

STATE OF MICHIGAN
DEPARTMENT OF ENERGY, LABOR & ECONOMIC GROWTH
OFFICE OF FINANCIAL AND INSURANCE REGULATION
Before the Commissioner of Financial and Insurance Regulation

In the matter of

XXXXX

Petitioner

File No. 104112-001

v

United HealthCare Insurance Company
Respondent

Issued and entered
This 7th day of July 2009
by Ken Ross
Commissioner

ORDER

I
PROCEDURAL BACKGROUND

On April 7, 2009, XXXXX (Petitioner) filed a request for external review with the Commissioner of Financial and Insurance Regulation under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.* The Commissioner reviewed the request and accepted it on April 14, 2009.

The Commissioner notified United HealthCare Insurance Company (UHC) of the external review and requested and received the information used in making its adverse determination.

The case presented a medical question so the Commissioner assigned it to an independent review organization, which provided its analysis and recommendation to the Commissioner on June 19, 2009.

II
FACTUAL BACKGROUND

The Petitioner has group health care coverage with UHC. Her benefits are defined in the

UnitedHealthCare Choice Plus certificate of coverage (the certificate) and its applicable riders and amendments. The Petitioner's coverage includes an Outpatient Prescription Drug rider (the rider).

The Petitioner sought coverage for the prescription drug Nexium and UHC declined to cover it. The Petitioner appealed UHC's decision. After completing UHC's internal grievance process, the Petitioner received UHC's final adverse determination dated March 25, 2009, upholding its decision.

III ISSUE

Was UHC correct in denying coverage for Nexium for the Petitioner?

IV ANALYSIS

Petitioner's Argument

The Petitioner has a history of digestive problems. The Petitioner said:

My doctors have tried all the medicines and the only one that seems to work for my symptoms is the Nexium. I have been on this medication for nearly 5 years. I was told that the only other alternative would be to have surgery. *** Due to the cost of the medication here in the states, \$97.97 for a 15 day supply I have had to resort to ordering the medication from Canada.

Her doctor said:

[The Petitioner] has a long, complex history of GERD [gastroesophageal reflux disease]. From age of infancy, has had digestion problems with projectile vomiting. Very numerous scopes and tests. She has tried multiple PPI's [*proton pump inhibitors, drugs that reduces gastric acid secretion in the stomach*] including Prevacid, Prilosec, Protonix and has been on Nexium since February 16, 2004 and Nexium has been the only medication that has helped.

The Petitioner asks that UHC be required to cover her Nexium prescriptions because it is the only medication that works for her.

Respondent's Argument

UHC told the Petitioner in the final adverse determination:

We reviewed the request to reconsider our previous decision regarding the Nexium that you will receive.

* * * We confirmed...that this medication(s) is not eligible for payment as you requested. You are responsible for all costs related to this medication(s).

UHC went on to say that the reason for its denial is found in this exclusion in Section 2 of the rider:

Exclusions from coverage listed in the *Certificate of Coverage* apply also to this rider.... In addition, the following exclusions apply:

* * *

18. Drugs available over-the-counter that do not require a Prescription Order or Refill by federal or state law before being dispensed, unless we have designated the over-the-counter medication as eligible for coverage as if it were a Prescription Drug Product and it is obtained with a Prescription Order or Refill from a Physician. Prescription Drug Products that are available in over-the-counter form or comprised of components that are available in over-the-counter form or equivalent. Certain Prescription Drug Products that we have determined are Therapeutically Equivalent to an over-the counter drug. Such determinations may be made up to six times during a calendar year, and we may decide at any time to reinstate Benefits for a Prescription Drug Product that was previously excluded under this provision. [Underlining added]

The Petitioner's prescription drug coverage includes a three-tier prescription drug list. Each tier is assigned a copayment amount. Tier 1 drugs have the lowest out-of-pocket expense, and tier 3 the highest. Nexium is shown as "excluded" in tier 3. The prescription drug list explains what "excluded" means: "Many benefit plans exclude coverage of medications that are classified by the Pharmacy and Therapeutics Committee as therapeutically equivalent to over-the-counter and prescription medications."

In the formal 2nd level appeal summary, UHC noted, "An initial review has determined that Nexium is not a covered prescription drug product as it is therapeutically equivalent to Prilosec OTC [over-the-counter]." The rider says a drug is "therapeutically equivalent" if it "can be expected to produce essentially the same therapeutic outcome and toxicity."

Therefore, UHC concluded that its denial of coverage was correct because Nexium's equivalent (Prilosec OTC) is available without a prescription.

Commissioner's Review

The Commissioner assigned this matter to an independent review organization (IRO) for an

analysis and recommendation regarding the medical issue involved. The IRO reviewer is a physician board certified in gastroenterology who has been in practice for more than 15 years. The IRO reviewer concluded that Nexium is not medically necessary for the treatment of the Petitioner's condition at this time. The IRO report said:

The MAXIMUS physician consultant indicated that Prilosec over the counter is produced in 20 mg pills. The MAXIMUS physician consultant also indicated that two of these tablets would be equivalent to a Nexium 40 mg. The MAXIMUS physician consultant explained that Nexium is esomeprazole, which is a single enantiomer of omeprazole (Prilosec). The MAXIMUS physician consultant also explained that the metabolism of these two drugs may differ. The MAXIMUS physician consultant noted that for some patients, one particular proton pump inhibitor works best. However, the MAXIMUS physician consultant indicated that there is no documentation demonstrating that the [Petitioner] has completed a trial of Prilosec 20 mg twice a day for four weeks. The MAXIMUS physician consultant explained that such a trial is appropriate before considering coverage of Nexium in this case.

Pursuant to the information set forth above and available documentation, the MAXIMUS physician consultant determined that Nexium is not medically necessary for treatment of the [Petitioner's] condition at this time.

The Commissioner is not required in all instances to accept the IRO's recommendation. However, the IRO recommendation is afforded deference by the Commissioner. The IRO analysis is based on extensive expertise and professional judgment and the Commissioner can discern no reason why the recommendation should be rejected in this case.

In accepting the IRO's conclusion that Nexium is not medically necessary for the Petitioner at this time, the Commissioner notes that the rider requires step therapy for certain drug products. Step therapy is the practice of beginning drug therapy for a medical condition with the most cost-effective and safest drug therapy and progressing to other more costly or risky therapy, only if necessary. The aims of step therapy are to control costs and minimize risks. Although the Petitioner and her physician say she has tried other medications without success, the record contains no documentation of that effort, as the IRO reviewer observed.

The Commissioner further notes that Section 3406o of the Insurance Code of 1956, MCL 500.3406o, requires an insurer that provides prescription drug coverage and limits that coverage to

drugs included in a formulary to make exceptions when a nonformulary alternative is medically necessary and appropriate. That section 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:

(a) Provide for participation of participating physicians, dentists, and pharmacists in the development of the formulary.

(b) Disclose to health care providers and upon request to insureds the nature of the formulary restrictions.

(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. [Emphasis added]

However, based on the record in this case, neither the IRO reviewer nor the Commissioner could conclude that the Petitioner has established that a nonformulary alternative (i.e., Nexium) is medically necessary for her at this time. Therefore, the Commissioner upholds UHC's final adverse determination.

V ORDER

The Commissioner upholds United HealthCare Insurance Company's March 25, 2009, final adverse determination. UHC is not required to cover the Petitioner's Nexium at this time.

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 Commissioner of Financial and Insurance Regulation, Health Plans Division, Post Office Box 30220, Lansing, MI 48909-7720.

Ken Ross
Commissioner