

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

**In the matter of:**

██████████  
**Petitioner**

**v**  
**Health Alliance Plan of Michigan**  
**Respondent**

**File No. 151726-001**

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**Issued and entered**  
this 10<sup>th</sup> day of February 2016  
by **Randall S. Gregg**  
**Special Deputy Director**

**ORDER**

**I. BACKGROUND**

On January 15, 2016, ██████████ (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.*

The Petitioner receives prescription drug coverage from Health Alliance Plan of Michigan (HAP), a health maintenance organization. The Director notified HAP of the external review request and asked for the information it used to make its final adverse determination. HAP provided its response on January 15, 2016. On January 19, 2016, after a preliminary review of the material submitted, the Director accepted the request.

Because the case involves medical issues, it was assigned to an independent medical review organization. The IRO provided its analysis and recommendation to the Director on February 2, 2016.

**II. FACTUAL BACKGROUND**

The Petitioner is ██████ years old and has a history of idiopathic pulmonary fibrosis. Her physician prescribed Gammagard, an intravenous immunoglobulin (IVIG) as part of the Petitioner's preparation for a lung transplant. HAP denied coverage, ruling that IVIG medications are experimental in the preparation for an organ transplant.

The Petitioner appealed the denial through HAP's internal grievance process. At the conclusion of that process, HAP issued a final adverse determination dated December 30, 2015, upholding the denial. The Petitioner now seeks from the Director a review of the denial.

### III. ISSUE

Did HAP properly deny preauthorization and coverage for Gammagard IVIG infusion treatment?

### IV. ANALYSIS

#### Respondent's Argument

In its final adverse determination to the Petitioner, HAP stated:

The use of IVIG for the preparation for organ transplant is not listed in compendia, and efficacy has not been confirmed in at least two randomized controlled studies. Therefore, this use is considered experimental. Additional information submitted to HAP did not include at least two randomized, placebo-controlled clinical trials published in major peer-reviewed journals, to support the use of IVIG for preparation for organ transplant. Based on the HAP Formulary Policy, when medications are not used according to their FDA approved labels, coverage must be supported by a prevalence of evidence. Qualifying evidence may be documented efficacy in compendia (references recognized by CMS) or by at least two randomized, placebo-controlled clinical trials published in major peer-reviewed journals. Uses that are not supported by clinical research are considered experimental and are not medically necessary. Your prescription drug plan does not cover experimental use of medications. Therefore, denial of IVIG is upheld.

#### Petitioner's Argument

In a January 13, 2016 letter filed with the request for an external review, the Petitioner stated:

I have IPF (Idiopathic Pulmonary Fibrosis) and have been put on an active transplant list as of July 18, 2014. I have elevated antibodies/antigens and my doctor...at the University of Michigan Medical Center has recommended that I receive Gammagard liquid injection infusions (IVIG), once a month for three months to suppress or lower the antibodies/antigens in my system. (This is in addition to the mycophenolate I am already taking and has been approved through my insurance.) This treatment together will increase my chance to receive a donor match for a double lung transplant.

#### Director's Review

The HAP Subscriber Contract excludes coverage for experimental and investigational medications or services. Experimental and investigative medications and treatments are defined in section 11 of the Subscriber Contract:

**11.21. Experimental and Investigative**—means any medication, treatment, device, procedure, service or benefit that is experimental or investigational.

- a. A medication, treatment, device, procedure, service or benefit may be considered experimental or investigational by HAP if it meets any one of the following criteria:

1. It cannot be lawfully marketed without the approval of the FDA and such approval has not been granted at the time of its use or proposed use.
2. It is the subject of a current investigational new medication or new device application on file with the FDA.
3. It is being provided pursuant to a written protocol that describes, among its objectives, determinations of safety, effectiveness and effectiveness in comparison to conventional alternatives or toxicity.
4. It is being delivered or should be delivered subject to the approval and supervision of an Institutional Review Board as required and defined by federal regulations, particularly those of the FDA or the Department of Health and Human Services.
5. The predominant opinion among experts as expressed in the published authoritative literature is that usage should be substantially confined to research settings.
6. The predominant opinion among experts as expressed in the published authoritative literature is that further research is necessary in order to define safety, toxicity, efficacy or efficacy in comparison to conventional alternatives.
7. It is not investigational in itself pursuant to any of the foregoing criteria and would not be Medically Necessary but for the provision of a medication, device, treatment, or procedure that is investigational or experimental.

The Director notes that the reason for denying coverage cited by HAP in its final adverse determination (the absence of “at least two randomized, placebo-controlled clinical trials published in major peer-reviewed journals.”) is not among the criteria cited in the Subscriber Contract definition of “experimental and investigational” reprinted above.

The question of whether Gammagard IVIG infusions are experimental or investigational as part of the Petitioner’s treatment 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 physician reviewer is a physician in active practice who is board certified in surgery and critical care and specializes in transplant surgery. The IRO reviewer’s report included the following analysis and recommendation:

The member is on the lung transplant waiting list at the University of Michigan Medical Center....[T]he member apparently has a high PRA and allo-sensitization, as evidenced by the plan’s response, the client’s appeal letter and the inclusion of University of Michigan’s protocol for the management of the highly sensitized potential lung recipient....[T]he use of IVIG for sensitized patients is a well-established practice in transplantation and is supported both by the articles as well as the extensive references in the University of Michigan protocol provided in the case file. [Citations omitted.]

transplantation and is supported both by the articles as well as the extensive references in the University of Michigan protocol provided in the case file. [Citations omitted.]

Pursuant to the information set forth above and available documentation... Gammagard (IVIG) liquid injection infusions are not investigational for treatment of the member's condition.

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's recommendation is not contrary to any provision of the Petitioner's coverage. MCL 550.1911(15).

The Director, discerning no reason why the IRO's recommendation should be rejected in the present case, finds that Gammagard IVIG infusions are not investigational in the treatment of Petitioner's condition.

#### V. ORDER

The Director reverses HAP's December 30, 2015 final adverse determination. HAP shall immediately provide coverage for the Petitioner's Gammagard IVIG liquid injection infusions and shall, within seven days of providing coverage, furnish the Director with proof it implemented this order. See MCL 550.1911(17).

To enforce this order, the Petitioner may report any complaint regarding the implementation to the Department of Insurance and Financial Services, Health Care Appeals Sections, 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 sixty 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