

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. 152125-001

Blue Cross Blue Shield of Michigan,

Respondent.

Issued and entered
this 8th day of March 2016
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

██████████ (Petitioner) was denied coverage for a prescription drug by her health insurer, Blue Cross Blue Shield of Michigan (BCBSM).

On February 9, 2016, the Petitioner filed a request with the Director of Insurance and Financial Services for an external review of the denial under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.* After a preliminary review of the material submitted, the Director accepted the request on February 17, 2016.

The Petitioner receives prescription drug benefits through a group plan underwritten by BCBSM. The Director immediately notified BCBSM of the external review request and asked for the information it used to make its final adverse determination. BCBSM responded on February 17, 2016.

To address the medical issue in the case, the Director assigned it to an independent medical review organization which provided its analysis and recommendation on March 1, 2016.

II. FACTUAL BACKGROUND

The Petitioner's benefits are described in BCBSM's *Preferred Rx Program Certificate SG* (the certificate).

The Petitioner was diagnosed with female hypogonadism in 2004 and has been treated with the prescription drug AndroGel since that time. When her physician prescribed the continued use of AndroGel, BCBSM denied continued coverage, saying that the Petitioner does not meet its criteria for

coverage and the drug is therefore not medically necessary.

The Petitioner appealed the denial through BCBSM's internal grievance process. At the conclusion of that process, BCBSM affirmed its decision in a final adverse determination dated January 8, 2016. The Petitioner now seeks a review of that final adverse determination from the Director.

III. ISSUE

Did BCBSM correctly deny coverage for AndroGel to treat the Petitioner?

IV. ANALYSIS

Petitioner's Argument

In a February 9, 2016, letter included with the external review request, the Petitioner wrote:

Per BCBS's January 8, 2016, denial of coverage for the prescription AndroGel, enclosed you will find [my physician's] medical records and a letter dated January 19, 2016, stating that she does not see any issues with me taking AndroGel. BCBS had requested [her] records, but did not receive them immediately.

Also enclosed please find a letter . . . dated April 17, 2015, recommending that I reinstate AndroGel therapy. The goal is to keep my hormones, testosterone level, thyroid, etc., in the upper range level of "normal" for optimal health, immune system function, fatigue, energy, lack of libido, etc.

I was initially prescribed AndroGel approximately 12 years ago . . . and continued it on through other family physicians. I am currently seeing Dr. Kimber Gauthier, who has prescribed AndroGel for me as well. I have been trying to get the prescription covered by BCBS since October of 2015. It used to be covered by BCBS at a co-pay of \$80.00. It is now approximately \$450.00 because of BCBS's denial to cover the prescription.

BCBSM's Argument

In its final adverse determination, BCBSM's representative told the Petitioner:

A Clinical Pharmacist, RPh, reviewed your appeal and your health care plan benefits for Blue Cross Blue Shield of Michigan (BCBSM) and determined the following:

The coverage guidelines for your Custom Drug List benefit require criteria be met before coverage can be authorized. Our criteria for coverage of this medication [*AndroGel*] require the member be male. Per package labeling, the only approved FDA indication is for hypogonadism in males. We have no record that this criterion has been met.

Director's Review

The certificate says (p. 25):

We do not pay for the following:

- Prescription drugs that are not medically necessary. . . .

The certificate also has this exclusion (pp. 17, 18):

We will not pay for the following:

* * *

- Any drug or device prescribed for uses or in dosages other than those specifically approved by the Federal Food and Drug Administration. This is often referred to as the off-label use of a drug or device. (However, we will pay for such drugs and the reasonable cost of supplies needed to administer them, if the prescribing M.D. or D.O. can substantiate that the drug is recognized for treatment of the condition for which it was prescribed. See criteria under "Covered Drug" in "The Language of Health Care" section.) Some chemotherapeutic drugs may be subject to prior authorization review.

Because the United States Food and Drug Administration (FDA) has only approved AndroGel for use in hypogonadism in men, BCBSM declined to cover it for off-label use by the Petitioner.¹

The help answer the question of whether BCBSM correctly denied coverage for AndroGel, this case was assigned to an independent review organization (IRO) for analysis and a recommendation 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 Family Medicine; is a senior staff physician for an east coast metropolitan hospital; and is in active practice. The IRO report included the following analysis and recommendation:

Clinical Rationale for the Decision:

Female hypogonadism syndrome is defined as a condition in which the sex glands produce little or no sex hormones, coupled with signs or symptoms including decreased libido, diminished energy and state of vitality and depressed mood. In the United States approximately forty-three percent (43%) of woman experience sexual dysfunction.

* * *

¹ "Off-label" means the use of a drug for clinical indications other than those stated in the labeling approved by the federal food and drug administration." MCL 500.3406q(5)(c). Section 3406q of the Insurance Code, MCL 500.3406q, requires health plans that provide pharmaceutical coverage to cover the off-label use of an FDA-approved drug if certain conditions are met. However, it is not shown in this record that AndroGel, an FDA-approved drug, has met the conditions for off-label use to treat female hypogonadism.

Symptoms of woman with hypogonadism include lack of menstruation, low to absent sex drive, loss of body hair, and/or milky discharge from the breasts. Diagnostic work up includes assessment of hormone levels of follicle stimulating hormone (FSH) and luteinizing hormone (LH) along with estrogen levels in females and testosterone levels in males. Prolactin, iron, and thyroid levels also been linked to with hypogonadism.

The goal of treatment in hypogonadism is to replace the missing hormone to restore normal levels and improve symptoms. The benefits of testosterone treatment in women include improved bone mineralization, protection of memory and improved sense of well-being, along with an increased desire / interest / frequency of sex and orgasm. Studies used to assess the benefits of testosterone treatment used testosterone in combination with estrogen, rather than testosterone alone.

AndroGel (1.62%) is a Category III, controlled substance for daily testosterone replacement therapy used to treat adult males with low or no testosterone levels due to certain medical conditions. Testosterone treatment in men is controversial for men and even more so for women as long term outcome data are not available. It is not meant for use for women. However, testosterone treatments have been used in both males and females with improved sexually functioning and with decreased incidence of hot flashes in women.

The United States Food and Drug Administration (FDA) has approved AndroGel for use in hypogonadism in men, but safety concerns still linger where similar treatment in women are concerned. At this time, testosterone treatment is not FDA recommended for women with hypogonadism. It is considered an off label use for the treatment of hypogonadism in females with combination therapy with estrogen and testosterone in small studies supplemented by anecdotal evidence.

Due to the uncertain safety profile for testosterone replacement therapy, monitoring patients has been recommended by the American Association of Clinical Endocrinologists. Guidelines have been issued for testosterone supplementation for men and are being developed for women. In women, side effects are closely monitored rather than testosterone levels with recommendations for baseline and semi-annual breast exams, complete blood count, lipid profile, annual mammograms, and annual endometrial sonograms.

The enrollee had a normal menarche, was never pregnant, and was having irregular menses presumed to be a postmenopausal stage. The documentation submitted for review did not establish the diagnosis of hypogonadism for the enrollee, although the enrollee did state in a correspondence that her hormone levels were on the low end of normal. The enrollee's symptoms of sexual dysfunction, fatigue and poor well-being are the only documentation as to her diagnosis of female hypogonadism syndrome.

Therefore, based on the documentation submitted for review and current medical literature, the prescription drug AndroGel is not medically necessary for the treatment of the enrollee's condition of hypogonadism. [References omitted]

The Director is not required to accept the IRO's recommendation. *Ross v Blue Care Network of Michigan*, 480 Mich 153 (2008). However, the IRO's recommendation is afforded deference by the Director; it is based on extensive experience, expertise, and professional judgment. 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). Further, the Director finds that the IRO's recommendation is not contrary to any provision of the Petitioner's coverage. MCL 550.1911(15).

The Director, discerning no reason why the IRO's analysis should be rejected in the present case, accepts the IRO's recommendation and finds that AndroGel is not medically necessary to treat the Petitioner's condition.

V. ORDER

The Director upholds BCBSM's January 8, 2016, final adverse determination.

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:



Randall S. Gregg
Special Deputy Director