewed the documentation provided by [REDACTED] [REDACTED] determined that the Medical Policy for Treatment of Advanced Rheumatoid Arthritis requires that the patient has a diagnosis of Rheumatoid Arthritis. We have no record the patient the patient has this diagnosis. According to our record you have a diagnosis of unspecified inflammatory polyarthropathy associated with chronic Hepatitis C infection.

AND

The Medical Policy for Treatment of Advanced Rheumatoid Arthritis requires that the patient was treated (or could not be treated) with at least two of these drugs: Enbrel, Humira, or Remicade. While you have received Remicade, treatment with Enbrel or Humira is needed.

Because you do not meet the criteria required for prior authorization, the authorization remains denied.

#### Director's Review

BCBSM denied coverage for Simponi Aria because the Petitioner did not meet its criteria for use of the drug, i.e., it is not medically necessary to treat her condition.

The question of whether Simponi Aria infusions are medically necessary for treatment of the Petitioner's condition 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 physician reviewer is board certified in internal medicine and rheumatology and has been in practice for more than ten years and is familiar with the medical management of patients with the member's condition. The IRO report included the following analysis and recommendation:

#### **Rationale:**

The MAXIMUS physician consultant explained that Simponi Aria is currently approved for treatment of moderate rheumatoid arthritis. Simponi Aria is not indicated to treat this member's medical condition. The physician consultant indicated that the use of this medication to treat other conditions is considered

off-label and investigational. The consultant explains that the safety and efficacy of Simponi Aria for treatment of types of arthritis other than rheumatoid arthritis is currently unproven. Additionally, the member does not meet the health plan's criteria for coverage of this medication.

Pursuant to the information set forth above and available documentation, the MAXIMUS physician consultant determined that Simponi Aria infusions are not medically necessary for treatment of the member's condition. [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, discerning no reason why the IRO's recommendation should be rejected in this case, finds that Simponi Aria is not medically necessary for treatment of the Petitioner's condition and is therefore not a covered benefit under the certificate.

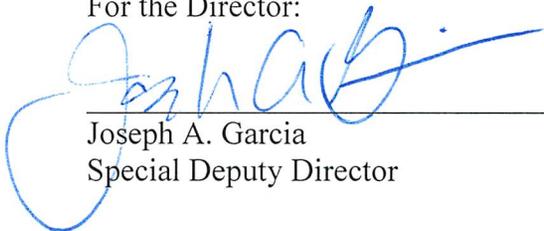
#### V. ORDER

The Director upholds BCBSM's final adverse determination of February 18, 2015.

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.

Annette E. Flood  
Director

For the Director:

  
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Joseph A. Garcia  
Special Deputy Director