

**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. 153894-001

Blue Cross Blue Shield of Michigan,  
Respondent.

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Issued and entered  
this 26<sup>th</sup> day of June 2016  
by Randall S. Gregg  
Special Deputy Director

**ORDER**

**I. PROCEDURAL BACKGROUND**

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

On May 26, 2016, 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 June 3, 2016.

The Petitioner receives prescription drug benefits through a 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 June 7, 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 June 16, 2016.

**II. FACTUAL BACKGROUND**

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

The Petitioner has a history of low testosterone (hypogonadism). His physician asked BCBSM to cover the prescription drug testosterone cypionate for testosterone replacement therapy. BCBSM denied the request, saying the Petitioner does not meet its criteria for coverage and it 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 May 16, 2016. The Petitioner now seeks a review of that final adverse determination from the Director.

### III. ISSUE

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

### IV. ANALYSIS

#### BCBSM's Argument

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

... After review, the denial of prior authorization for Testosterone Cypionate is maintained because you do not meet the criterion for approval of Testosterone Cypionate. Therefore, prior authorization cannot be approved.

\* \* \*

A Clinical Pharmacist, RPh, reviewed your appeal and your health care plan benefits for [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 Testosterone Cypionate (testosterone replacement therapy) require a recent (within 6 months) lab report that documents the morning free testosterone level is within the normal range of the lab while receiving treatment. We have no record of a recent testosterone level that is within the normal range. According to the record provided by your provider you had a free testosterone level which was above the normal range drawn on May 2, 2016.

\* \* \*

We understand that you feel this prior authorization request is based on your medical need; however, BCBSM must administer your prescription drug coverage based on the benefits that align with the provisions of your health care plan.

#### Petitioner's Argument

In the request for external review, the Petitioner wrote:

My total test was well within range. I had my injection 1 day before the test the free range (which was high) will come down significantly as the week goes, and will be under normal levels by day 4 of weekly injections. The important number is total testosterone, which was well within normal range. I am having another blood draw on 7/9. We should base on that number.

### Director's Review

The Petitioner's plan requires prior authorization for certain drugs. The purpose of prior authorization is to insure that BCBSM enrollees "have tried the preferred alternatives - drugs with a proven track record that may be better tolerated, less expensive or less likely to cause interactions – and the drug is being prescribed appropriately."

The prior authorization criteria for testosterone cypionate are found in BCBSM's "Prior Authorization and Step Therapy Guidelines"<sup>1</sup> (p. 57):

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

1. Two morning testosterone levels in the past year below normal range.
2. For BMI > 30, two morning free testosterone levels must be submitted.
3. At least two signs or symptoms specific to testosterone deficiency.

Renewal criteria:

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

To help the Director decide if testosterone cypionate is medically necessary to treat the Petitioner's condition, the question 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 Family Medicine with a subspecialty in geriatric medicine, is familiar with the medical management of patients with the Petitioner's condition, and is in active clinical practice. The IRO report included the following analysis and recommendation:

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

##### **Does the enrollee meet BCBSM's criteria for the prescription drug Testosterone Cypionate?**

No. It is the determination of this reviewer that the enrollee does not meet the BCBSM criteria for the prescription drug. The free testosterone level is outside of

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<sup>1</sup> May 2016 version.

the company's coverage guidelines. The guidelines indicate that a serum free testosterone level must be measured and documented within the past six (6) months and the level must not be above the normal reference range.

**Is BCBSM's criteria the standard of care for this drug?**

No. It is the determination of this reviewer that the BCBSM criteria is not the standard of care for this drug. The standard of care is to measure a total testosterone level every 6-12 months during treatment. If the levels are inconsistent with clinical findings, or if the patient is significantly overweight, a free testosterone level can be ordered.

**If it is not the standard of care, is the medication Testosterone Cypionate considered medically necessary for the treatment of the enrollee's condition?**

Yes. It is the determination of this reviewer that the prescription drug Testosterone Cypionate is medically necessary for the treatment of the enrollee's condition. There are two (2) documented results for total testosterone that fall below the reference values, one on February 12, 2008 and one on July 12, 2012. This is adequate to make a diagnosis of hypogonadism.

**Clinical Rationale for the Decision:**

UpToDate and the Endocrine Society Clinical Guideline both agree that the standard of care for treatment of hypogonadism in males is, in the setting of appropriate history and clinical findings, two (2) values of serum total testosterone below the reference range when obtained between the hours of eight (8) and ten (10) in the morning. The standard of care is to measure a serum testosterone level every six (6) to twelve (12) months during treatment and it should be measured as serum total testosterone. If serum total testosterone levels are inconsistent with clinical findings, or if a patient is significantly overweight, a free testosterone level can be ordered. The free testosterone level requires specialized laboratories and protocols and is not always accurate without clinical laboratory expertise.

Per the limited documentation submitted for review, there are two (2) documented results for total testosterone that fall below the reference values, one on February 12, 2008 and one on July 12, 2012. This is adequate to make a diagnosis of hypogonadism. Therefore, based on current practice guidelines and medical literature, the prescription drug Testosterone Cypionate is medically necessary for this enrollee.

**Recommendation:**

It is the recommendation of this reviewer that the denial issued by Blue Cross and Blue Shield Michigan for the prescription drug Testosterone Cypionate be overturned.

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'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 recommendation should be rejected in this case, adopts the IRO analysis and finds that it is medically necessary to treat the Petitioner's condition with testosterone cypionate and therefore it is a covered benefit.

**V. ORDER**

The Director reverses BCBSM's final adverse determination of May 16, 2016.

BCBSM shall immediately cover testosterone cypionate for the Petitioner, MCL 550.1911(17), and shall, within seven days of providing coverage, 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, at this toll free telephone number (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 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