

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
OFFICE OF FINANCIAL AND INSURANCE REGULATION
Before the Commissioner of Financial and Insurance Regulation

In the matter of

XXXXX

Petitioner

File No. 116653-001-SF

v

Blue Cross Blue Shield of Michigan
Respondent

Issued and entered
this 28th day of April 2011
by R. Kevin Clinton
Commissioner

ORDER

I
PROCEDURAL BACKGROUND

On August 26, 2010, XXXXX (Petitioner) filed a request for external review with the Commissioner of Financial and Insurance Regulation under Public Act No. 495 of 2006, MCL 550.1951 *et seq.* The Commissioner reviewed the material submitted and accepted the request on September 9, 2011.

The Petitioner receives health care benefits through the State of Michigan's State Health Plan PPO, a governmental self-insured plan under Act 495. Blue Cross Blue Shield of Michigan (BCBSM) administers the plan. Under Section 2(2) of Act 495, MCL 550.1952(2), the Commissioner conducts this external review as though the Petitioner was a covered person under the Patient's Right to Independent Review Act (PRIRA), MCL 550.1901 *et seq.*

Because this case involves medical issues, the Commissioner assigned the case to an independent review organization which provided its recommendation to the Commissioner on September 23, 2010.

II FACTUAL BACKGROUND

The terms of the Petitioner's coverage are contained in the State Health Plan's *Your Benefit Guide*. This plan also includes *Rider RXP Prescription Drug Preauthorization Requirement*.

In July 2010 the Petitioner's physician gave her a prescription for HP Acthar Gel. BCBSM denied preauthorization for this drug, saying she did not meet criteria for approval.

The Petitioner appealed the denial through BCBSM's internal grievance process but BCBSM maintained its denial. BCBSM issued a final adverse determination dated August 4, 2010.

III ISSUE

Did BCBSM properly deny coverage for the Petitioner's prescription for HP Acthar Gel?

IV ANALYSIS

Petitioner's Argument

The Petitioner suffers from rheumatoid arthritis and, as a complication, mononeuritis multiplex, a neurological disorder that involves nerve damage. The Petitioner argues that she has been on several other drugs for her rheumatoid arthritis and nothing works for her. She says she needs approval for the HP Acthar Gel "so I can prevent being put in a hospital or nursing home."

The Petitioner believes that this drug is medically necessary in order to maintain her quality of life. She wants BCBSM to approve this drug.

BCBSM's Argument

The Petitioner's contract requires that BCBSM preauthorize certain prescription drugs before it will consider them for payment. HP Acthar Gel for treatment of rheumatoid arthritis is one of the drugs that requires preauthorization.

BCBSM explained its decision to deny authorization to the Petitioner in its final adverse determination:

[O]ur Pharmacy staff and our medical consultants' reviewed the

documentation submitted, and confirmed that you do not meet the criteria for approval. To clarify, coverage will only be provided for the treatment of infantile spasms, or for the diagnostic testing of adrenocortical function only if use of cosyntropin is contraindicated. Use of HP Acthar Gel is not considered medically necessary as treatment of steroid responsive conditions, unless there are medical contraindications or intolerance to corticosteroids that are not also expected to occur with use of the drug. Additionally, it is not approved for use in patients with the diagnosis of mononeuritis multiplex. As a result, authorization cannot be granted. If you choose to purchase it, the entire cost will remain your liability.

BCBSM maintains that its denial of preauthorization for the HP Acthar Gel is appropriate.

Commissioner's Review

The State Health Plan PPO requires services to be medically necessary in order to be covered. The question of whether the Petitioner's prescription for HP Acthar Gel care is medically necessary was presented to an independent review organization (IRO) for an analysis and recommendation as required by Section 11(6) of the Patient's Right to Independent Review Act, MCL 550.1911(6).

The IRO reviewer is certified by the American Board of Internal Medicine with a subspecialty certification in rheumatology (diplomate); a member of the American College of Rheumatology; published in the peer reviewed medical literature; and in active clinical practice.

The reviewer offered the following analysis:

The health plan provides coverage of HP Acthar Gel for the treatment of infantile spasms or for the diagnostic testing of adrenocortical function. It considers the use of HP Acthar gel not medically necessary for the treatment of steroid responsive conditions unless there is medical contraindication or intolerance to corticosteroids that is not expected to occur with use of the product.

There is no evidence in the medical literature or standard treatment guidelines supporting the efficacy, safety, or improved tolerability of ACTH treatment of either rheumatoid arthritis or mononeuritis multiplex. Furthermore, there is no evidence to support the potential superiority of ACTH treatment for either rheumatoid arthritis or mononeuritis multiplex in [the Petitioner] who is noted to have had an adverse effect of recent methylprednisolone therapy. Therefore, the medical necessity of HP Acthar Gel for [the Petitioner] cannot be established.

The IRO reviewer concluded that the medical necessity for HP Acthar Gel had not been

shown. 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 reviewer's analysis is based on expertise and professional judgment and the Commissioner can discern no reason why the recommendation should be rejected in the present case.

V
ORDER

BCBSM's August 4, 2010, final adverse determination is upheld. BCBSM is not required to preauthorize or cover the Petitioner's prescription for HP Acthar Gel since it is found to be not medically necessary for treatment of her condition.

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 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.

R. Kevin Clinton
Commissioner