

**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. 114682-001

v

Priority Health  
Respondent

Issued and entered  
this 9<sup>th</sup> day of February 2011  
by Ken Ross  
Commissioner

**ORDER**

**I**  
**PROCEDURAL BACKGROUND**

On August 5, 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.* On August 12, 2010, after a preliminary review of the information sent, the Commissioner accepted the request for external review.

The Commissioner notified Priority Health of the external review and requested the information used in making its adverse determination. The Office of Financial and Insurance Regulation received the information on August 17, 2010.

The case involves medical issues. Pursuant to MCL 550.1911(6), the Commissioner assigned the matter to an independent review organization, which submitted its analysis on August 26, 2010.

**II**  
**FACTUAL BACKGROUND**

The Petitioner is a member of Priority Health, a health maintenance organization. Her

benefits are defined in the Priority Health certificate of coverage and prescription drug rider.

Petitioner, who is 52 years old, experienced a decreased libido and depression since undergoing a hysterectomy and related surgery thirteen years ago. Her primary care physician prescribed testosterone in the form of Androgel, to treat these conditions. The Petitioner requested coverage for the Androgel. Priority Health denied the request.

The Petitioner appealed the denial through Priority Health's internal grievance process. Priority Health issued a final adverse determination dated July 8, 2010.

### **III ISSUE**

Did Priority Health properly deny coverage for Androgel?

### **IV ANALYSIS**

#### Petitioner's Argument

In her request for external review, the Petitioner stated that she wanted Priority Health to provide coverage for Androgel because it was prescribed by her doctor and because the drug is approved by the FDA.

In a letter of April 15, 2010, to Priority Health, Petitioner's physician, Dr. XXXXX, wrote:

[Petitioner] has had significant problems with menopausal symptoms and decreased libido over the years. She has tried numerous different medications including every type of estrogen as well as Estratest and testosterone injections. The only thing that seemed to work for her was Androderm and Androgel. While on the other medications she had significant menopausal symptoms causing profound depression. . . . She is here today requesting to be placed back on either Androgel or Androderm, as this seems to be the only thing in the past that worked for her menopausal symptoms and decreased libido.

For these reasons the Petitioner believes Priority Health should provide coverage for the Androgel because it is medically necessary and the only medication that significantly improves her menopausal symptoms.

#### Respondent's Argument

In its July 8, 2010, final adverse determination, Priority Health denied coverage for the Androgel stating: “[Petitioner] does not meet the coverage criteria as outlined in Priority Health’s drug policy. Testosterone is not approved by the FDA to treat females.” In addition, Priority Health excludes coverage for drugs for the treatment of sexual dysfunction, regardless of age, gender or health status (Drug Rider, Section 5). Priority Health also states that the only FDA-approved use of Androgel is for male hypogonadism and related syndromes.

Priority Health believes that its denial was appropriate under the terms of the certificate, prescription drug rider and medical policy.

#### Commissioner’s Review

Michigan law, MCL 500.3406(q), requires health maintenance organizations to provide coverage for “off-label” use of an FDA approved drug when certain conditions are met. “Off-label” means the use of a drug for clinical indications other than those stated in the labeling approved by the FDA. Sections 1 and 2 of the statute provide:

- (1) An expense-incurred hospital, medical, or surgical policy or certificate delivered, issued for delivery, or renewed in this state that provides pharmaceutical coverage and a health maintenance organization contract that provides pharmaceutical coverage shall provide coverage for an off-label use of a federal food and drug administration approved drug and the reasonable cost of supplies medically necessary to administer the drug.
- (2) Coverage for a drug under subsection (1) applies if all of the following conditions are met:
  - (a) The drug is approved by the federal food and drug administration.
  - (b) The drug is prescribed by an allopathic or osteopathic physician for the treatment of either of the following:
    - (i) A life-threatening condition so long as the drug is medically necessary to treat that condition and the drug is on the plan formulary or accessible through the health plan's formulary procedures.
    - (ii) A chronic and seriously debilitating condition so long as the drug is medically necessary to treat that condition and the drug is on the plan formulary or accessible through the health plan's formulary procedures.
  - (c) The drug has been recognized for treatment for the condition for which it is prescribed by 1 of the following:
    - (i) The American medical association drug evaluations.
    - (ii) The American hospital formulary service drug information.

- (iii) The United States pharmacopoeia dispensing information, volume 1, "drug information for the health care professional."
- (iv) Two articles from major peer-reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer-reviewed medical journal.

The question of whether Androgel has been recognized for treatment of depression and decreased libido in women was presented to an independent review organization (IRO) for review. The IRO reviewer is a physician who is board certified in obstetrics and gynecology and has been in practice for more than 10 years. The IRO reviewer's report includes the following:

. . . Androgel is a hydroalcoholic gel that is to be applied to the clean, dry skin of the shoulders, upper arms and/or abdomen. . . . [T]he gel is absorbed through the skin and delivers testosterone to a patient for approximately 24 hours. . . . Androgel is intended for men with primary hypogonadism or hypogonadotropic hypogonadism that results from insufficient secretion of testosterone and is characterized by low serum testosterone concentrations. . . . Androgel is not indicated for the treatment of decreased libido and depression in women. . . . [T]he FDA has not approved Androgel for use in women due to the lack of controlled evaluations in women and potential virilizing effects. . . . [T]he long term safety profile of Androgel in women is not known.

The IRO reviewer concluded that Androgel is not medically necessary for treatment of the Petitioner's condition.

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 Androgel is not a recognized treatment for Petitioner's condition.

**V  
ORDER**

The Commissioner upholds Priority Health's July 8, 2010, final adverse determination. Priority Health is not responsible for providing prescription drug coverage for Androgel.

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.

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Ken Ross  
Commissioner