

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. 150690-001

Alliance Health and Life Insurance Company
Respondent

Issued and entered
this 27th day of December 2015
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On November 3, 2015, Dr. ██████████, authorized representative of his patient ██████████ (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 through a group insurance policy underwritten by Alliance Health and Life Insurance Company (Alliance). The Director notified Alliance of the external review request and asked for the information used to make its final adverse determination. The material was received on November 3, 2015. After a preliminary review of the material received, the Director accepted the request on November 10, 2015.

Because the case presents a medical issue the Director assigned it to an independent medical review organization for analysis. The review was submitted to the Director on November 24, 2015.

II. FACTUAL BACKGROUND

The Petitioner is █ years old and has been diagnosed with insulin resistance. Her physician prescribed Glumetza ER to treat her condition. Alliance denied coverage.

The Petitioner appealed the denial through Alliance's internal grievance process. At the conclusion of that process, Alliance issued a final adverse determination dated October 29, 2015, affirming its denial of coverage. The Petitioner now seeks a review of that final adverse determination from the Director.

III. ISSUE

Did Alliance correctly deny coverage for the prescription drug Glumetza ER?

IV. ANALYSIS

Respondent's Argument

In its final adverse determination Alliance wrote:

After considering all available evidence, previous decisions, and your medication history, we upheld the denial for [Glumetza]. Glumetza (Metformin) extended release (ER) is a non-formulary medication. The HAP formulary¹ provides coverage for other agents to help control your blood sugar. Formulary agents include: Glyburide, Glipizide, Glimepiride, Januvia, Nateglinide, Repaglinide, and other combination oral formulations. Many formulations of insulin are also available on the HAP formulary, without requiring prior authorization. Other injectable medications, such as Byetta, are available with prior authorization for patients who meet the coverage criteria.

A formulary exception may be considered for a non-formulary medication, if all formulary options have been tried and failed. [REDACTED] has not given any reason as to why you cannot attempt a trial of all the formulary options available to treat your condition. Therefore, the criteria for a formulary exception have not been met, and the denial is upheld.

Petitioner's Argument

In a letter dated November 1, 2015, accompanying the request for external review, the Petitioner's physician wrote:

[Petitioner] is under my care for Insulin Resistance (Dx E88.81) since September of 2015, was diagnosed in 2013. This letter is in regards to a denial of her brand name DAW Glumetza ER medication. We started the prior authorization request with her insurance company Alliance Health and Life and it was originally denied because we were told that the patient did not try and fail on **all** of the alternative medications. We then had the patient try the other alternative that she had not tired [sic] yet; the Glucophage XR and she did have side effects on it also. She was not able to tolerate the generic medication the Glucophage XR. She stopped

1. In making determinations of prescription drug coverage, Alliance uses the drug formulary of Health Alliance Plan (HAP), an affiliated company.

the medication due to side effects of vomiting and diarrhea. We then wrote another letter to her insurance company...asking for the initial coverage of the brand name medication the Glumetza ER and again we were told it was denied. The reason for the denial this time was stated that "Dr. Rosenblatt has not given any reason as to why you cannot attempt a trial of all the formulary options available to treat your condition." The medications that were listed as part of the formulary include: Glyburide, Glipizide, Glimepiride, Januvia, Nateglinide and other combinations oral formulations. Many forms of injectable medications, such as Byetta are available with prior authorization for patients who meet the coverage criteria. All of the medications just listed as "part of the formulary" (listed above) **are not used** to treat the diagnosis of the member for Insulin Resistance. Those medications are for patients with the diagnosis of Type 2 Diabetes. Therefore, we are again asking that the brand name medication the Glumetza ER be approved for the member for the diagnosis of Insulin Resistance (Dx E88.81). The patient has been on and taking the Glumetza ER prior to seeing me in September 2015. The member has tried and failed on the generic medications and they just do not work for her.

Director's Review

Glumetza ER is not on Alliance's formulary. However, individuals may receive a formulary exception to receive coverage for a nonformulary drug. The formulary exception process is described in HAP's policy titled, "Coverage Determinations for Commercial and Qualified Health Plan Members" which provides:

You or your doctor can ask us to make an exception to our requirements or limits. You may also ask us to cover a medication not included on our formulary or ask us to exempt you from a formulary requirement through the exception process. Your doctor must submit a request to us indicating why formulary requirements should not apply.

However, this document does not provide the standards to be applied in granting or denying an exception. The Petitioner's certificate of coverage includes the following prescription drug provision:

3.25 Drugs, Dietary Drugs, Food and Food Supplements

- a. Alliance covers all medications that are administered in an Inpatient facility (inpatient facility is defined as a facility like an Inpatient Hospital, Inpatient psychiatric Hospital, Inpatient chemical dependency facility and long term acute care facility that provides diagnostic, therapeutic, and rehabilitation services).
- b. Outside of the Inpatient setting, Alliance covers medications that cannot be self-administered, according to Alliance's benefit practice and referral policies that are available by contacting the Alliance Client Services department by phone at 313-872-8100 or 1-800-422-4641.

c. Medications that can be self-administered are covered by Alliance only for Urgent Care services, Emergency services or if covered through an Alliance-approved Prescription Drug Rider.

This provision does not include any information about standards for considering exceptions to the drug formulary. The only reason given by Alliance for denying coverage for the requested drug is that the Petitioner had not first tried all of the numerous alternative drugs included in the formulary. The Petitioner's physician, in his November 1, 2015 letter, described the reasons why he believed those alternative drugs were not appropriate for the Petitioner.

In order to resolve this dispute, the Director asked an independent review organization (IRO) to evaluate Alliance's denial and the medical necessity of Glumetza ER as treatment for the Petitioner's condition. 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 physician reviewer is board certified in endocrinology and has been in practice for more than 10 years. The reviewer is familiar with the medical management of patients with the Petitioner's condition. The IRO report provided this analysis and recommendation:

Glumetza ER is a medically appropriate treatment for the member's condition.

* * *

[T]he approved drugs on the Health Plan's formulary are medically appropriate treatment for type 2 diabetes, but are not used to treat the member's diagnosed condition of insulin resistance. The sulfonylureas are secretagogues, Januvia is a dpp-4 inhibitor, byetta is a glp-1 agonist and metformin and pioglitazone are insulin sensitizers....[W]hile there is not much information about the member and her medical history provided for review, she has the diagnosis of insulin resistance....[M]etformin is an insulin sensitizer and all forms of metformin are included in this category....[S]ome forms are tolerated better than others and some patients do better with Glumetza than with other forms of metformin.

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. 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, discerning no reason why the IRO's recommendation should be rejected in this case, finds that Glumetza ER is an appropriate treatment for the Petitioner's condition.

V. ORDER

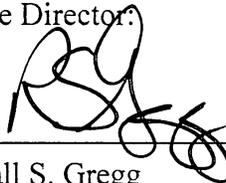
The Director reverses Alliance Health and Life Insurance Company's final adverse determination of October 29, 2015. Alliance shall immediately provide coverage for the requested Glumetza ER and shall, within seven days of providing coverage, furnish the Director with proof it has implemented this order.

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



Randall S. Gregg
Special Deputy Director