

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

In the matter of:

████████████████████

Petitioner

v

Alliance Health and Life Insurance Company  
Respondent

File No. 146297-001

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Issued and entered  
this 18<sup>th</sup> day of March 2015  
by Randall S. Gregg  
Special Deputy Director

**ORDER**

**I. PROCEDURAL BACKGROUND**

On February 13, 2015, ██████████ (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 medical and prescription drug benefits under a group insurance policy underwritten by Alliance Health and Life Insurance Company (AHL). The Director notified AHL of the external review request and asked for the information it used to make its final adverse determination. After a preliminary review of the material received, the Director accepted the request on February 23, 2015.

The case involves medical issues so the Director assigned the matter to an independent review organization, which completed its review and sent its recommendation to the Director on March 9, 2015.

**II. FACTUAL BACKGROUND**

The Petitioner has a 17-year history of chronic idiopathic thrombocytopenic purpura (ITP), a blood disorder characterized by low platelet counts that can lead to easy or excessive bruising and bleeding. She also has a history of breast cancer. Her physician prescribed Promacta, a prescription drug, to treat her ITP.

AHL denied coverage for the Promacta. The Petitioner appealed the denial through AHL's internal grievance process. At the conclusion of that process, AHL issued a final adverse determination dated December 31, 2014, affirming its denial of coverage. The Petitioner now seeks a review of that adverse determination from the Director.

### III. ISSUE

Did AHL correctly deny coverage for the prescription drug Promacta?

### IV. ANALYSIS

#### Respondent's Argument

In its final adverse determination to the Petitioner, AHL wrote:

On November 20, 2014, our Pharmacy Care Management (PCM) Department received a prior authorization request from [REDACTED] requesting approval for prescription drug, Promacta. The request was denied because coverage criteria for Promacta had not been met. Our Formulary policy provides coverage after specific criteria has been met for prior authorization and/or step-therapy and/or quantity limits.

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Promacta is a Thrombopoiesis-Stimulating agent for the treatment of immune related Idiopathic Chronic Thrombocytopenic Purpura (ITP). The coverage criteria for the use of Promacta states documentation must show adequate trials and failure of the following treatment options before coverage for Promacta may be considered: (1) history of corticosteroids use, (2) history of use of high dose Intravenous Immunoglobulin (IVIG) (2g/kg divided over 2 to 5 days), (3) use of Anti-(Rh) D Immunoglobulin if appropriate, (4) Splenectomy (most effective) and (5) history of Rituximab use.

[B]ased on your claims records and the information submitted by the provider, criteria have not been met. Specifically, you have only tried Corticosteroids and only one infusion of IVIG to treat your medical condition. You have not tried other treatment options as listed above. Therefore, Pharmacy Care Management upholds the original denial for the prescription drug, Promacta.

#### Petitioner's Argument

In a letter of appeal to AHL dated February 8, 2015 accompanying her request for an external review the Petitioner wrote:

After being twice denied for Promacta, I am writing to you on behalf of myself and [REDACTED], my Oncologist. He feels this medication would be of great benefit instead of a splenectomy, to correct my low platelet issue, which are and have been dangerously low for many years....

I have read your reasons for denial, and understand that there is a standard operating procedure that you follow however, I as a patient, feel that you should consider my other health issues and general wellness. In December of 2013 I was diagnosed with breast cancer and am currently recovering from the surgery and radiation treatment. I am also taking a new medication (Arimedix). In addition to Predisone and IVG treatments, which despite being successful were short-lived in keeping an elevated platelet count.

A consideration for Rituxan, but after reviewing the possible negative side-effects, and discussing this with my PC, this medication was dismissed as a possible candidate. A splenectomy was recommended by [REDACTED] which raised many concerns with myself and PC.

The reasons are as follows

- 1) No guarantee this will resolve the problem.
- 2) Additional Predlstone treatment to ramp up platelet counts before surgery.
- 3) The risks of a Spleentomy and possible immunity issues are not favorable.

After consulting with my PC, he has recommended that a second surgery not be performed, and simple rest and recovery was suggested. I am inclined to agree.

My employment status is unemployed at this time as I work at a golf course and [the work] is seasonal. A surgery of this magnitude would not be financially feasible as the recovery time is 6-8 weeks.

In a letter dated March 4, 2015, the Petitioner's oncologist wrote:

This appeal letter is written on behalf of [Petitioner] who is followed in my office for chronic immune thrombocytopenia. [Petitioner] has previously received steroids which, while effective, caused side effects which impacted her quality of life. She has also received intravenous immunoglobulin with modest but not durable effects. I have suggested Rituxan and/or splenectomy as alternatives, but [Petitioner] has reservations due to concerns about side-effects. She has also had unrelated surgery recently which has resulted in reservations about splenectomy. I have therefore recommended the use of Promacta based on its efficacy and indication for this disorder. I believe that Promacta is indicated for this chronic, refractory ITP, based on severity and prior therapies and should be covered, to allow for maintenance of a safer platelet level as per usual practice.

### Director's Review

AHL provides prescription drug coverage for Promacta under its formulary, but only after other treatments have been tried without success. The requirements for coverage are described in AHL's final adverse determination, above.

The Director requested an independent review organization (IRO) evaluate the medical necessity of Promacta and the requirements imposed by AHL for coverage. Review of medical questions by an IRO is required by section 11(6) of the Patient's Right to Independent Review Act, MCL 550.1911(6).

The IRO reviewer is a licensed physician in active practice who is certified by the American Board of Internal Medicine with a subspecialty in hematology and medical oncology. The reviewer provided the following analysis and recommendation:

The enrollee has been diagnosed with steroid-refractory chronic ITP. Based on the documentation submitted for review, her most recent platelet counts in the range of 10,000 or less have been noted in at least February and March of 2015. She does not have any bleeding. She has previously failed corticosteroids. She received one dose of IVIG in late September of 2014 with some modest but not durable response. She has not tried and failed rituximab or splenectomy due to concerns for the possible side effects as well as inconvenience to her work schedule as documented in [REDACTED] note on December 18, 2014. Given that her platelet counts are less than 10,000, treatment is appropriate.

Standard of care for the treatment of chronic ITP in this enrollee includes rituximab or splenectomy. The use of Promacta for the treatment of chronic ITP in this enrollee is not clinically appropriate at this time according to current standard of care because she has not tried and failed rituximab or splenectomy. Promacta is not medically necessary for the enrollee's condition because it is not clinically appropriate and essential for the treatment of her condition, and appears to be requested for the convenience of the enrollee.

The enrollee does not meet the plan's coverage criteria for Promacta. Although she has failed corticosteroids, she has not tried and failed other standard options for the treatment of chronic ITP such as rituximab or splenectomy. She has only tried IVIG once in September of 2014. The documentation submitted for review does not indicate a contraindication to rituximab or splenectomy. Treatment with rituximab or splenectomy would be clinically appropriate before Promacta can be covered.

Expert consensus in UpToDate and other published review articles state that second-line therapy is generally reserved for patients with thrombocytopenia that

is associated with significant bleeding symptoms (such as mucosal purpura, more serious bleeding) or for severe, persistent or recurrent thrombocytopenia (such as platelet count <20,000/microL), following treatment with glucocorticoids or IVIG.

For all patients with persistent ITP who have experienced clinically important bleeding despite first-line therapy with glucocorticoids and IVIG, the experts recommend second-line therapy with splenectomy or rituximab rather than observation or chronic glucocorticoids. They also use these second-line therapies such as splenectomy or rituximab in patients with a platelet count <20,000/microL despite initial therapy who do not have bleeding, due to the potential bleeding risk (as in this enrollee's case).

Furthermore, the expert consensus states that there are several choices of second-line and third-line ITP therapies, which differ in their efficacy and risks. The major options for second-line therapy include splenectomy and rituximab; while thrombopoietin (TPO) receptor agonists such as Promacta have an evolving role.

Most patients with severe and symptomatic thrombocytopenia following failure of treatment with glucocorticoids, splenectomy, and/or rituximab respond to TPO receptor agonists such as Promacta with significantly increased platelet counts. However, these agents do not appear to induce remission, and indefinite maintenance therapy is likely to be required for most patients.

Therefore, current expert consensus states it is standard of care to reserve TPO receptor agonists such as Promacta for the following settings:

- Persistent thrombocytopenia despite splenectomy and/or rituximab (as third-line therapy)
- Lack of suitability of splenectomy or rituximab (for example due to high surgical or infection risks)
- Requirement for a temporary increase in platelet count in preparation for surgery or while awaiting more definitive treatment, for patients who do not have a response to first-line therapies.

Given that this enrollee has not failed splenectomy or rituximab, and is considered an appropriate candidate for splenectomy or rituximab per the attending physician's notes as documented in the progress notes on December 18, 2014 and subsequent notes, the use of Promacta is not medically necessary at this time. It is not clinically appropriate and is mainly for the convenience of the enrollee.

[Citation omitted.]

The Director is not required in all instances to accept the IRO's recommendation. 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. In addition, the IRO's recommendation is not contrary to any provision of the Petitioner's certificate of coverage. See MCL 550.1911(15).

The Director can discern no reason why the IRO's analysis should be rejected in this case and, therefore, finds that AHL's denial of coverage for the Petitioner's Promacta as not medically necessary is consistent with the terms the Petitioner's policy.

#### V. ORDER

The Director upholds Alliance Health and Life Insurance Company's December 31, 2014 final adverse determination. Alliance Health and Life is not required to provide coverage for the prescription Promacta.

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.

Annette E. Flood  
Director

For the Director:



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Randall S. Gregg  
Special Deputy Director