

STATE OF MICHIGAN
DEPARTMENT OF ENERGY, LABOR & ECONOMIC GROWTH
OFFICE OF FINANCIAL AND INSURANCE REGULATION
Before the Commissioner of Financial and Insurance Regulation

In the matter of

XXXXX

Petitioner

File No. 107117-001

v

Blue Care Network of Michigan
Respondent

Issued and entered
this 14th day of January 2011
by Ken Ross
Commissioner

ORDER

I
BACKGROUND

On September 2, 2009, XXXXX (Petitioner) filed a request for an external review with the Commissioner of Financial and Insurance Regulation under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.*

Blue Care Network of Michigan (BCN) was notified of the request for external review and furnished the documentation and information it considered in making its final adverse determination.

On September 3, 2009, after a preliminary review of the material submitted, the Commissioner accepted the request for external review.

This case involves medical issues. Therefore, the Commissioner assigned the matter to an independent review organization which submitted its recommendation on March 12, 2010.

II FACTUAL BACKGROUND

The Petitioner is a member of BCN effective August 1, 2009. His health care benefits and the terms of his coverage are contained in the *BCN 1 General Provisions and Schedule of Benefits* (the certificate). His prescription drug coverage is defined in the PDF \$5/\$11/\$16 prescription drug rider (the rider) which amends the certificate.

Following hip replacement surgery the Petitioner experienced chronic pain and he became addicted to pain medication. On August 8, 2009, his physician requested coverage for Suboxone for the treatment of his pain. Suboxone is a drug that is generally used to treat opiate addiction, not pain.

After BCN denied the request on August 12, 2009, as being experimental for pain treatment, the Petitioner filed an expedited appeal. At the conclusion of BCN's expedited internal grievance process the Petitioner received its final adverse determination dated August 20, 2009.

III ISSUE

Did BCN properly deny the Petitioner coverage for Suboxone under the terms of the certificate?

IV ANALYSIS

Petitioner's Argument

The Petitioner has a history of addiction to pain medications and participates in a twelve step program to address this dependency. He says he needs Suboxone for the pain related to hip and back osteoarthritis and uses it because of his past dependency on pain medications. In his September 1, 2009, request for external review the Petitioner stated:

Have been using the drug Suboxone for a little over a year now for chronic pain of the back and hip. Being a person in recovery it is maybe the only safe medicine for use as a treatment. Dr. XXXXX is board

certified in addictive medicine. This medicine helps me function in day to day activities with a minimal amount of pain.

The Petitioner's use of Suboxone was explained in the July 15, 2009, office notes of XXXXX, MD:

Chronic pain related to advanced osteoarthritis of the hips status post left hip replacement. Brought in copies of some x-rays which showed some advanced bone on bone osteoarthritis in the right hip as well but functionally he's doing well enough that he wants to wait on surgery.

Addictive disease currently in remission with an active recovery program. At this point will continue his current dosing on the Suboxone for the chronic pain and will see him back here in follow-up in another three months.

In his August 8, 2009, request to BCN for authorization to prescribe Suboxone for the Petitioner, Dr. XXXXX said, "This is the only drug available for safe treatment of chronic pain in the setting of a person in recovery from addiction."

The Petitioner says he has had success with Suboxone and maintains that it is necessary for his medical condition (pain). He therefore wants BCN to provide coverage.

Respondent's Argument

In its August 20, 2009, expedited grievance adverse determination, BCN denied coverage for the Suboxone because "the use of Suboxone for the treatment of pain is not recommended or supported by medical studies, is considered investigational and is not approved by the Food and Drug Administration (FDA)."

BCN's denial of coverage is based on this provision in the rider:

E. EXCLUSIONS

* * *

2. There is no coverage under this Rider for any drug which is experimental or which is being used for experimental purposes, including but not limited to, those regarded by the U.S. Food and Drug Administration as investigational.

A similar exclusion is contained in BCN's medical policy title "Prescription Drugs" (p. 5).

BCN argues that the requested services do not meet its criteria for coverage and therefore its denial was appropriate.

Commissioner's Review

The Petitioner requested coverage of Suboxone to treat chronic pain. BCN says the Petitioner's use of Suboxone as a pain medicine is investigational. In order to resolve the question of whether the Petitioner's use of Suboxone is investigational for his condition, the Commissioner obtained the recommendation of an independent review organization (IRO).

The IRO initially assigned the review to a physician who is certified by the American Board of Psychiatry. Concerned that the initial IRO reviewer was not an expert in pain management, the Commissioner asked that the Petitioner's case be reviewed by a more appropriate expert. The case was then assigned to a reviewer certified by the American Board of Anesthesiology and Pain Management and is in active practice. The second IRO report said:

The Physician Reviewer's clinical experience is consistent with the requesting physician's recommendation for the use of Suboxone in this case. This [Petitioner's] documented history of 1) opiate abuse requiring treatment, 2) stability in ongoing drug treatment programs, and 3) chronic pain condition, support the use of Suboxone. In the opinion of the Reviewer, the use of traditional opiates would be deemed too risky in a patient with this history. The Reviewer noted relapse would unduly place the [Petitioner] at risk for complications from opiate addiction and would potentially lead to the need for additional therapies to manage the underlying addiction and its complications. According to the Reviewer, in all cases of chronic pain, reasonable alternatives to treat the pain without opiates are strongly recommended. The Reviewer believes in this case these alternatives might already have been pursued.

The Reviewer indicated Suboxone (Buprenorphine-naloxone) is generally approved for the use in opiate addiction to prevent illicit opiate abuse. The Reviewer noted soon after its introduction Suboxone has been used "off-label" to treat pain in patients with opiate abuse histories and legitimate chronic pain that has been recalcitrant to other treatments. In addition, the Reviewer noted Suboxone has been commonly used in situations where opiate-strength medications are required for the treatment of pain conditions, as has occurred in this case. The Reviewer indicated Suboxone's non-approved use is routinely practiced and well established in the pain management community.

The Reviewer noted the advantages of this preparation are as follows: 1) it provides effective analgesia. 2) It has a tamper-resistant formulation given the addition of Naloxone (an opiate antagonist), which is activated if crushed or dissolved to counteract the analgesia and euphoria of the active ingredient Buprenorphine. And 3) the partial agonist-antagonist opiate effect of the Buprenorphine limits the degree of analgesia and euphoria that may place patients at risk for abuse. Beyond a certain amount (e.g., 32 mg/day), there is no additional pain relief or euphoric effects. The Reviewer cited this property has been shown in a group of patients with opiate abuse history to reduce the risk of illicit opiate abuse [citation omitted].

The Reviewer further cited government panels have stated in special patient populations, such as those with chronic pain and substance abuse histories, Suboxone is a legitimate therapy [citation omitted].

In summary, in the opinion of the Physician Reviewer, the use of Suboxone is a reasonable treatment in [the Petitioner], given his documented chronic pain, which has been unresolved by simpler measures, and history of drug abuse, as long as he continues to show benefit and compliance. Based on this rationale and given [the Petitioner's] history a documented chronic pain condition, the Reviewer indicated use of Suboxone is medically necessary and recommends the use of this medication for treatment of [Petitioner's] condition.

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

The Commissioner accepts the conclusion of the IRO reviewer and finds that BCN's denial of Suboxone for the Petitioner was incorrect.

V ORDER

The Commissioner reverses BCN's August 20, 2009, final adverse determination. BCN shall cover the Petitioner's Suboxone prescription subject to the terms and conditions of his

prescription drug coverage. BCN shall, within 60 days, provide coverage and shall, within seven days of providing coverage, provide the Commissioner with proof it has implemented this Order.

To enforce this Order, the Petitioner may report any complaint regarding implementation to the Office of Financial and Insurance Regulation, Health Plans Division, toll free (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 sixty 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.