

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

001

File No. 119349-

v

Blue Cross Blue Shield of Michigan
Respondent

_____ /

Issued and entered
this 8th day of August 2011
by R. Kevin Clinton
Commissioner

ORDER

I. PROCEDURAL BACKGROUND

On January 31, 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 February 7, 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 February 16, 2011.

Because medical issues were involved, the Commissioner assigned the case to an independent review organization which provided its analysis and recommendations to the Commissioner on February 22, 2011.

II. FACTUAL BACKGROUND

The Petitioner's prescription drug benefit is found in the BCBSM *Preferred Rx Program Certificate* (the certificate).

The Petitioner has a history of homocysteinemia, the elevation of the homocysteine level in the blood, and requested coverage for the substance Metanx. BCBSM denied coverage, stating Metanx is not a benefit under the certificate.

The Petitioner appealed BCBSM's denial through its internal grievance process. BCBSM held a managerial-level conference on January 13, 2011, and issued a final adverse determination dated January 26, 2011, upholding its denial.

III. ISSUE

Did BCBSM correctly deny coverage for Metanx for the Petitioner?

IV. ANALYSIS

Petitioner's Argument

The Petitioner notes that homocysteinemia increases the risk of stroke and heart attack and may result in premature death. He indicates that all of his maternal uncles died before the age of 55. He states that since he began using Metanx in 1995, his homocysteine levels have dropped by 67%. He further states that BCBSM covered his Metanx for many years but then classified it as medical food and stopped paying for it.

The Petitioner believes that the Metanx is medically necessary and a covered benefit under the certificate. He asks that BCBSM be required to pay for it.

BCBSM's Argument

Under the certificate, anything other than covered drugs and services are not payable. The certificate contain these provisions:

Section 3: Prescription Drugs Not Covered

We will not pay for the following:

* * *

- Anything other than covered drugs and services

* * *

Section 4: General Conditions of Your Contract

Certain general conditions apply to your contract. These conditions may make a difference in how, where and when benefits are available to you. This section lists and explains these conditions.

* * *

Care and Services That Are Not Payable

* * *

We do not pay for the following care and services:

* * *

- Any services not listed in this certificate as being payable

BCBSM states it had its medical consultants review the information submitted by the Petitioner and determined that Metanx is a medical food, not a prescription drug, and therefore not a benefit under the certificate. It also states there is little medical evidence to support the use of Metanx for the Petitioner's condition.

BCBSM also reviewed available records of the Petitioner's prescription drug utilization and did not find that it had previously reimbursed him for Metanx. Further, if he did receive reimbursement for Metanx it was done in error and does not obligate BCBSM to cover future claims.

Commissioner's Review

The question of whether Metanx should be covered under the certificate was presented to an independent review organization (IRO) for analysis as required by Section 11(6) of Patient's Right to Independent Review Act, MCL 550.1911(6). The IRO reviewer is a physician who is board certified in cardiology and had been in active practice for more than 18 years.

The IRO physician reviewer concluded that Metanx is a medical food, which is not medically necessary for treatment of the Petitioner's condition. The IRO reviewer's report stated, in part:

The MAXIMUS physician consultant noted that the [Petitioner's]

homocysteine levels were reported to be as high as 30 umol/L and to have decreased to between 7 and 15 umol/L with treatment using Metanx. The MAXIMUS physician consultant also noted that Metanx is a prescription medical food that is FDA approved for dietary management of endothelial dysfunction in patients with diabetic peripheral neuropathy. The MAXIMUS physician consultant indicated that each pill of Metanx contains 2 mg of methylcobalamin (Vitamin B12), 35 mg of pyridoxal 5' – phosphate (Vitamin B6) and 3 mg of L-methylfolate calcium (bioactive form of folic acid) and that Metanx can be used for the treatment of hyperhomocysteinemia. The MAXIMUS physician consultant explained that each of these substances are nutritional supplements and there are no other active ingredients in Metanx. The MAXIMUS physician consultant also explained that Metanx should be more accurately categorized as a nutritional supplement as opposed to a prescription medication.

The MAXIMUS physician consultant noted that typically, a homocysteine level of less than 13 umol/L is consider[ed] normal, a level between 13 and 60 umol/L is considered moderately elevated, and a value greater than 60 to 100 umol/L is severely elevated. The MAXIMUS physician consultant explained that even though the [Petitioner's] level is elevated, it is not clear whether lowering homocysteine levels actually decreases the risk for atherosclerosis and thrombosis. The MAXIMUS physician consultant also explained that recent studies show that lowering homocysteine levels does not decrease the risk for atherosclerosis or thrombosis. [Citations omitted] The MAXIMUS physician consultant indicated that a reasonable and appropriate option is to purchase folic acid, vitamin B6 and vitamin B12 supplements separately.

While the Commissioner is not required in all instances to accept the IRO's recommendation, it is afforded deference. 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 this case.

The Commissioner accepts the conclusion of the IRO that Metanx is neither a prescription drug nor medically necessary for the Petitioner and finds that BCBSM’s denial of coverage is consistent with the terms of the certificate.

V. ORDER

BCBSM's final adverse determination of November 12, 2010, is upheld. BCBSM is not responsible for covering the Petitioner's Metanx because it is a medical food and not a prescription drug under the certificate and is not medically necessary for treatment of the Petitioner's condition.

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