

**STATE OF MICHIGAN**  
**DEPARTMENT OF INSURANCE AND FINANCIAL SERVICES**  
**Before the Director of Insurance and Financial Services**

**In the matter of:**

██████████  
**Petitioner**

v

**Van Dyke Board of Education**  
**and**  
**Blue Cross Blue Shield of Michigan**  
**Respondents**

**File No. 150435-001-SF**

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**Issued and entered**  
this 18<sup>th</sup> day of November 2015  
by **Joseph A. Garcia**  
**Special Deputy Director**

**ORDER**

**I. PROCEDURAL BACKGROUND**

On October 20, 2015, ██████████, authorized representative of ██████████ (Petitioner), filed a request with the Department of Insurance and Financial Services for an external review under Public Act No. 495 of 2006 (Act 495), MCL 550.1951 *et seq.* Act 495 authorizes the Director to conduct reviews of claim denials in governmental self-funded health plans in the same manner as reviews under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.*

The Petitioner receives health care benefits through a plan sponsored by Van Dyke Board of Education, a self-funded governmental health plan. Blue Cross Blue Shield of Michigan (BCBSM) administers the plan. The benefits are described in BCBSM's *Community Blue Group Benefits Certificate ASC*.

On October 27, 2015, after a preliminary review of the information submitted, the Director accepted the request.

The Director notified BCBSM of the external review request and asked for the information it used to make its final adverse determination. BCBSM's response was received on November 3, 2015.

The medical issues in the case were assigned for analysis by an independent review organization which submitted its report to the Director on November 10, 2015.

## II. FACTUAL BACKGROUND

The Petitioner has been diagnosed with systemic lupus erythematosus. She has been treated with the prescription drug Plaquenil which has apparently been covered under her benefit plan. Her physician now believes she should be treated with Benlysta. BCBSM has denied coverage for Benlysta.

The Petitioner appealed the denial through BCBSM's internal grievance process. At the conclusion of that process BCBSM issued a final adverse determination on October 13, 2015, affirming its denial. The Petitioner now seeks review of that final adverse determination from the Director.

## III. ISSUE

Is the prescription drug Benlysta medically necessary for treatment of the Petitioner's condition?

## IV. ANALYSIS

### BCBSM's Argument

In its final adverse determination, BCBSM wrote:

Benlysta is a specialty pharmaceutical that requires prior authorization. For this reason, a Clinical Pharmacist, RPh reviewed the submitted documentation and the notes from your conference and determined the following:

The Medical Policy for Benlysta, for the diagnosis of systemic lupus erythematosus, requires a documented disease activity score of 6 or higher. We have no record of your activity score being 6 or higher.

AND

The Medical Policy for Benlysta, for the diagnosis of systemic lupus erythematosus requires that you have been treated or could not be treated with two or more of the following drugs for at least 12 weeks each, such as: chloroquine, methotrexate, azathioprine, cyclophosphamide or mycophenylate mofetil. While you have tried one drug, you need to try another agent such as: methotrexate, azathioprine, cyclophosphamide or mycophenylate mofetil.

AND

The Medical Policy for Benlysta, for the diagnosis of systemic lupus erythematosus (SLE), requires that you are currently and will continue to receive standard therapies to treat SLE (examples: antimalarials, corticosteroids, and non-biologic immunosuppressives). We have no record that you are currently receiving and will continue to receive standard therapies from the list above.

Therefore, prior authorization could not be approved.

### Petitioner's Argument

In the request for external review, the Petitioner's representative wrote that the Petitioner has a global assessment score of 7 and the Benlysta is a continuation of the Petitioner's therapy.

### Director's Review

The question of whether the drug Benlysta is medically necessary for treatment the Petitioner's condition was presented to an independent review organization (IRO) for analysis and a recommendation as required by section 11(6) of the Patient's Right to Independent Review Act, MCL 550.1911(6).

The IRO physician reviewer is a physician in active practice who is certified by the American Board of Internal Medicine with a subspecialty in rheumatology. The IRO reviewer's report included the following analysis and recommendation:

The American College of Rheumatology (ACR) Medication Guide Pertaining to the drug Benlysta [citation omitted], states that this drug is indicated, per the Food and Drug Administration (FDA) approval, for the treatment of adult patients with active, autoantibody positive, SLE who are already receiving standard therapy.

The documentation submitted for review does not prove the enrollee's diagnosis of SLE and does not indicate any sign of "active" disease. The onset and duration of this enrollee's stated diagnosis is not indicated or elucidated in the medical records provided. Furthermore, the basis for the diagnosis is also not substantiated by the documentation of minimal criteria needed to make a diagnosis of SLE. The only "positive" criterion met according to the "1997 Update of the 1982 American College of Rheumatology Revised Criteria for Classification of Systemic Lupus Erythematosus" [citation omitted] is a minimally invasive positive antinuclear antibody (ANA) test at a titer of 1:160. Anti-nuclear antibodies are measureable in approximately 25% of the general population. "Most individuals with a positive ANA do not have an autoimmune disease and most also are unlikely to develop one." [citation omitted] The revised

ACR Criteria for Diagnosis of SLE are not satisfied in this case to be certain the enrollee's diagnosis of SLE is accurate. [Citation omitted]

\* \* \*

There is evidence provided that the enrollee has been on hydroxychloroquine (Plaquenil), but the dose, duration, and response of that therapy is not readily clear. A Selena-Sledai scoring template was submitted with no positive responses. This would indicate that if the enrollee indeed has the disease, then it can be presumed that she is in full remission on the previous medication stated. She would therefore not need additional or alternate forms of medication.

The physician note dated August 31, 2015 revealed a checklist positive for inflammatory polyarthritis and SLE, but no clarification, descriptions or physical support of these claimed diagnoses. The physical examination section stated synovitis, but no joint count or description of which joint(s) and how bad. The review of systems was negative, but there is a statement that the physician global assessment was seven (7). There was no clarification of what scale this global assessment was based on. The registered nurse note during a Benlysta infusion on August 10, 2015 stated the enrollee complained of "mild joint stiffness just in the last few days, took nothing for pain today." There was no further documentation of which joints or any other descriptions of signs of inflammation.

The clinical data submitted by the treating physician does not indicate that there is a need for any change in therapy, since there are minimal complaints or documentation of active disease. The enrollee's complaint of stiffness in joints is vague, non-diagnostic and unconvincing according to the records submitted. If this enrollee does in fact have SLE, then her current condition is stable on her current medication regimen.

Indications of the use of Benlysta are not as per the medication guide recommended by the ACR. [Citation omitted] In addition, per the documentation submitted for review, the enrollee has not tried and failed or not tolerated at least two previous medications in the list of traditional therapies for the treatment of SLE. Furthermore, there is no documentation or proof of active disease (Selena-Sledai Score). For the reasons noted above, the prescription drug Benlysta does not meet the health plan's criteria and is not medically necessary for this enrollee.

\* \* \*

It is the recommendation of this reviewer that the denial issued by Blue Cross Blue Shield of Michigan for the prescription drug Benlysta 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 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 review is based on extensive experience, expertise, and professional judgment and 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 the present case, adopts the IRO's conclusion that the prescription drug Benlysta does not meet BCBSM's criteria for coverage and is not medically necessary for treatment of the Petitioner's condition.

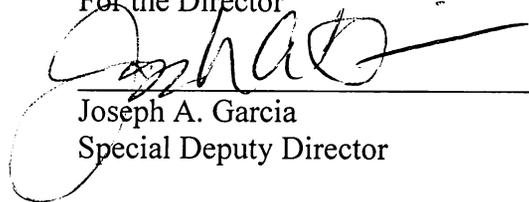
**V. ORDER**

The Director upholds BCBSM's final adverse determination dated October 13, 2015. BCBSM is not required to provide coverage for the drug Benlysta.

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



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Joseph A. Garcia  
Special Deputy Director