

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. 118180-001

v

Physicians Health Plan of Mid-Michigan
Respondent

Issued and entered
this 6th day of January 2011
by Ken Ross
Commissioner

ORDER

I
PROCEDURAL BACKGROUND

On November 22, 2010, Dr. XXXXX, M.D., authorized representative of his patient 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 notified Physicians Health Plan of Mid-Michigan (PHP) of the external review and requested the information used in making its adverse determination. PHP responded on November 29, 2010. After a preliminary review of the material submitted the Commissioner accepted the request for external review.

This case involves medical issues. Therefore, the Commissioner assigned the matter to an independent review organization which submitted its recommendation to the Commissioner on December 13, 2010.

II FACTUAL BACKGROUND

Effective July 1, 2010, Petitioner became a member of PHP, a health maintenance organization. His benefits are defined in the *PHP Plus Certificate of Coverage* (the certificate), PHP's *Outpatient Prescription Drug Rider*. Prior to enrolling with PHP, Petitioner had coverage with Blue Cross and Blue Shield of Michigan (BCBSM).

Petitioner is a 63-year-old male who was diagnosed in 2007 with Type II diabetes. He was initially treated with several oral medications but experienced side effects that included nausea, weight gain and edema, hypoglycemia, and bowel issues. As a result, in March 2010 his primary care physician prescribed Victoza, an injectable drug.

Petitioner's BCBSM medical plan covered the drug. In July 2010, Petitioner's physician requested authorization from PHP for Victoza. PHP denied the request ruling that its criteria for coverage of this nonformulary drug were not met.

Petitioner appealed the denial through PHP's internal grievance process. PHP issued a final adverse determination dated November 3, 2010.

III ISSUE

Did PHP properly deny coverage for the Victoza under the terms of the certificate?

IV ANALYSIS

Respondent's Argument

In its November 3, 2010, final adverse determination, PHP denied coverage for the Victoza saying, in part:

The original decision to deny your request was upheld because your benefits do not include coverage for Victoza when criteria are not met. To meet the criteria, you need to have an Hgb A1c level greater than 8%. Since your level is too low, you do not meet criteria. This decision was based on the following section of your Certificate of Coverage. . . .

- Outpatient Prescription Drug Rider, Section 2: What's Not Covered – Exclusions, #13

This provision excludes coverage for “Prescription Drug Products, including New Prescription Drug Products or new dosage forms that are determined to not be a Covered Health Service.”

PHP’s final adverse determination also suggested the Petitioner talk to his physician about several related medications that would be covered:

- Biguanide: Metformin extended release, Glumetza, Riomet, Fortamet
- DPP-4 inhibitor: Onglyza, Januvia
- TZD: Avandia
- AGI: Acarbose

PHP maintains that its denial was appropriate under the terms of the certificate.

Petitioner’s Argument

Petitioner argues that Victoza is the only medication that “stabilizes” his Type II diabetes without adverse side effects. Petitioner’s physician, in a letter dated November 16, 2010, wrote:

[C]urrent recommendations for good diabetic control requires reaching an A1c of 6.5% maximum, certainly 6.2% being better . . . for those who still enjoy a functioning beta cell mass and have been diagnosed and treated prior to the onset of cardiovascular (CV) events. In short, for good outcomes, intensive therapy must be initiated well prior to the onset of adverse events from the disease. . . In short, there is a point of “no return” in the treatment of diabetes wherein good glycemic control . . . becomes increasingly difficult and insulin becomes the only reasonable option – this point, while yet to be defined in perfect detail, is now known to occur far earlier in the course of the disease than previously thought is apparently closely related to the degree of beta cell mass survival. [Petitioner] certainly falls into this group of patients – early identification of disease, lack of CV events, and, undoubtedly, still within the “point of no return.” There is no question, however, that an A1c of 8.0% is well beyond this point of return, undoubtedly because at such a level, the beta cell mass is extensively, if not virtually completely, absent. . . . This is an essential point, as products that are dependent upon a functioning beta cell mass to exert their function, such as the incretin mimetics, are illogical – there are inadequate beta cells available to produce enough insulin to perform the job.

Petitioner’s physician then addressed in detail other diabetes medication, including some drugs cited in PHP’s final adverse determination, and explained why he believes they are not suitable for Petitioner’s condition.

Commissioner's Review

A health maintenance organization such as PHP that covers prescription drugs but limits coverage to drugs on a formulary must provide certain exceptions to the formulary list. Section 3406o of the Michigan 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. . . .

In order to determine if Victoza is “a medically necessary and appropriate alternative,” the Commissioner assigned the issue to an independent review organization (IRO) for analysis and recommendation. The review was conducted by a physician who is board certified in endocrinology, has been in active practice for more than 15 years, and is familiar with the medical management of patients with Petitioner’s condition. The reviewer examined all medical records and other communications submitted by the parties for this review. The IRO reviewer’s report included the following analysis:

. . . [T]he [Petitioner] has tried other medications for treatment of his type II diabetes mellitus. . . . [T]he [Petitioner] reported gastrointestinal side effects with metformin, edema with Actos and nausea with Byetta. . . . [T]he [Petitioner’s] A1c is well controlled with Victoza. . . . [T]he [Petitioner] reported that he started taking Victoza before becoming covered by the Health Plan. . . . [T]he Health Plan’s list of preferred medications includes DPP-4 inhibitors Januvia and Onglyza. . . . [A]ccording to the information provided for review, the [Petitioner] has never been treated with these medications. . . . [A] DPP-4 inhibitor is likely to meet the [Petitioner’s] A1c goal.

The reviewer concluded that “Victoza 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; in a decision to

uphold or reverse an adverse determination the Commissioner must cite “the principal reason or reasons why the Commissioner did not follow the assigned independent review organization’s recommendation” MCL 550.1911(16)(b). The IRO’s analysis is based on extensive expertise and professional judgment. The Commissioner can discern no reason why that judgment should be rejected in the present case. The Commissioner accepts the conclusion of the IRO and finds that Victoza is not medically necessary for treatment of the Petitioner’s condition at this time.

The Commissioner also finds that PHP’s denial was consistent with the terms of the certificate and Michigan law.

**V
ORDER**

The Commissioner upholds PHP’s November 3, 2010, final adverse determination. PHP is not required to provide coverage for Petitioner’s Victoza 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.