

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. 153107-001

Priority Health Insurance Company,

Respondent.

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Issued and entered  
this 3<sup>rd</sup> day of May 2016  
by Randall S. Gregg  
Special Deputy Director

**ORDER**

**I. PROCEDURAL BACKGROUND**

On April 6, 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.*

The Petitioner receives health care coverage, including prescription drug benefits, through an individual plan underwritten by Priority Health Insurance Company (Priority). The Director immediately notified Priority of the external review request and asked for the information it used to make its final adverse determination. Priority initially responded on April 12, 2016. After a preliminary review of the material submitted, the Director accepted the request on April 13, 2016.

The case involves medical issues so it was assigned to an independent medical review organization which submitted its recommendation to the Director on April 25, 2016.

**II. FACTUAL BACKGROUND**

The Petitioner's health care benefits are defined in Priority's *MyPriority HSA PPO Insurance Policy* (the policy).

The Petitioner has benign prostatic hypertrophy (BPH). His physician prescribed Cialis 5

mg tablet daily. Priority denied coverage for this drug, saying the Petitioner did not meet its criteria for use.

The Petitioner appealed the denial through Priority's internal grievance process. At the conclusion of that process, Priority issued a final adverse determination dated March 25, 2016, affirming its decision. The Petitioner now seeks a review of that final adverse determination by the Director.

### III. ISSUE

Did Priority correctly deny coverage for the prescription drug Cialis?

### IV. ANALYSIS

#### Petitioner's Argument

On the external review request form the Petitioner wrote:

I am a 64-year old sexually active married male suffering with BPH. Early last year my Urologist prescribed Tamsulosin HCL. After several months of use I found the side effects unacceptable. The side effects included headaches, dizziness, decreased sexual interest and a noticeable decrease of semen released during sex. Complaining about the side effects I was put on Cialis 5mg. I've had virtually no side effects with Cialis and my BPH has been under control. On January 1, 2016 I switched insurance companies from HealthPlus (which covers Cialis) to Priority Health. My insurance premiums increased over 30% to over \$2,600.00 per month. After getting over the sticker shock I was informed that Priority would not cover Cialis unless I go on a 6-month regiment of Proscar. Researching Proscar I found that the side effects would be very much like Tamsulosin. Also, Proscar may cause a certain type of high grade prostate cancer and that the sexual side effects may continue even after I stop taking the drug. I will not take a drug that promises adverse side effects (which I experienced) when Cialis controls my BPH with none.

#### Priority's Argument

In its final adverse determination, Priority told the Petitioner:

**Issue:**

[The Petitioner] is requesting coverage of Cialis 5mg tablets, A Non-Preferred Brand name medication.

[He] states: I have tried other drugs including Flomax to treat BPH, resulting in adverse sexual reactions. Cialis controlled the symptoms with no side effects. I have been on Cialis for the last 10 months.

**Decision:**

Uphold denial - requested coverage will not be provided as [the Petitioner] does not meet the coverage criteria for Cialis. Specifically, records reviewed indicate [he] has not a documented trial and clinical failure with finasteride for a period of 6 months.

The Appeal Committee noted [the Petitioner's] concerns regarding the potential side effects of finasteride, however, the committee did not feel an exception to the step-therapy criteria was appropriate in this situation.

**Director's Review**

Priority denied coverage for Cialis stating the Petitioner did not meet its step therapy criteria for use of Cialis. Priority's criteria for coverage of Cialis are found in its approved drug list which says:

Must first try tamsulosin or alfuzosin for 1 month and finasteride for 6 months when used for BPH. . . .

In order to determine if Priority correctly denied coverage for Cialis, the issue was presented 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 physician reviewer is certified by the American Board of Urology in General Urology; is published in the peer reviewed literature; and is in active practice. The IRO report included the following analysis and recommendation:

**Reviewer's Decision and Principal Reasons for the Decision:**

- **Is the Priority Health medical policy for use of Cialis the standard of care for treatment of BPH?** No. The Priority Health medical policy for use of Cialis is not the standard of care for treatment of BPH. The health plan requires step therapy with one (1) month of alpha blocker (eg. Tamsulosin or alfuzosin) and six (6) months of 5-ARI (eg. Finasteride).
- **If it is not the standard of care, is this drug medically necessary for treatment of the enrollee's condition?** Yes. It is the determination of this reviewer that Cialis is medically necessary for the treatment of the enrollee's condition.

**Clinical rational for the Decision:**

The use of Cialis or surgical therapy is the appropriate standard of care for a patient with this clinical scenario. Phosphodiesterase type 5 (PDE5) inhibitors like Cialis (tadalafil) have been studied in men with BPH and lower urinary tract symptoms (LUTS). The efficacy of tadalafil for BPH/LUTS is based on findings that show the expressions of the PDE5 enzyme in the lower urinary tract (prostate, bladder, urethra and vascularity). PDE5 inhibition results in smooth muscle relaxation and may increase pelvic blood perfusion, which is suspected to affect smooth muscle tone. Clinical studies have demonstrated that tadalafil 5 mg once daily leads to statistically significant improvements in symptoms scores (using the International Prostatic Symptom Score [IPSS] objective questionnaire to assess LUTS) as early as one to two weeks after beginning therapy. Improvements in total IPSS that occurred over the initial twelve weeks of tadalafil treatment were maintained over a one year open-label extension period.

Five alpha reductase inhibitors (5-ARI) inhibits the conversion of testosterone to dihydrotestosterone. In men with moderate to severe lower urinary tract symptoms (LUTS) and confirmed prostate enlargement, 5-ARI therapy is indicated to prevent BPH progression, reduce prostate size, and reduce the risk of urinary retention and future surgery (per the Medical Therapy of Prostatic Symptoms [MTOPS] and Combination of Avodart and Tamsulosin [COMBAT] trials). In both studies these medications were used in Combination with alpha blockers for more than one year continuously. When used as monotherapy, significant improvements in LUTS is typically not observed before six to twelve months of therapy. Hence, these medications are usually not to alleviate BPH symptoms but to prevent long-term complications of BPH.

This enrollee has intolerance to alpha blocker therapy. Even if the enrollee tolerates 5-ARI, he would not experience symptom improvement for six to twelve months. This would lead to an unnecessary bother to the enrollee due to continuing symptoms. Therefore, based on the documentation submitted for review and current standard of care in the field, treatment with Cialis is appropriate and medically necessary for the treatment of this enrollee's condition.

The Director is not required to accept the IRO's recommendation. *Ross v Blue Care Network of Michigan*, 480 Mich 153 (2008). However, the 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 certificate of coverage. MCL 550.1911(15). The Director, discerning no reason why

the IRO's recommendation should be rejected in this case, finds that Cialis is both the standard of care and medically necessary for the treatment of the Petitioner's condition.

**V. ORDER**

The Director reverses Priority's final adverse determination of March 25, 2016.

Priority shall immediately cover Cialis to treat the Petitioner's BPH. MCL 550.1911 (17). Priority shall, within seven days of covering Cialis, furnish the Director with proof it has implemented this Order.

To enforce this Order, the Petitioner may report any complaint regarding its implementation to the Department of Insurance and Financial Services, Health Care Appeals Section, 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:



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Randall S. Gregg  
Special Deputy Director