

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. 154011-001

Alliance Health and Life Insurance Company,

Respondent.

Issued and entered
this 15th day of July 2016
by Joseph A. Garcia
Special Deputy Director

ORDER

I. BACKGROUND

██████████ (Petitioner) has Crohn's disease. His health insurer, Alliance Health and Life Insurance Company (Alliance) denied his request for a prescription drug to treat that condition.

On June 6, 2016, the Petitioner filed a request with the Director of Insurance and Financial Services for an external review of that denial under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.*

The Petitioner receives prescription drug coverage through a group plan that is underwritten by Alliance. The Director immediately notified Alliance of the external review request and asked for the information it used to make its final adverse determination. Alliance responded on June 8, 2016. On June 13, 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, which provided its analysis and recommendation to the Director on June 27, 2016.

II. FACTUAL BACKGROUND

The Petitioner's health care benefits are described in Alliance's *PPO Preferred Provider Organization Group Health Insurance Policy* (the policy).

The Petitioner has Crohn's disease. His doctor prescribed the drug Remicade (infliximab) to treat his condition. Alliance declined to approve the drug on the basis that the Petitioner had not met its medical criteria.

The Petitioner appealed the denial through Alliance's internal grievance process. At the conclusion of that process, Alliance issued a final adverse determination dated April 28, 2016, upholding its decision. The Petitioner now seeks a review of that final adverse determination from the Director.

III. ISSUE

Did Alliance properly deny coverage for Remicade?

IV. ANALYSIS

Petitioner's Argument

The Petitioner's condition was assessed in a May 4, 2016, letter from his gastroenterologist's office that was included with his external review request:

Assessment & Plan

Crohn's disease of both small and large intestine with other complication

Today's Impression: 42 yr old male with moderate to severe crohn's ileocolitis with colonic stricture seen today for follow up appointment. Given the severity of his crohn's disease with stricture at original diagnosis he is likely to need a bowel resection unless intervention. Primary therapy with immunomodulator is not recommended to avoid primary resection for crohn's disease. Therefore the insurance recommendation to fail solo immunomodulator therapy is not recommended. I recommend that he be placed on dual therapy with methotrexate AND remicade to avoid primary resection for his Crohn's disease. Studies have shown that once a patient has primary resection that they are more likely to require more bowel resections, obstructions and hospitalizations. Therefore increasing the morbidity and mortality of crohn's disease in this individual.

Respondent's Argument

In its final adverse determination, Alliance told the Petitioner:

... [A]fter considering all available evidence, previous decisions, and your medication history, the recommendation is to uphold denial for Remicade. Remicade is an anti-TNF inhibitor used for the treatment of Crohn's

Disease. For the treatment of Crohn's Disease with Remicade, the member's Benefits Administration Manual (BAM) Policy titled "Biologic Drug Management of Inflammatory Bowel Disease: Ulcerative Colitis and Crohn's Disease" states that documentation in the medical record must show a trial and failure of maximum doses and duration of conventional therapy with a corticosteroid (oral or rectal) and at least one oral immunomodulator (example: azathioprine). Based on the information submitted to HAP, you have tried corticosteroid; however, you have not tried and failed immunomodulators such as methotrexate, azathioprine or 6-mercaptopurine. The information submitted with the appeal does not provide any support that immunomodulators have been tried and failed or reasons as to why an immunomodulator cannot be attempted in treating your symptoms. Therefore, you do not meet the above criteria for use of Remicade and the denial is upheld.

Director's Review

Alliance denied authorization for Remicade because the Petitioner did not meet its medical criteria. To address the medical issue, the case was assigned 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 gastroenterology and has been in practice for more than 15 years. The IRO report concluded that Remicade was medically necessary for the Petitioner and explained why Alliance's criteria was not medically appropriate:

The Health Plan [*i.e.*, Alliance] indicated that the member does not meet its criteria for coverage of this medication. The Health Plan explained that its policy states that documentation in the medical record must show a trial and failure of maximum doses and duration of conventional therapy with a corticosteroid and at least one immunomodulator. The Health Plan indicated that based on the information submitted to it, the member has tried corticosteroid treatment but has not tried and failed immunomodulators such as methotrexate, azathioprine or 6-mercaptopurine. The Health Plan also indicated that the information submitted did not provide any support that immunomodulators have been tried or failed or reasons as to why an immunomodulator could not be attempted in treating the member's symptoms ...

* * *

Recommended Decision:

The MAXIMUS physician consultant determined that Remicade is medically necessary for treatment of the member's condition.

Rationale:

* * *

The member's treating provider describes the disease as moderate to severe. The member has pan-colitis and apparently has developed a stricture as well in the ascending colon. Endoscopically, the disease is most severe in the ileum. The member has been treated recently with tapering doses of prednisone along with methotrexate and has experienced modest improvement. An MRI/MRE showed no complications of Crohn's disease such as fistula, abscess or stricture. The treating provider has prescribed Remicade to be used in conjunction with methotrexate.

Three anti-tumor necrosis factor (anti-TNF) therapies, including Remicade, are approved for treatment of Crohn's disease in adults in the United States and are effective in the treatment of luminal Crohn's disease. The MAXIMUS physician consultant explained that clinical trials and experience have demonstrated significant utility of infliximab (Remicade) for induction of remission in moderately active, steroid refractory Crohn's disease and for maintenance of remission in these patients for up to 54 weeks after initial infusion. The physician consultant indicated that in addition, the use of this medication has been associated with improved quality of life and reduction in the risk of hospitalization and surgery. The consultant noted that the odds of achieving steroid-free remission are significantly higher for infliximab than monotherapy with an immune modulator. There is limited data for methotrexate, however, in a landmark study using azathioprine as the immunomodulatory agent, the combination of azathioprine plus infliximab was superior to monotherapy with either infliximab alone or azathioprine alone. In this randomized trial, 508 patients with moderate to severe Crohn's disease who had not previously received immunosuppressive agents or biologic agents, were assigned to treatment with infliximab, azathioprine or combination therapy with the two drugs for 30 weeks. At 26 weeks, patients with moderate to severe Crohn's disease who were treated with infliximab plus azathioprine or infliximab monotherapy were more likely to have a glucocorticoid-free clinical remission than those receiving azathioprine monotherapy. The physician consultant explained that it can be extrapolated from this data that monotherapy with methotrexate is not sufficient and is not the standard of care in 2016.

Pursuant to the information set forth above and available documentation, the MAXIMUS physician consultant determined that Remicade is medically necessary for treatment of the member's condition.
[References 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 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. The Director, discerning no reason to reject the IRO's recommendation, accepts it and finds that Remicade is medically necessary.

V. ORDER

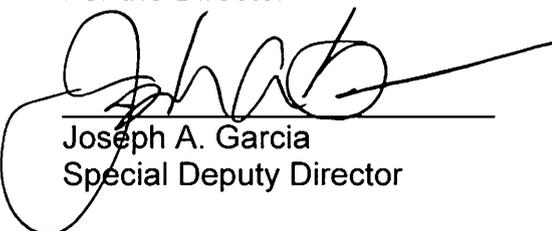
The Director reverses Alliance's final adverse determination of April 28, 2016. Alliance shall immediately cover the prescription drug Remicade for the Petitioner. See MCL 550.1911(17). Alliance shall also, within seven days of providing coverage, furnish the Director with proof it implemented this order.

To enforce this order, the Petitioner may report any complaint regarding its implementation to the department of Insurance and Financial Services, Health Care Appeals Section, 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



Joseph A. Garcia
Special Deputy Director