

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. 150396-001

Blue Cross Blue Shield of Michigan,

Respondent.

Issued and entered
this 20th day of November 2015
by Joseph A. Garcia
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

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

On October 19, 2015, the Petitioner filed a request with the Director of Insurance and Financial Services for an external review of that 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 October 26, 2015.

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 provided its response on November 3, 2015.

To address the medical issues in the case, the Director assigned it to an independent medical review organization which provided its analysis and recommendation on November 9, 2015.

II. FACTUAL BACKGROUND

The Petitioner's prescription drug benefits are defined in BCBSM's *Preferred Rx*

*Program Certificate LG*¹ (the certificate). The certificate is amended by *Rider PD-TTC \$15/\$50/50%/\$70/\$100-RXCM LG Prescription Drug Triple-Tier Copayment With Minimum and Maximum Amounts and a Cost Management Program* (the rider).

The Petitioner has hypogonadism, a condition that causes erectile dysfunction, low sexual drive, and fatigue resulting from low testosterone level. He has received testosterone treatment since 2011. When he failed treatment with Andro Gel 1.62% and could not tolerate Fortesta, his physician prescribed injectable testosterone cypionate to treat his condition.

BCBSM denied coverage for the drug, saying the Petitioner did not meet its criteria. The Petitioner appealed the denial through BCBSM's internal grievance process. At the conclusion of that process BCBSM affirmed its denial in a final adverse determination dated September 23, 2015. The Petitioner now seeks a review of that final adverse determination from the Director.

III. ISSUE

Did BCBSM correctly deny authorization for the prescription drug testosterone cypionate?

IV. ANALYSIS

Petitioner's Argument

The Petitioner stated in his request for an external review:

Problem – BCBS - refusal to pay for medication Testosterone Cypionate, which is used to balance my testosterone levels to a stable non-Hypogonadism state.

Resolution Requested – [BCBSM] needs to cover this hormone replacement medication so my quality of life is improved [and] not suffering the consequences of low T-levels.

BCBSM's Argument

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

... After review, I confirmed the denial must be maintained.

You are covered under the *Preferred Rx Program Certificate for Large Groups (LG)*. This *Certificate* is amended by *Rider PD-TTC \$15/\$50/50%/\$70/\$100-RXCM LG Prescription Drug Triple-Tier Copayment with a Cost Management Program*, which explains the following:

¹ BCBSM form no. 834E, approved 10/14, effective 2015.

Mandatory Preauthorization

Certain drugs require preauthorization. We will pay for each drug, each refill of a drug, and select over-the-counter (OTC) drugs prescribed by a physician, as follows:

When preauthorization of a prescription drug is required, authorization must be obtained from BCBSM before we will consider them for payment. If the required preauthorization is not requested or approval is not obtained, we will deny payment and you will be responsible for 100 percent of the pharmacy's charge.

We will pay our approved amount for select prescription drugs obtained from a pharmacy or in-network mail order provider if both of the following are met:

- The prescribing physician requests preauthorization and demonstrates that the drug meets BCBSM's preauthorization criteria.
- We approve the request.

For this reason, a Clinical Pharmacist, RPh reviewed the appeal and the notes from your Conference, along with additional medical documentation provided by [your physician], 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 renewal of this medication require a recent (within 6 months) record (lab report) that the morning total or free testosterone level is within the normal range of the lab. We have no record (lab report) of a testosterone level that is within the normal range.

Therefore, preauthorization could not be approved. You will be liable for the charges if this prescription is filled.

Director's Review

The certificate (p. 31) says that prescription drugs must be medically necessary to be covered. Further, the rider (p. 5) says that certain drugs require prior authorization from BCBSM. BCBSM's *September 2015 Prior Authorization and Step Therapy Guidelines* (p. 66) lists the criteria that must be met before testosterone cypionate will be authorized:

Male members who have a diagnosis of androgen deficiency confirmed by:

1. Two morning testosterone levels in the past year below normal range.
2. At least two signs or symptoms specific to testosterone deficiency.

Initial authorization: 1 year.

Renewal criteria:

1. Testosterone levels are at or below normal range.
2. Improvement in signs or symptoms specific to testosterone deficiency.

The Director asked an independent review organization (IRO) to review this case as required by section 11(6) of the Patient's Right to Independent Review Act, MCL 550.1911(6), to determine if BCBSM's denial should be upheld. The IRO physician reviewer is board certified in internal medicine and has been in active practice for more than 12 years. The IRO report included this analysis and recommendation:

Recommended Decision:

The MAXIMUS physician consultant determined that testosterone cypionate 100mg IM twice weekly is not medically necessary for treatment of the member's condition.

Rationale:

* * *

The member has been evaluated by his primary care physician and had a full endocrinology evaluation, resulting in a diagnosis of hypogonadism. Testosterone agents are used for sex steroid replacement in males. All testosterone preparations are regulated as Schedule III controlled substances according to the Anabolic Steroids Control Act. Several testosterone salts, including enanthate and cypionate, are available in long-acting oil-based preparations and several preparations are available as topical gels or transdermal patches.

. . . [T]he member has responded to testosterone replacement therapy with testosterone cypionate intramuscular (IM) with a documented increase in levels of testosterone and free testosterone and improvement in his symptoms of fatigue, low sex drive and erectile dysfunction. The member has been monitored for side effects of hyperviscosity and elevation in his prostate specific antigen (PSA) levels. The member developed folliculitis and contact dermatitis to topical testosterone therapy with [Fortesta] and has been maintained on treatment with testosterone cypionate for a period of 3 years. According to his primary care physician, the member has been recently maintained on testosterone cypionate 100mg IM twice weekly. The member's most [recent] testosterone level was 1191 ng/dL with a free testosterone level of 4.19 ng/dL. The physician consultant indicated standard replacement dose of testosterone cypionate is 50 to 400 mg IM every 2 to 4 weeks. The consultant explained that the documentation provided for review indicates that the member's present dose of testosterone is

too high. The physician consultant also explained that there is no indication for the testosterone level to be above normal (270 to 1070 ng/dL) during replacement therapy. The consultant indicated that the member requires a decrease in dose of his present testosterone cypionate therapy.

Pursuant to the information set forth above and available documentation, the MAXIMUS physician consultant determined that testosterone cypionate 100mg IM twice weekly is not medically necessary for treatment of the member'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 IRO's 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 recommendation is not contrary to any provision of the Petitioner's certificate of coverage. MCL 550.1911(15).

The Director can discern no reason why the IRO's recommendation should be rejected in the present case and finds that the dosage of testosterone cypionate the Petitioner is requesting is not medically necessary to treat his condition and is therefore not a covered benefit under the certificate.

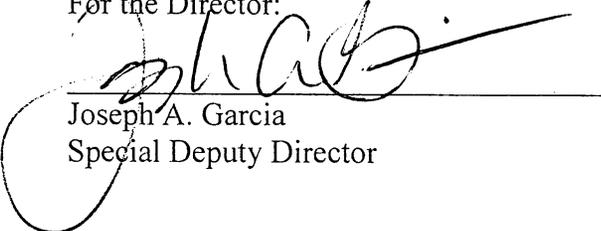
V. ORDER

The Director upholds BCBSM's final adverse determination of September 23, 2015.

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:



Joseph A. Garcia
Special Deputy Director