

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

In the matter of:

██████████

Petitioner,

File No. 152803-001

v

Blue Cross Blue Shield of Michigan,

Respondent.

Issued and entered
this 2nd day of May 2016
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On March 22, 2016, ██████████ (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 March 29, 2016.

The Petitioner receives prescription drug benefits through a group plan underwritten by Blue Cross Blue Shield of Michigan (BCBSM). The Director immediately notified BCBSM of the external review request and asked for the information it used to make its final adverse determination. BCBSM responded on April 4, 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 April 12, 2016.

II. FACTUAL BACKGROUND

The Petitioner's prescription drug benefits are described in BCBSM's *Preferred Rx Program Certificate SG* (the certificate).

The Petitioner has a history of gastrointestinal problems, including *H. pylori*, epigastric

pain, mild-to-severe gastritis, mild bulb duodenitis, substernal chest pain, a small hiatal hernia, and bile reflux. In January 2016 her physician asked BCBSM to cover the drug Dexilant (dexlansoprazole) to treat her gastritis and esophageal reflux disease. BCBSM denied coverage because Dexilant is not on the list of drugs covered for her plan.

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 dated February 25, 2016. The Petitioner now seeks a review of that adverse determination from the Director.

III. ISSUE

Did BCBSM correctly deny coverage for the prescription drug Dexilant?

IV. ANALYSIS

BCBSM's Argument

In its final adverse determination to the Petitioner, BCBSM's reviewer, a clinical pharmacist, explained to the Petitioner:

. . . After review, I confirmed the denial must be maintained.

You are covered under the *Preferred Rx Program Certificate for Small Groups (SG)*. **Section 3: Prescription Drugs Not Covered** (Pages 17 through 19) of the *Certificate* explains that your plan does not cover anything other than drugs and services listed as covered. The covered drugs for the group's plan are listed in the *BCBSM Custom Select Drug List* (available on www.bcbsm.com). As Dexilant is not listed in the *Drug List*, it is not covered by your plan.

To ensure all possible consideration was given, a Clinical Pharmacist, RPh reviewed the submitted appeal, along with the notes from your Conference, and determined the following:

The requested medication is excluded from coverage under your Custom Select drug plan. Covered alternatives include: generic Protonix (pantoprazole) and generic Aciphex (rabeprazole).

For that reason, preauthorization could not be approved. You will be liable for the charges if this prescription is filled.

Petitioner's Argument

On the external review request form the Petitioner explained her problem: "epigastric pain, GERD, gastritis, history H. pylori."

Director's Review

In its final adverse determination, BCBSM said it would not cover Dexilant for the Petitioner because it is not on the list of drugs for her plan (i.e., the "Custom Select Drug List"). However, the certificate (p. 14) says exceptions from that limitation may be made:

Request for Drugs Not on BCBSM Drug List

If your prescription drug coverage is limited to an approved drug list, you may request an exception. BCBSM must approve your request for a drug not on the list before it is dispensed. If approval is not obtained before the drug is dispensed, the drug will not be covered.

To request an exception, you must follow BCBSM's exception request process. The process is as follows:

- You, your designee or the provider who prescribed you the drug must contact BCBSM and request an exception for the drug that is not on BCBSM's drug list.
- We will decide whether to grant the request once we receive all of the information we need to make a decision. We will notify you, your designee, the prescribing provider or the provider's designee whether the request has been granted within 24 hours of receiving all of the needed information.

* * *

If your physician does not get approval before the drug is dispensed, the drug will not be covered. You will be responsible for 100% of the pharmacy's charge. If the exception request is approved, you will have to pay your deductibles, coinsurances or copayments.

This provision is consistent with section 3406o of the Insurance Code, MCL 500.3406o, which says:

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. This subdivision does not prevent an insurer from establishing prior authorization requirements or another process for consideration of coverage or higher cost-sharing for nonformulary alternatives. Notice as to whether or not an exception under this

subdivision has been granted shall be given by the insurer within 24 hours after receiving all information necessary to determine whether the exception should be granted.

The Director must therefore determine if BCBSM was correct when it declined to make an exception for Dexilant. The question of whether Dexilant is a "medically necessary and appropriate alternative" to the drugs on the "Custom Select Drug List" was presented to an independent review organization (IRO) for analysis and a recommendation as required by section 11(6) of the Patient's Right to Independent Review Act, MCL 550.1911(6).

The IRO physician reviewer is certified by the American Board of Surgery and the American Board of Quality Assurance and Utilization Review Physicians; is a Fellow of the American College of Surgeons; and is in active practice. The IRO report said:

Reviewer's Decision and Principal Reasons for the Decision:

Is the prescription drug Dexilant medically necessary for the treatment of the patient's condition?

No. It is the determination of this reviewer that the prescription drug Dexilant is not medically necessary for the treatment of the enrollee's condition.

Clinical Rationale for the Decision:

The introduction of proton pump inhibitors (PPIs), since the 1980's, has revolutionized the treatment of gastroesophageal reflux disease (GERD) and other upper gastrointestinal diseases. Currently, the following PPIs are available in the United States: omeprazole (Prilosec), lansoprazole (Prevacid), rabeprazole (Aciphex), pantoprazole (Protonix), esomeprazole (Nexium) and dexlansoprazole (Dexilant). The three (3) that can be obtained over-the-counter are omeprazole, lansoprazole, and omeprazole-sodium bicarbonate (Zegrid).

The PPIs are the most potent inhibitors of gastric acid secretion available. All PPIs work by inhibiting the hydrogen/potassium (H⁺/K⁺) adenosine triphosphatase (ATPase) enzyme system in the gastric parietal cells. Although PPIs are similar in structure and mechanism of action, there are some differences in their bioavailability features, peak plasma levels and routes of excretion. When comparing the various PPIs to each other, studies have shown some differences, though the outcomes have been small and the clinical significance of such are not clear. As noted in UpToDate: "The degree to which any of the reported differences would justify the selection of one versus another PPI, particularly when considering cost-effectiveness, is unclear."

It is important to understand the concept of medical necessity and the role of scientific evidence as it relates to coverage and the decisions that physicians must

make when formulating diagnostic work-ups and treatment plans. Medical necessity or medically necessary is understood to mean that the services of a physician in exercising prudent clinical judgment would provide to the patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms and that are:

- A. In accordance with generally accepted standards of medical practice.
- B. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease.
- C. Not primarily for the convenience of the patient, physician or other health provider, and not more costly than an alternative service. . .

Based on the submitted documentation, it is clear that the enrollee has a long history of PPI use. The January 11, 2016 Medication Non-Formulary/Benefit [Exemption] Request Form states the enrollee has used Zantac in 2014, Prilosec in 2015 and Prevacid in 2015. However, the medical records submitted for review did not mention the use of Zantac in 2014 nor Prilosec in 2015. There was no specific documentation submitted by the provider as to why a trial of Aciphex (rabeprazole) or Protonix (pantoprazole) could not have been instituted for a reasonable period of time. If these medications had been tried, documentation of treatment failure or a reason why those specific PPIs were medically contraindicated was not noted.

In addition, the American College of Gastroenterology has recommended twice daily dosing in individuals that are not responding to the once a day dosing that is usually taken before the first meal of the day. In this case, there was no documentation that a trial of Prilosec twice daily or Prevacid twice daily had been implemented and failed. Specific documentation has not been provided to support medical necessity for Dexilant. Therefore, for the reasons noted above, the prescription drug Dexilant 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 the prescription drug Dexilant 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 that analysis should be rejected in the present case, adopts the IRO recommendation and finds that Dexilant is not medically necessary to treat the Petitioner.

V. ORDER

The Director upholds BCBSM's February 25, 2016, 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 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