

**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. 152061-001**

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

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

**ORDER**

**I. PROCEDURAL BACKGROUND**

On February 8, 2016, ██████████, 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.*

The Petitioner receives health care benefits through Health Alliance Plan of Michigan (HAP), a health maintenance organization. Her benefits are defined in HAP's *HMO Subscriber Contract*.

The Director notified HAP of the external review request and asked for the information used to make its adverse determination. HAP furnished its response on February 12, 2016. After a preliminary review of the material received, the Director accepted the request on February 16, 2016.

To address the medical issues in this case, the Director assigned it to an independent medical review organization which provided its analysis and recommendation on February 29, 2016.

**II. FACTUAL BACKGROUND**

The Petitioner has multiple sclerosis. Her doctor prescribed Tysabri (natalizumab) injections to treat her condition. HAP denied coverage for the drug. The Petitioner appealed

HAP's decision through its internal grievance process. At the conclusion of that process, HAP issued a final adverse determination dated January 14, 2016, affirming its decision. The Petitioner now seeks the Director's a review of that final adverse determination.

### III. ISSUE

Did HAP correctly deny coverage for the Tysabri (natalizumab) injections requested by the Petitioner?

### IV. ANALYSIS

#### HAP's Argument

In its final determination, HAP wrote:

The medical policy entitled NATALIZUMAB (Tysabri), outlines Criteria, Limitations and Exclusions for agents used in the treatment of Multiple Sclerosis (MS). Specifically, members must have an inadequate response, or be unable to tolerate, one of the Interferons for MS (Avonex, Betaseron, Rebif) and Copaxone 20mg. In addition, members must have an inadequate response, or be unable to tolerate Gilenya; or clinical rationale provided as to why Gilenya cannot be used (i.e. medical contraindication for use).

According to the information provided you were started on Rebif in September of 2015. In November of 2015 due to the aggressive nature of your MS and symptoms of abdominal hugs, burning in feet, cold tongue, and flu-like symptoms, the decision was made to start Tysabri. The criteria for Tysabri were not met because you have not tried Copaxone or Gilenya. The documentation and medical records do not support the medical necessity for receiving Tysabri instead of Copaxone or Gilenya.

#### Petitioner's Argument

In a letter to HAP dated January 20, 2016, the Petitioner's doctor wrote:

[Petitioner] has been under my care since September 17, 2015 for Multiple Sclerosis.

I'd like you to consider this report from the ANNALS of Neurology, March of 2015 the article "Switch to natalizumab versus fingolimod in active relapsing-remitting multiple sclerosis." This study shows a 2.8 higher rate of sustained disability regression was observed after the switch to Tysabri in comparison to Gilenya...the change in the overall disability burden was also greater in the Tysabri group....There were 792 patients observed in this study between Tysabri and Gilenya.

My patient has tried and failed Rebif, therefore it would be a moot point to try and fail on Gilenya as well.

[Petitioner] has an aggressive form of Multiple Sclerosis, based on her brain and lumbar spine MRI results (included in this letter) show multiple enhancing and infratentorial and supratentorial lesions on the brain and spine. In August of 2015 my patient experienced right sided face and tongue numbness, 4 days later her left leg became numb. She went to the ER and was admitted, although she was not given a specific diagnosis at the time, there was some stroke concern.

[Petitioner] has tried and failed Rebif, although she does remain on Rebif, the pt is experiencing abdominal hags, burning of feet, bruising, numbness in feet, cold tongue as well as flu-like symptoms. Due to the progression of this disease I am requesting a positive outcome to this appeal for TYSABRI. A delay could further debilitate [Petitioner's] ability to [perform] her activities of daily living.

### Director's Review

To determine if the Tysabri (natalizumab) injections are medically necessary and appropriate the Director assigned this case 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 reviewer is a physician in active practice for more than 15 years who is board certified in neurology and is familiar with the medical management of patients with the Petitioner's condition. The IRO reviewer's report included the following analysis and recommendation:

[T]he opinion of both of the neurologists who have treated the member in this case is that her MRI demonstrates active and aggressive disease... Tysabri is clearly superior to interferon products in these circumstances. (Rudick RA, et al. Natalizumab plus interferon beta 1a for relapsing multiple sclerosis. *New Eng J Med.* 2006;354(9):911-23.)... [I]n pooled analyses, Copaxone does not demonstrate adequate data for disease progression and should not be considered a first line drug or a required drug to fail... [W]ith respect to Gilenya, there are no direct comparisons to Tysabri or Lemtrada, but in the setting of similar placebo responses, the primary endpoints and secondary endpoints demonstrate relative superiority of both these products compared to Gilenya. (Munari L, et al. Therapy with glatiramer acetate for multiple sclerosis. *Cochrane Database Syst Rev.* 2004(1):CD004679.) [B]ased on the demonstrated side effects of difficulty with the interferon injection, the demonstrated active aggressive disease and the shorter latency of efficacy, Tysabri is the drug of choice in this case.

Pursuant to the information set forth above and available documentation... natalizumab injections are medically necessary treatment of the member's condition... [T]he member does meet the Health Plan's criteria for coverage for natalizumab injections, but the Health Plan's criteria for coverage for these injections are not consistent with the current recognized medical standard of care 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 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 the IRO's recommendation should be rejected in the present case.

The Director finds that Tysabri (natalizumab) injections are medically necessary to treat the Petitioner's condition and, therefore, are a covered benefit.

#### V. ORDER

The Director reverses HAP's January 14, 2016, final adverse determination. HAP shall immediately provide coverage for the requested injections and shall, within seven days of providing coverage, furnish the Director with proof it has implemented this order.

To enforce this order, the Petitioner may report any complaint regarding its 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 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