

**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. 151142-001-SF**

**State of Michigan, Plan Sponsor,**

**and**

**Blue Cross Blue Shield of Michigan, Plan Administrator,**

**Respondents.**

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**Issued and entered**  
this 15<sup>th</sup> day of January 2016  
**by Randall S. Gregg**  
**Special Deputy Director**

**ORDER**

**I. PROCEDURAL BACKGROUND**

██████████ (Petitioner) asked his health plan to cover the prescription drug Privigen for intravenous immunoglobulin (IVIG) therapy. The request was denied.

On December 3, 2015, the Petitioner filed a request with the Director of Insurance and Financial Services for an external review of the denial under Public Act No. 495 of 2006 (Act 495), MCL 550.1951 *et seq.* On December 10, 2015, after a preliminary review of the information submitted, the Director accepted the Petitioner's request.

The Petitioner receives health care benefits through a plan sponsored by the State of Michigan (the State Health Plan or the plan), a self-funded governmental health plan as defined in Act 495. The plan is administered 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 the plan's final adverse determination. BCBSM furnished its response on December 18, 2015.

Section 2(2) of Act 495, MCL 550.1952(2), authorizes the Director to conduct this external review as though the Petitioner were a covered person under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.*

To address the medical issue in this case, the Director assigned it to an independent medical review organization which provided its analysis and recommendation on December 24, 2015.

## II. FACTUAL BACKGROUND

The Petitioner's health care benefits are described in a booklet called *Your Benefit Guide State Health Plan PPO* (the benefit guide).<sup>1</sup>

The Petitioner's physician requested authorization and coverage for the specialty drug Privigen. Acting for the plan, BCBSM denied the request saying the treatment was not medically necessary for treatment of the Petitioner's condition.

The Petitioner appealed the denial through the plan's internal grievance process. At the conclusion of that process, BCBSM issued a final adverse determination dated November 3, 2015, upholding the denial. The Petitioner now seeks a review of that final adverse determination from the Director.

## III. ISSUE

Did BCBSM correctly deny authorization for the specialty prescription drug Privigen?

## IV. ANALYSIS

### Petitioner's Argument

On the external review request form the Petitioner wrote:

I have regular re-occurring upper respiratory and sinus infections. Over the last two years I have been on antibiotics more than I have been off and I continue to get the infections. I have been on oral antibiotics, as well as antibiotics by nebulizer. According to the physicians I have low gamma globulins and they feel that if I was to receive supplemental intravenous therapy that I would have more immunity to fight off these infections. The infections have become very debilitating and affect how I live my life.

My insurance keeps turning down the prior authorization and I am asking you to

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<sup>1</sup> Effective October 12, 2014.

overturn them. At least for some kind of trial period (6 Months??) to see if my overall condition improves.

The Petitioner's condition was described in a progress note dated October 13, 2015:

**CHIEF COMPLAINT:** Combined immunodeficiency

Personality disorder

**HPI:** ■ years old ■ male who is here accompanied by his mother. His mother states that he had Lyme Disease diagnosed about 6 years ago, which was treated with IV Rocephin for 6 months. At the time, he had hormonal imbalances, which his mother remembers included low testosterone levels. In June of 2014 he was admitted to Providence Hospital due to a psychotic event, which was described as paranoid schizophrenia. He remains with a chronic headache, which was evaluated by neurologists, and as part of the evaluation he was found to have a decreased IgG and IgM levels. The IgG is 653 and IgM is 46. The neurologists is of the opinion that IVIG replacement therapy could be beneficial. . . . The patient had one episode of pneumonia, and he suffers from episodes of sinusitis.

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**IMPRESSION:** 1. Combined immunodeficiency,  
2. History of personality disorder  
3. History of Lyme Disease.

**PLAN:** 1. IVIG to start in one week, provided insurance approves. We have appealed the first denial.

Respondent's Argument

In the final adverse determination, BCBSM explained the plan's decision to the Petitioner:

. . . After review, I confirmed the denial must be maintained.

You are covered by the *State of Michigan*. Page 55 of *Your Benefit Guide for the State Health Plan Preferred Provider Organization (PPO)* explains that medical procedures must meet criteria for medical necessity before payment can be approved. Page 55 of *Your Guide* goes on to define medical necessity services as "health care services or supplies needed to prevent, diagnose or treat an illness, injury, disease or its symptoms and that meet accepted standards of medicine."

For this reason, a Clinical Pharmacist, RPh reviewed the documentation provided, along with the notes from the [*grievance*] Conference, and determined the following:

The Medical Policy for Immune Globulin Replacement Therapy, in patients with hypogammaglobulinemia, requires you must experience recurrent infections despite management of other sinus / pulmonary conditions such as asthma, preventative antibiotics, increased monitoring and appropriate antibiotic therapy for infections, AND conjugate vaccines in patient who have not responded to polysaccharide vaccinations. While we have record you are experiencing recurrent infections, we have no record that you have not responded to polysaccharide vaccinations and received conjugate vaccines. Therefore, preauthorization could not be approved. You will be liable for the charges if this procedure is performed.

### Director's Review

The benefit guide (p. 5) says that services must be medically necessary to be covered by the plan. BCBSM based the plan's denial on the criteria in its medical policy, "Immune Globulin Replacement Therapy (IVIG, SQIG) Medication Use Guidelines."

The question of whether intravenous immunoglobulin (IVIG) therapy with Privigen is medically necessary to treat the Petitioner's condition, the Director presented the issue 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 physician reviewer is board certified in allergy and immunology and has been in active practice for more than 15 years. The IRO report included the following analysis and recommendation:

#### **Recommended Decision:**

The MAXIMUS physician consultant determined that Privigen is not medically necessary for treatment of the member's condition.

#### **Rationale:**

\* \* \*

Replacement immunoglobulin is a pooled blood product and there are significant risks involved in the administration of IVIG including thrombosis, renal dysfunction, acute failure and infection. The physician consultant explained that the information provided for review does not support that IVIG is safe and effective for treatment of the member's condition. The physician consultant also explained that the available medical records do not support a diagnosis of hypogammaglobulinemia, primary immunodeficiency, CVID or specific antibody dysfunction, there is no documentation of response to vaccines, and there is no documentation that other therapies have been used and failed such as being vaccinated with the conjugate pneumococcal vaccines or a trial of prophylactic

antibiotics. The consultant indicated that the use of IVIG/SCIG is not warranted in this case. [Citations omitted]

Pursuant to the information set forth above and available documentation, the MAXIMUS physician consultant determined that Privigen is not medically necessary for treatment of the member's condition. [Citations 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 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 experience, expertise, and professional judgment. In addition, the IRO's recommendation is not contrary to any provision of the Petitioner's certificate of coverage. MCL 550.1911(15).

The Director, discerning no reason to reject the IRO's recommendation, finds that the prescription drug Privigen is not medically necessary and is therefore not a covered benefit under the Petitioner's Benefit Guide.

#### V. ORDER

The Director upholds the plan's final adverse determination of November 3, 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.

Patrick M. McPharlin  
Director

For the Director:



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Randall S. Gregg  
Special Deputy Director