

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. 118916-001

v

Blue Cross Blue Shield of Michigan
Respondent

Issued and entered
this 3rd day of August 2011
by R. Kevin Clinton
Commissioner

ORDER

I. PROCEDURAL BACKGROUND

On January 6, 2011, XXXXX (Petitioner) filed a request for external review with the Commissioner of Financial and Insurance Regulation under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.* The Commissioner reviewed the request and accepted it on January 13, 2011.

The Commissioner notified Blue Cross Blue Shield of Michigan (BCBSM) of the external review and requested the information used in making its adverse determination. The Commissioner received BCBSM's response on January 18, 2011.

The issue in this external review can be decided by a contractual analysis. The contract here is the BCBSM *Group Conversion Comprehensive Health Care Benefit Certificate* (the certificate). The *OTG Prescription Drug Affinity Program Certificate* (the Affinity program) also applies. The Commissioner reviews contractual issues pursuant to MCL 550.1911(7). This matter does not require a medical opinion from an independent review organization.

II. FACTUAL BACKGROUND

The Petitioner has a relapsing-remitting form of multiple sclerosis for which she takes Copaxone, an injectable drug. Copaxone is a disease-modifying drug therapy designed to delay the progression and severity of MS as there is no cure for this disease.

On June 8, 2010, BCBSM declined to authorize the Copaxone, indicating that under the terms of the certificate the therapy was not eligible for reimbursement because it is not administered by or under the supervision of a physician.

The Petitioner appealed BCBSM's denial through its internal grievance process. BCBSM held a managerial-level conference on October 25, 2010, and issued a final adverse determination dated November 17, 2010, upholding its denial.

III. ISSUE

Did BCBSM correctly deny Petitioner's request for coverage for the drug Copaxone under the terms of the medical care certificate?

IV. ANALYSIS

Petitioner's Argument

The Petitioner states that regular use of Copaxone delays the progression of MS and will ensure that she remains mobile as long as possible. Without it, her MS will progress and ultimately render her partially or fully paralyzed. She contends that Copaxone is a medically necessary treatment and states it is FDA approved, its efficacy is supported by clinical studies, and it meets the generally accepted standards of medical practice.

She further indicates that the certificate (p. 3.2) covers injectable drugs when they are FDA approved, ordered by physician, and administered by the physician or under the physician's supervision. The Petitioner believes that "under the physician's supervision" includes self injection after training by a physician.

The Petitioner argues that she meets the criteria of the certificate and therefore Copaxone should be covered under the terms of the certificate.

BCBSM's Argument

BCBSM cites the following provision in the certificate as the basis for its decision to deny coverage. In *Section 3: Coverage for Physician and Other Professional Provider Services* (pp. 3.17–3.18), the certificate states:

Specialty Pharmaceuticals

We pay for BCBSM-approved specialty pharmaceuticals administered by a participating professional provider . . .

- We pay for the drug and its administration when ordered and billed by the physician, **or**
- We pay for the drug when billed by the specialty pharmacy provider and we pay the physician for administration of the drug.

Note: Self-injected drugs are not covered.

Injectable Drugs¹

We pay for covered injectable drugs or biologicals and their administration. The injectable drugs and biologicals must be FDA approved in order to be covered. The injectable drug or biological must be ordered or furnished by a physician and administered by the physician or under the physician's direct supervision.

BCBSM states that the Petitioner's medical certificate does not cover prescription drugs. Coverage under the certificate is limited to specialty pharmaceuticals and injectable drugs that are administered by a physician or under the physician's direct supervision. BCBSM indicates that self-injected drugs are specifically excluded from coverage.

The Petitioner is also enrolled in the Affinity program, which allows her to purchase eligible drugs like Copaxone at reduced cost. BCBSM states that the Petitioner can purchase Copaxone through the Affinity program at a discount but must pay the entire cost herself. The

¹ The term "Injectable drugs" is defined on p. 6.11 of the certificate: "Payable drugs that are ordered or furnished by a physician and administered by the physician or under the physician's supervision."

Affinity program (p. 4.1) does not cover the cost of administering injectable drugs or non-self-administered injectable drugs.

Commissioner's Review

The certificate covers specialty pharmaceuticals and prescription drugs only in very limited circumstances. It pays for injectable drugs but specifically excludes injectables that are self-administered and not provided under physician supervision.

Copaxone is a self-injected drug. The Petitioner indicated that her physician has offered to administer the injection to her. However, since the Copaxone is self-administered, it is not covered under the terms of the certificate. It would only be covered if it was required to be administered by a physician or under the direct supervision of a physician.

The Commissioner finds that BCBSM's denial of coverage was in compliance with the terms of the certificate.

V. ORDER

BCBSM's final adverse determination of November 17, 2010, is upheld. BCBSM is not required to cover Copaxone for the Petitioner.

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 Commissioner of Financial and Insurance Regulation, Health Plans Division, Post Office Box 30220, Lansing, MI 48909-7720.

R. Kevin Clinton
Commissioner