

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. 146817-001

Alliance Health and Life Insurance Company

Respondent

Issued and entered
this 14th day of April 2015
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

On March 16, 2015, ██████████ (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 medical and prescription drug benefits through a group insurance plan underwritten by Alliance Health and Life Insurance Company (AHL). The Director immediately notified AHL of the external review request and asked for the information it used to make its final adverse determination. After a preliminary review of the material received, the Director accepted the request on March 23, 2015.

The case involves medical issues so the Director assigned it to an independent review organization, which completed its review and sent its recommendation to the Director on April 6, 2015.

II. FACTUAL BACKGROUND

The Petitioner, born ██████████ has a history of hypogonadism and gynecomastia. He has been using the prescription testosterone gel AndroGel 1.62% to treat his condition. AHL approved coverage for the drug from January 15, 2014, until January 15, 2015.

When the Petitioner's physician requested continued coverage for AndroGel 1.62% beyond January 15, 2015, for "other testicular hypofunction" (diagnosis code 257.2), AHL denied the request on the basis the Petitioner did not meet its criteria for coverage.

The Petitioner appealed the denial through AHL's internal grievance process. At the conclusion of that process, AHL issued a final adverse determination dated February 26, 2015, affirming its denial of coverage. The Petitioner now seeks a review of that final adverse determination from the Director.

III. ISSUE

Did AHL correctly deny coverage for the prescription drug AndroGel 1.62%?

IV. ANALYSIS

Respondent's Argument

In its final adverse determination AHL informed the Petitioner of its reason for denying coverage of AndroGel 1.62%:

In January 2014, the Food and Drug Administration (FDA) issued a safety communication that Testosterone products are approved only for use in men who lack or have low Testosterone levels in conjunction with an associated medical condition. Examples of these medical conditions include: failure of the Testicles to produce Testosterone because of reasons such as: Genetic problems or Chemotherapy. Other examples include: problems with the brain structures called Hypothalamus and Pituitary that control the production of Testosterone by the Testicles.

As part of our investigation, your case was forwarded to our Pharmacy Care Management (PCM) Department where it was reviewed by one of our licensed Pharmacists, who was not involved in the initial denial request. The coverage criteria for Testosterone Replacement Therapy requires documentation in the medical records regarding low Testosterone with an associated medical condition. The information submitted does not provide supporting evidence that an associated medical condition exists. Therefore, your request for the prescription drug, Androgel has been denied because there is no indication of an underlying medical condition.

Petitioner's Argument

In an undated letter accompanying his request for an external review, the Petitioner wrote:

... I've been taking Androgel 1.62% for around a year and since taking the medication I have felt great, my free testosterone levels are in normal range, it has really helped me with feeling good, I sleep better and have more energy and

motivation in doing daily routines. I was put on this medication because I was diagnosed with Gynecomastia and Hypogonadism.

This medication has not only helped with my symptoms it has helped with my daily life.

In an undated letter to AHL seeking a review of its denial of coverage, the Petitioner's physician wrote:

I received a fax today stating that my request has been denied because there has been a statement saying there was no information was given to confirm the failure or tolerance to all formulary to alternatives but the fact of the matter is the patient has failed on ALL alternatives.

[The Petitioner] has been using the AndroGel since 2014. . . .

His Testosterone levels are normal while on the medication, and his levels were low without the AndroGel.

In my medical opinion, I strongly believe that he needs to be on AndroGel. I am sure that AndroGel would be the best option for him because it can be applied topically.

Patient has tolerated the medication and it is working well for him.

Director's Review

AndroGel 1.62% is on AHL's formulary and is covered subject to quantity limits and prior authorization. According to AHL, testosterone products, like AndroGel, are covered only for male enrollees who have an associated medical condition.

The Director asked an independent review organization (IRO) to evaluate the medical necessity of AndroGel and the requirements imposed by AHL for coverage. Review of medical questions by an IRO is required by section 11(6) of the Patient's Right to Independent Review Act, MCL 550.1911(6).

The IRO physician reviewer is board certified in family medicine and has been in practice for more than 15 years. The IRO report provided this analysis and recommendation:

Recommended Decision:

The MAXIMUS physician consultant determined that AndroGel is not medically necessary for treatment of the member's condition at this time.

Rationale:

* * *

The results of the consultant's review indicate that this case involves a [REDACTED] year-old male who has a history of hypogonadism. At issue in this appeal is whether Androgel is medically necessary for treatment of the member's condition.

The member and his treating physician state that he has been found to have low serum testosterone levels, has failed other testosterone preparations and has improved on Androgel in terms of laboratory results and from a clinical perspective. The Health Plan denied the request for coverage of Androgel for lack of a defined associated medical condition underlying the hypogonadism, as mentioned in current FDA warnings related to prescription of testosterone products. The FDA has stated the following with respect to testosterone replacement therapy: "The U.S. Food and Drug Administration (FDA) cautions that prescription testosterone products are approved only for men who have low testosterone levels caused by certain medical conditions. The benefit and safety of these medications have not been established for the treatment of low testosterone levels due to aging, even if a man's symptoms seem related to low testosterone." . . .

The MAXIMUS physician consultant explained that the medical records provided for review do not provide evidence of hypogonadism prior to treatment with Androgel, of failure of other testosterone preparations or of a known or suspected underlying cause of the member's condition. The physician consultant noted that as the member is [REDACTED], his hypogonadism, if present, would not be age-related and would be coverable under the recent FDA warnings. However, the consultant noted that the medical records provided for review include recent laboratory assays showing normal serum testosterone levels. No prior laboratory results showing low levels of testosterone were submitted for review. The information provided for review also does not include medical records documenting the suspected nature of the member's low serum testosterone levels. Therefore, the consultant explained that information provided for review does not support the medical necessity of Androgel for treatment of the member's condition at this time.

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. See MCL 550.1911(15).

The Director, discerning no reason why the IRO's recommendation should be rejected in this case, concludes and finds that Androgel Gel 1.62% is not medically necessary for the Petitioner's condition at this time.

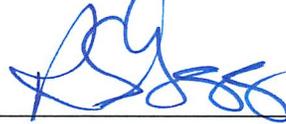
V. ORDER

The Director upholds Alliance Health and Life Insurance Company's February 26, 2015, 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.

Annette E. Flood
Director

For the Director:



Randall S. Gregg
Special Deputy Director