

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. 112281-001

v

Physicians Health Plan of Mid-Michigan
Respondent

Issued and entered
this _9th_ day of March 2011
by Ken Ross
Commissioner

ORDER

I
BACKGROUND

On June 15, 2010, 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 (PHPMM) of the request for external review and requested the information used in making its final adverse determination. On June 22, 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 (IRO) which submitted its recommendation on July 8, 2010.

II FACTUAL BACKGROUND

The Petitioner is a member of PHPMM. His prescription drug benefits are defined in the outpatient prescription rider to his certificate of coverage.

In June 2006 the Petitioner was prescribed Cialis 20 mg (five pills every 31 days) for erectile dysfunction. In August 2008, the Petitioner was diagnosed with high blood pressure and was prescribed Lisinopril 10 mg twice daily for that condition.

The Petitioner, who is also a diabetic, charted his glucose and blood pressure daily. He noticed that when he used Cialis his blood pressure was lower. Because of this benefit, the Petitioner requested coverage for Cialis 5 mg for daily use. PHPMM denied the request.

The Petitioner appealed the denial through PHPMM's internal grievance process, and PHPMM affirmed its decision in a final adverse determination letter dated April 15, 2010.

III ISSUE

Did PHPMM properly deny the Petitioner coverage for Cialis 5 mg for daily use?

IV ANALYSIS

Petitioner's Argument

Petitioner argues Cialis 5 mg daily is medically necessary for the treatment of this high blood pressure. In his March 23, 2010, "thesis" to PHPMM, he explains:

[N]o one has prescribed Cialis (Tadalafil 5 mg) for daily use for blood pressure. However the literature shows that indeed, "as with other PDES inhibitors, Tadalafil has mild vasodilatory properties that may result in transient decreases in blood pressure." Therefore, though it is licensed for treatment of ED the transient decreases in blood pressure do exist and "clinical pharmacological studies were conducted to assess the effect of Tadalafil on the potentiation of the blood-pressure-lowering effects of select antihypertensive medication" -- including enalapril an ACE inhibitor like lisinopril, the drug I take for hypertension. ...

This blood pressure lowering property of tadalafil is so true that at much higher doses of 20 and 40 mg, it is licensed as Adeirca for treatment of

Pulmonary Arterial Hypertension and this with the additional benefits related to ED as a bonus but not the main purpose.

... I already have Cialis 36 hours (Tadalafil 20 mg) approved for treatment of ED since June 2006. Now there is...Cialis for daily use...which was prescribed to me.... Due to a free monthly supply plus two samples of 7 days each, I have my own data showing that this new form of Tadalafil has beneficial side effect highly desirable in my case, since I am Diabetic and have been taking Lisinopril since August 2008: these two vasodilators used in combination seem [to] present an additive effect without causing hypotension.

The Petitioner's cardiologist, XXXXX, MD, supports this position, stating in an April 6, 2010, letter:

I have been caring for [the Petitioner] since August 2008. He was diagnosed with Hypertension and Erectile dysfunction. The patient has been very diligent in his care and after reviewing his chart it is recommended that the patient take Cialis 5 mg daily. While taking Cialis 5 mg daily with Lisinopril 10 mg twice daily the patient's blood pressure and symptoms have improved.

The Petitioner wants PHPMM to cover Cialis for daily use.

Respondent's Argument

In its April 15, 2010, final adverse determination, PHPMM based its denial on three exclusions in the outpatient prescription rider:

Section 2: What's Not Covered – Exclusions

[T]he following exclusions apply:

* * *

2. Coverage for Prescription Drug Products for the amount dispensed (days' supply or quantity limit) which exceeds the supply limit.

* * *

5. Experimental, Investigational or Unproven Services and medications; medications used for experimental indications and/or dosage regimens determined by us to be experimental, investigational or unproven. ...

* * *

15. Prescription Drug Products not included on Tier-1 or Tier-2 of the Prescription Drug List at the time the Prescription Order or Refill is dispensed.

PHPMM notes that Cialis is included on the prescription drug list as a Tier 2 drug with a “quantity per duration limit.” PHPMM also says that the Petitioner’s urologist indicated that the Cialis 5 mg daily dosage was prescribed for erectile dysfunction, not hypertension.

PHPMM argues that Cialis 5 mg daily dosage is excluded and therefore its denial was appropriate.

Commissioner’s Review

To resolve the medical issues in this case, the Commissioner obtained the recommendation of an independent review organization (IRO) pursuant to MCL 550.1911. The review was conducted by a physician who is certified by the American Board of Urology, and is a member of the American Urological Association; the Society for Urodynamics and Female Urology; the American Urogynecologic Society; the International Continence Society; and the Society for University Urologists. The IRO reviewer is also assistant professor of urology at a major college of medicine and is published in peer-reviewed literature. The IRO reviewer recommended upholding PHPMM’s denial of coverage for Cialis 5 mg daily. The IRO report said:

This case concerns a sixty two (62) year old male with a history of diabetes mellitus, erectile dysfunction, and essential hypertension. He has been using tadalafil (Cialis) for his erectile dysfunction and noted that he has significant improvement in his hypertension. He states that his blood pressure control on Tadalafil is better than his current blood pressure medication.

Reviewer’s Decision and Principal Reasons for the Decision:

It is the determination of this reviewer that the use of Cialis, 5 mg daily, for the treatment of essential hypertension is considered experimental at the present time.

The IRO reviewer noted that the *Milliman Care Guidelines* do not include the use of Cialis among the current standard of care treatments for hypertension. The IRO report continued:

Tadalafil is Food and Drug Administration (FDA) approved for the

treatment of erectile dysfunction and pulmonary hypertension. It is not approved for essential hypertension and therefore is considered experimental.

There is only one reported trial of the use of PDE 5 inhibitor for the treatment of essential hypertension. Although helpful in these patients, the study concludes the need for a larger long term trial. Therefore, the use of Cialis for treatment of essential hypertension cannot be considered the standard of care at the present time and must be considered experimental.

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 experience, expertise and professional judgment. The Commissioner can discern no reason why the IRO's recommendation should be rejected in the present case.

The Commissioner upholds PHPMM's denial of coverage for Cialis because it is experimental for the Petitioner's hypertension and therefore excluded under the terms of the prescription drug rider. In finding that Cialis for hypertension is experimental, the Commissioner does not reach the other bases cited by PHPMM as reasons for denying coverage.

V
ORDER

The Commissioner upholds PHPMM's April 15, 2010, final adverse determination. PHPMM is not required to provide coverage for Cialis 5 mg for daily use.

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