

**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. 153933-001**

**United Healthcare Insurance Company**

**Respondent**

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**Issued and entered**  
this 24<sup>th</sup> day of June 2016  
by **Randall S. Gregg**  
**Special Deputy Director**

**ORDER**

**I. PROCEDURAL BACKGROUND**

On May 31, 2016, Dr. ██████████, authorized representative of ██████████ (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 550.1901 *et seq.*

The Petitioner receives prescription drug benefits through a group plan underwritten by United Healthcare Insurance Company (UHIC). The Director notified UHIC of the external review request and asked for the information used to make its final adverse determination. UHIC provided its response on May 31, 2016. After a preliminary review of the material submitted, the Director accepted the request on June 2, 2016.

To address the medical issue in the case, the Director assigned it to an independent medical review organization, which provided its analysis and recommendation on June 16, 2016.

**II. FACTUAL BACKGROUND**

The Petitioner is 47 years old and has occipital neuralgia which causes extreme cranial pain. His physician prescribed the opioid pain medication Fentora (fentanyl) in the quantity of 12 800 mcg tablets per day. The Petitioner requested that UHIC provide coverage for the drug. UHIC denied the request.

The Petitioner appealed the denial through UHIC's internal grievance process. At the conclusion of that process, on January 29, 2016, UHIC issued a final adverse determination

affirming its denial. The Petitioner now seeks the Director's review of that adverse determination.

### III. ISSUE

Did UHIC correctly deny the Petitioner coverage for Fentora?

### IV. ANALYSIS

#### UHC's Argument

In its January 29, 2016 final adverse determination, UHIC stated that the Petitioner's request was evaluated by a physician who concluded:

Fentora is FDA-approved for the treatment of breakthrough cancer pain. There are no studies of its use in other clinical situations, and the manufacture has applied to the FDA to expand the indications and was denied. There is no literature to support the use of Fentora for this member, especially at the dose requested.

#### Petitioner's Argument

In a May 27, 2016 letter included with the request for external review, the Petitioner's authorized representative wrote:

I am [Petitioner's] psychiatrist and designated representative for his external review request regarding [UHIC's] current refusal to cover the appropriate dosage of Fentora necessary for pain management. I am asking you to review his case and to compel [UHIC] to cover 12 doses per day of this drug, which is a life sustaining medication for him. I am deeply concerned that without the appropriate dose of this medication, the severity of his pain will result in his suicide. At present, only four doses per day are covered. The dose [UHIC] is willing to cover is well below the 12 doses daily that have been effective for [Petitioner]. This man has a long history of intractable cranial pain that has been described fully in the correspondence I have provided from his pain management physician ... My gravest concern is the high probability of suicide that will result from lack of access to this medication.

In a letter dated June 2, 2016, another of the Petitioner's doctors wrote:

This letter is an addendum to the letter I wrote 01-26-16. In addition to the innumerable invasive procedures performed by multiple board-certified pain specialist across the country, [Petitioner] has tried innumerable medication from every class of medications that have any potential pain relieving properties. Some of the medications that I am aware of include:

Opioids: Oxycodone, Actiq, Subsys, Kadian, Opana, MS Cantin, Dilaudid, methadone

Muscle Relaxers: Skelaxin, Flexeril, Zanaflex

Antidepressants: Zoloft

[Petitioner] has been stable on his current regimen of pain medication. He has shown no adverse reaction or aberrant behavior. He has passed all of his drug screens and Michigan Automated Prescription Service queries. The Fentora enables him to continue working part-time in furniture sales and participating as a father and husband in his family. [Petitioner's] previous insurance company paid for the Fentora. He had to change his insurance company because his wife's company made a switch.

[Petitioner] has unimaginable attacks of pain. There is no warning and no relief except for Fentora. The pain is so severe that if left uncontrolled he would not be able to bear to live. [Petitioner] has repeatedly told me he would take his life. In other words, the only medication that is going to keep [Petitioner] from killing himself is Fentora.

United Healthcare has approved and paid for another immediate release fentanyl medication called Actiq in addition to a limited quantity of Fentora. [Petitioner] has tried this brand of immediate release fentanyl. The difference he reports (like most patients) is that the Actiq is less expensive but also markedly less effective.

Both Actiq and Fentora contain fentanyl but the delivery system of Fentora is superior in terms of speed of onset of pain relief and length of pain relief. Fentora works in a few minutes and Actiq can take an hour.

If [Petitioner] has a severe attack of pain in the middle the night he is able to get pain relief within a few minutes with Fentora and get back to sleep. If he has to take an Actiq then it takes an hour of pain relief and there is no getting back to sleep.

Actiq has a number of intolerable side effects. It causes severe gum pain and bleeding. It contains sugar which cause cavities. The cavities and gum damage caused by the Actiq lead to severe tooth damage. Mr. [REDACTED] finds himself rubbing his gums all day to help relieve the pain. Fentora, on the other hand, contains no sugar and does not injure the teeth or gums.

In summary, it is apparent that United Healthcare has been willing to provide [Petitioner] immediate release fentanyl for his severe intractable pain. It is just that they have chosen a substitute an ineffective brand with intolerable side effects.

The total number of micrograms of Actiq and Fentora that United Healthcare has approved for is 9,600. However, it is not acceptable to make [Petitioner] suffer intolerable pain and side effects only in order to save money.

### Director's Review

Fentora is a prescription drug that is approved by the United States Food and Drug Administration (FDA) to treat cancer pain not controlled by other medications. The Petitioner is not being treated for cancer pain. For that reason, the use of Fentora is considered an "off-label

use” which is defined in Michigan law as “the use of a drug for clinical indications other than those stated in the labeling approved by the [FDA].” See MCL 500.3406q(5)(c).

Under some circumstances, Michigan law requires an insurer to provide coverage for the off-label use of a prescription drug. Section 3406q of the Michigan Insurance Code, MCL 500.3406q, provides:

- (1) An expense-incurred hospital, medical, or surgical policy or certificate delivered, issued for delivery, or renewed in this state that provides pharmaceutical coverage and a health maintenance organization contract that provides pharmaceutical coverage shall provide coverage for an off-label use of a federal food and drug administration approved drug and the reasonable cost of supplies medically necessary to administer the drug.
- (2) Coverage for a drug under subsection (1) applies if all of the following conditions are met:
  - (a) The drug is approved by the federal food and drug administration.
  - (b) The drug is prescribed by an allopathic or osteopathic physician for the treatment of either of the following:
    - (i) A life-threatening condition so long as the drug is medically necessary to treat that condition and the drug is on the plan formulary or accessible through the health plan's formulary procedures.
    - (ii) A chronic and seriously debilitating condition so long as the drug is medically necessary to treat that condition and the drug is on the plan formulary or accessible through the health plan's formulary procedures.
  - (c) The drug has been recognized for treatment for the condition for which it is prescribed by 1 of the following:
    - (i) The American medical association drug evaluations.
    - (ii) The American hospital formulary service drug information.
    - (iii) The United States pharmacopoeia dispensing information, volume 1, “drug information for the health care professional.”
    - (iv) Two articles from major peer-reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer-reviewed medical journal.

Section 2(a) requires that an off-label drug, in order to be covered, must be FDA-approved. Fentora is an FDA-approved drug. Consequently, the requirement of section 2(a) is satisfied.

Section 2(c) requires that the requested drug be recognized by one of four organizations or reference works as an appropriate treatment for the condition for which it is prescribed. No evidence has been presented that any of section 2(c)'s cited organizations or references recognize Fentora in the treatment of non-cancer pain.

Section 2(b) requires that the drug be prescribed for a life-threatening or seriously debilitating condition so long as the drug is medically necessary for the condition. The Petitioner's condition is, without question, seriously debilitating. The question of whether Fentora is medically necessary to treat that condition was presented by the Director 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 for more than ten years who is board certified in anesthesiology and pain management. The reviewer is familiar with the medical management of patients with the Petitioner's condition. The IRO report included the following analysis:

At issue in this appeal is whether Fentora 800 mcg at a quantity of 12 tablets daily is medically necessary for treatment of the member's condition.

[T]he use of immediate release fentanyl is subject to a Food and Drug Administration (FDA) mandated REMS [Risk Evaluation and Mitigation Strategy] program and the use of Fentora for pain relief from an occipital neuralgia is an off label use. The attestation for this program states "As the prescriber of any TIRF [Transmucosal Immediate Release Fentanyl] medication in this TIRF Access program, I acknowledge that: 1. I understand that TIRF medicines are indicated only for the management of breakthrough pain in patients with cancer who are already receiving, and who are tolerant to, around the clock opioid therapy for their underlying persistent pain."...[C]urrent clinical recommendations do not support the use of high dose opiates for pain control for patient with occipital neuralgia. [Citation omitted.] [T]here is no evidence that the member has attempted more trials of anticonvulsants, like Lyrica... [A]ppropriate measures should be taken to address member's suicidality, but...these measures should not include the requested continued opiate administration.

Pursuant to the information set forth above and available documentation... Fentora 800 mcg at a quantity of 12 tablets daily is not medically necessary for treatment of the member's condition.

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's analysis is based on extensive experience, expertise, and professional judgment. In addition, the IRO's recommendation is not contrary to any provision of the Petitioner's coverage. MCL 550.1911(15). The Director, discerning no reason why that analysis should be rejected in the present case, adopts the IRO analysis and finds that Fentora is not medically necessary for treatment of the member's condition.

Based on the IRO's conclusion that Fentora is not medically necessary to treat the Petitioner's condition and on the drug's lack of recognition as a treatment for the Petitioner's condition, the Director upholds UHIC's January 29, 2016 final adverse determination.

#### V. ORDER

UHIC is not required to provide coverage for Fentora at the requested dosage as part of the Petitioner's treatment.

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 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:



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Randall S. Gregg  
Special Deputy Director