

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. 149627-001

Blue Care Network of Michigan
Respondent

Issued and entered
this 30th day of September 2015
by Randall S. Gregg
Special Deputy Director

ORDER

I. BACKGROUND

On September 1, 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 550.1951 *et seq.*

The Petitioner receives group health care benefits through Blue Care Network of Michigan (BCN), a health maintenance organization. The Director notified BCN of the request for external review and asked for the information used to make its final adverse determination. BCN responded on September 2, 2015. On September 8, 2015, BCN submitted additional information and, after a preliminary review of the information submitted, the Director accepted the request.

The Director assigned an independent medical review organization to address the medical issue in this case. Their report was submitted on September 21, 2015.

II. FACTUAL BACKGROUND

The Petitioner has a variety of medical problems that cause severe pain in her right leg, neck, back, and abdomen. Her doctor prescribed the drug Actiq (fentanyl citrate) for her pain. BCN declined to provide coverage for the drug.

The Petitioner appealed the denial through BCN's internal grievance process. At the conclusion of that process, BCN issued a final adverse determination dated August 19, 2015, upholding the denial. The Petitioner now seeks a review of the adverse determination from the Director.

III. ISSUE

Did BCN properly deny Petitioner coverage for the prescription drug Actiq?

IV. ANALYSIS

Respondent's Argument

In its final adverse determination BCN stated:

We based our decision on you not meeting our required guidelines to fill this medication based on our authorization requirements. Your medical documentation did not indicate you have the required diagnosis for approval of Actiq. Only members who have specific cancer diagnosis can be approved for this medication.

Petitioner's Argument

In her request for external review the Petitioner wrote:

I am writing regarding the recent decision regarding a denial for a prescription for Fentanyl Citrate Lozenge Hd. Last year I was authorized for one year, which expired in June of this year. Since then my doctor has tried to help me control the pain with different medications. None of them have been effective for me.

I want to explain my story. I have been in pain since 1986, when my nightmare started with a ruptured ovarian cyst while pregnant. A series of mistakes by my doctor at the time has ended up resulting in 11 abdominal surgeries since 1986. These surgeries have left me with adhesions that have 'glued' my internal organs. I have adhesions on my colon and bowels. I can't eat large meals because it causes pain and bowel movements are unbearable. My last surgery occurred 9 years ago when it was found my appendix was being strangled by adhesions. Since that surgery the pain has been constant, extreme and unrelenting. I can only assume that this last surgery resulted in even more adhesions. Unfortunately there is no help for me surgically. No doctor will touch me now when they hear my story. Plus, I cannot risk another surgery and the possibility of even more adhesions or damage than I already have. I just can't risk being any worse than I am right now. I would not be able to survive that.

I have been in a pain clinic since that last surgery. Through a lot of trials and testing of different drug combinations, the combination that works the best for me is Oxycontin and Actiq. This combination of drugs makes my life and my situation bearable. I was prescribed this combination several years ago but my doctor could no longer prescribe them due to changes or restrictions in the prescribing of the drug Actiq. Since then I have suffered with less than adequate pain relief. Last year my doctor suggested I contact BC/BS to see if they would grant me the authorization. They allowed me the drug for one year. My plan does allow Fentanyl patches. Unfortunately, I cannot use them as they cause my skin to break out, severe itching and red blotches, when they stay on. One of my surgeries was a hysterectomy, which causes excessive sweating and they fall off. The problem is that when they fall off, because they are prescribed for 48 hours, I end up at the end of the month with not enough patches because I had to replace them earlier than I should have. They also take quite awhile to get into the bloodstream and offer relief. The

Actiq lozenges are immediate pain relief when I need it. It gives me more control over my pain.

* * *

Add to the abdominal surgeries I have two ruptured disks in my neck and back and an ankle injury 4 years ago which required surgery. Unfortunately, after this surgery I developed Chronic Regional Pain Syndrome, which by itself can cause unbearable pain....

Director's Review

BCN asserts that the Petitioner does not meet the medical necessity criteria in its "Prior Approval and Step Therapy Guidelines" which states on page 9 regarding Actiq:

Coverage is provided for the treatment of breakthrough cancer pain in members that are tolerant of high dose narcotics and are currently receiving a long-acting narcotic. The member must also have experienced treatment failure of or intolerance to the use of other oral immediate-release narcotics for the management of breakthrough pain.

The question of whether Actiq is medically necessary for treatment of the Petitioner's condition was presented to an independent review organization (IRO) for analysis as required by section 11(6) of the Patient's Right to Independent Review Act, MCL 550.1911(6).

The IRO reviewer is a physician in active practice who is certified by the American Board of Anesthesiology with a subspecialty in pain medicine. The IRO reviewer's report included the following analysis and recommendation:

Recommended Decision:

It is the determination of this reviewer that the prescription drug Actiq is not medically necessary for the treatment of the enrollee's condition.

Rationale:

The current standard of care for chronic neck and back pain is treatment in a multidisciplinary practice to include physical therapy, massage therapy, behavioral therapy, and injections to help reduce pain. There are a variety of anti-convulsants and anti-depressants considered adjunctive to this therapy. Chronic opioid use, such as Actiq, have been associated with a high risk of dependence and tolerance. Dr. Scott Fishman indicates this in his book, *Responsible Opioid Prescribing: A Physician's Guide*.

Baron, et al. [citation omitted] reported that high dose and short acting opiates might contribute to pain sensitization via opioid-induced hyperalgesia, decreasing patient pain threshold and potentially masking resolution of a preexisting pain condition. In this retrospective study, the majority of patients undergoing detoxification of high dose opiates for chronic pain reported a significant decrease in pain at the end of the study, further supporting the theory of opioid-induced hyperalgesia.

Long-term opiates are more likely to cause adverse outcomes and therefore the enrollee's requested authorization and coverage for the medication listed is not indicated. It has been

reported that prolonged use of high dose, short-acting opiates might induce tolerance and abnormal pain sensitivity. The aim of current guidelines is to protect patients from the adverse effects of opioid therapy. Actiq as requested is contradictory to providing safe and effective healthcare.

The enrollee is already taking an opioid around the clock, which includes the MS Contin 100 mg every eight (8) hours. Actiq is Food and Drug Administration (FDA) approved for malignant pain associated with a limited life expectancy. The enrollee does not have malignant pain. Additionally, long term use of opioid medications is not recommended. Finally, there is lack of documentation of improved function with Actiq in the clinical information submitted for review. Therefore, the medication at question is not medically necessary.

Recommendation:

It is the recommendation of this reviewer that the denial issued by Blue Care Network of Michigan for the prescription drug Actiq be upheld.

The Director is not required to accept the IRO's recommendation. *Ross v Blue Care Network of Michigan*, 480 Mich 153 (2008). However, the IRO's 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 analysis is based on extensive experience, expertise and professional judgment. The Director can discern no reason why the IRO's recommendation should be rejected in the present case. The Director finds that Actiq is not medically necessary for the Petitioner's condition and is, for that reason, not a covered benefit.

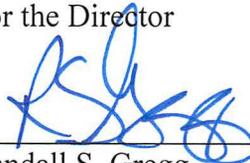
V. ORDER

The Director upholds BCN's August 19, 2015 final adverse determination.

This is a final decision of an administrative agency. 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. See MCL 550.1915. 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.

Patrick M. McPharlin
Director

For the Director



Randall S. Gregg
Special Deputy Director