

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. 150679-001

Blue Cross Blue Shield of Michigan
Respondent

Issued and entered
this 7th day of December 2015
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On November 2, 2015, ██████████, on behalf of her ██████████ son, ██████████ (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 November 9, 2015.

The Petitioner receives health care benefits under a group plan underwritten by Blue Cross Blue Shield of Michigan (BCBSM). The benefits are defined in BCBSM's *Preferred Rx Program Certificate LG*. The Director notified BCBSM of the external review request and requested the information used to make its final adverse determination. BCBSM provided its response on November 16, 2015.

To address the medical issues presented in this appeal, the Director assigned the case to an independent medical review organization which provided its analysis and recommendation on November 24, 2015.

II. FACTUAL BACKGROUND

The Petitioner, who is now ██████████ was born at ██████████ weeks gestation. He was diagnosed with severe gastroesophageal reflux (GER) and failure to thrive. After formula and feeding changes did not resolve his symptoms, he was tried on Zantac, First-Lansoprazole, Prevacid Solu-tab, and Prevacid compounded. First-Lansoprazole was the only medication that provided relief, so his pediatrician prescribed First-Lansoprazole as treatment for his condition. BCBSM denied coverage.

The Petitioner's mother appealed the denial through BCBSM's internal grievance process. At the conclusion of that process, BCBSM affirmed its denial in a final adverse determination issued September 18, 2015. The Petitioner's mother now seeks a review of that final adverse determination from the Director.

III. ISSUE

Did BCBSM correctly deny coverage for First-Lansoprazole?

IV. ANALYSIS

Petitioner's Argument

In the external review request, the Petitioner's mother wrote:

Due to severe acid reflux without medication and no insurance coverage for the only medication that works for my son, I am requesting an external review. Paying out of pocket is getting more expensive as my child grows and the dosage needs to be increased. It could take another 6.5 months before he outgrows this, and we just spent \$112 for a month's supply.

With the external review request, the Petitioner's mother included a copy of a September 16, 2015 letter to BCBSM from her son's pediatrician who wrote:

[Petitioner] (D.O.B 5/10/2015) is a [REDACTED] with a birth weight of [REDACTED]. [Petitioner] has a history of severe reflux and failure to thrive with a weight of [REDACTED] 5/29/16. Multiple formulas (Similac Sensitive, Similac Total Comfort, ProSobee, [and] Nutramagen), feeding schedules, and medications (Zantac, First-Lansoprazole, Prevacid Solu-tab, and Prevacid compounded at a compounding pharmacy) have been tried.

Of these medications, [Petitioner] does well on first lansoprazole, Zantac was tried 6/08/15 to 6/12/15 without relief. First Lansoprazole was tried 6/12/15 to 7/6/15 with relief. Due to insurance coverage denial, Prevacid Solutab was tried 8/14/15 to 8/29/15 without success, Compounded Prevacid at a compounding pharmacy was tried 8/29/15 to 9/9/15 without success. [Petitioner] was switched back to First Lansoprazole 3mg/ml 9/9/15 and has done well on 2.5ml twice daily since. [Petitioner] is now more comfortable and is now 15 lb.

BCBSM's Argument

In its final adverse determination, BCBSM's representative wrote:

Your son is covered under the *Preferred RX Program Certificate LG*. Page 13 of the *Certificate* explains that drugs that are not labeled "FDA approved," except for state-controlled drugs and insulin, or such drugs that BCBSM designates as covered are excluded from coverage.

A Clinical Pharmacist, RPh, reviewed the documentation provided in your son's appeal and determined:

This is a non-FDA approved "compound" kit; therefore, it is excluded from your Clinical drug plan. Covered alternatives include: Prilosec granules for suspension, Nexium granules for suspension, and Aciphex sprinkle.

Authorization for Nexium granules and Aciphex sprinkle has been approved for one year effective September 17, 2015 to September 17, 2016. First Lansoprazole is excluded from coverage. Consequently, authorization is denied.

Director's Review

The propriety of First-Lansoprazole to treat the Petitioner's GER was presented for analysis to an independent review organization (IRO) 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 Pediatrics with a subspecialty certification in neonatal-perinatal medicine. The reviewer is an assistant clinical professor at a university-based medical college; is a member of the American Academy of Pediatrics, the Society for Pediatric Research, and the American College of Osteopathic Pediatricians; and is published in peer reviewed medical literature. The IRO reviewer's report included the following analysis and recommendation:

When infants fail conservative measures for treatment of GER (reduced volumes of feedings, increased frequency of feedings, thickening of feedings, etc.), medications can be used to manage their GER symptoms. Per current standard of practice and peer reviewed publications, the use of H2 blockers, such as ranitidine (Zantac) and the use of PPI's (Prevacid, Prilosec) are acceptable medications for the management of GER disease in infants when other non-medication based strategies have failed. Pro-kinetic agents may also be considered.

While there are numerous medications for the management of gastroesophageal reflux disease (GERD), with the exception of ranitidine, none have been approved by the Food and Drug Administration (FDA) for use in infants less than one year of age. While the safety and effectiveness of Nexium (esomeprazole) has been established in pediatric patients age one month to less than one year, for short-term treatment (up to six weeks), it is not FDA approved for this group. Similarly, the safety and effectiveness of Prilosec (omeprazole magnesium) for the treatment of GERD in patients less than one year of age have not been established.

Current guidelines emphasize weight loss as a crucial warning sign that should alter clinical management of GER in infants. Because the physician caring for the enrollee diagnosed GER and noted associated FTT [failure to thrive], the enrollee met criteria for medical management of the GER. Conservative measures (formula changes, feeding schedules and other medications) were noted to have failed for this enrollee. Because other medications were trialed and the enrollee's condition did not improve, but the requested medication First Lansoprazole was successful for this enrollee, First Lansoprazole is an appropriate treatment.

The use of lansoprazole has been well studied in infants < 1 year of age. The physician's selection of lansoprazole is within the accepted standard of current practice for the management of GER in infants because conservative measures and other medications have failed.

* * *

Therefore, based on the current medical literature and documentation submitted for review, First Lansoprazole is 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 First-Lansoprazole be overturned.

[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. In addition, the IRO recommendation is not contrary to any provision of the Petitioner's certificate of coverage. MCL 550.1911(15). The Director can discern no reason why the IRO's recommendation should be rejected in the present case.

The Director finds that First-Lansoprazole is a medically necessary and appropriate treatment for the Petitioner's condition.

V. ORDER

The Director reverses BCBSM's final adverse determination of September 18, 2015. BCBSM shall immediately provide the Petitioner with prescription drug coverage for the prescription drug First Lansoprazole. See MCL 550.1911(17). BCBSM shall, within seven days of providing coverage, furnish the Director proof it has implemented this order.

To enforce this order, the Petitioner's representative may report any complaint regarding its implementation the Department of Insurance and Financial Services, Health Plans Division, toll free 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