

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

In the matter of:

██████████

Petitioner

v

Blue Cross Blue Shield of Michigan
Respondent

File No. 154562-001

Issued and entered
this 24th day of August 2016
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On July 19, 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.* After a preliminary review of the material submitted, the Director accepted the request on July 26, 2016.

The Petitioner receives prescription drug benefits through an individual plan underwritten by Blue Cross Blue Shield of Michigan (BCBSM). The benefits are described in BCBSM's *Premier Silver Extra Benefits Certificate*. The Director notified BCBSM of the external review request and asked for the information used to make its final adverse determination. BCBSM responded on August 2, 2016.

To address the medical issue in the case, the Director assigned it to an independent medical review organization, which provided its analysis and recommendation on August 15, 2016.

II. FACTUAL BACKGROUND

The Petitioner has uncontrolled type 2 diabetes for which he takes Lantus and metformin. He has tried and failed Bydureon due to side effects, and has been taking samples of the prescription drug Trulicity. His nurse practitioner requested coverage

from BCBSM for continued use of Trulicity. BCBSM denied the request.

The Petitioner appealed the denial through BCBSM's internal grievance process. At the conclusion of that process, BCBSM affirmed its decision in a final adverse determination issued July 6, 2016. The Petitioner now seeks the Director's review of that final adverse determination.

III. ISSUE

Did BCBSM correctly deny prescription drug coverage for Trulicity?

IV. ANALYSIS

BCBSM's Argument

In its final adverse determination BCBSM's representative wrote to the Petitioner:

You are covered under the Blue Cross Premier Silver Extra Benefits Certificate. On page 89 of the certificate, it explains as follows:

- We do not pay for anything other than covered drugs and services

A Clinical Pharmacist, RPh, reviewed your appeal and your health care plan benefits for [BCBSM] and determined the following:

The requested medication, Trulicity, is excluded from coverage under your Custom Select prescription drug plan. Covered alternatives with a prior authorization include: Byetta and Victoza.

Petitioner's Argument

In the external review request, the Petitioner's authorized representative explained:

We are trying to get approval for Trulicity. Per insurance he had to try Bydureaon, Byetta or Victora. He tried Bydureon and had side effects. The other 2 meds are daily injection and patient refuses to comply with them. Wants weekly injection.

In the BCBSM "Provider Appeal Form" dated June 8, 2016, the Petitioner's nurse practitioner explained why Trulicity is medically necessary:

Patient was on Bydureon for 3 weeks and had adverse reaction. Complained of nausea, vomiting, constipation decreased appetite and feeling extremely tired. Currently using Trulicity per sample product. Taking Lantus and Metformin. As previously on Glyburide in the past. Also has co-morbidities of elevated blood pressure, dyslipidemia, and proteinuria. Patient needs to be on a GIP-1 to get glucose under control.

Director's Review

BCBSM denied authorization for the drug Trulicity because it is not included in the Petitioner's drug formulary "Custom Select Drug List". However, a health plan that limits coverage for drugs to those on a formulary must provide an exception when a non-formulary alternative is "medically necessary and appropriate." Section 3406o of the Insurance Code, MCL 500.3406o, provides:

An insurer that delivers, issues for delivery, or renews in this state an expense-incurred hospital, medical, or surgical policy or certificate that provides coverage for prescription drugs and limits those benefits to drugs included in a formulary shall do all of the following:

* * *

(c) Provide for exceptions from the formulary limitation when a nonformulary alternative is a medically necessary and appropriate alternative.

To determine whether Trulicity is a medically necessary and appropriate alternative to the drugs that are on BCBSM's formulary, the issue 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 reviewer is a physician in active practice who is certified by the American Board of Internal Medicine with a subspecialty in endocrinology, diabetes and metabolism. The IRO report included the following analysis and recommendation:

It is the determination of this reviewer that the prescription drug Trulicity is not medically necessary for the treatment of the enrollee's condition.

Clinical Rationale for the Decision:

The standard of care for patients with type 2 diabetes who are uncontrolled on Lantus and metformin is described by the American Association of Clinical Endocrinologists/American College of Endocrinology (AACE/ACE) guidelines. The Trulicity Prescribing Information clearly states that a limitation of use is that it "has not been studied in combination with basal insulin." This shows that the requested usage of Lantus and Trulicity is off-label.

This enrollee is on Lantus insulin. Trulicity is not Food and Drug Administration (FDA) approved for usage with Lantus. As such, the request is off-label and should be considered experimental/investigational. As this is an off-label/ experimental request, it is NOT medically necessary nor appropriate as the manufacturer does not recommend this drug combination. Additionally, the enrollee is refusing to take formulary Victoza or Byetta as he is refusing a daily injection. His refusal for the formulary medications means that this request is simply for the enrollee's convenience, and as such, it does not

meet medical necessity criteria. Therefore, for the reasons noted above, the prescription drug Trulicity is not medically necessary for the treatment of the enrollee's condition.

Recommendation:

It is the recommendation of this reviewer that the denial issued by Blue Cross Blue Shield of Michigan for prescription drug Trulicity be upheld.

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 this case, adopts the IRO analysis and finds that Trulicity is not medically necessary to treat the Petitioner's condition. Therefore, it is not a covered benefit.

V. ORDER

The Director upholds BCBSM's final adverse determination.

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:



Randall S. Gregg
Special Deputy Director