

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. 153757-001

UnitedHealthcare Insurance Company,
Respondent.

Issued and entered
this 17th day of June 2016
by Randall S. Gregg
Special Deputy Director

ORDER

I. PROCEDURAL BACKGROUND

██████████ (Petitioner) was denied coverage for a specific dosage of a prescription drug by her health insurer, UnitedHealthcare Insurance Company (UHC).

On May 20, 2016, ██████████, the Petitioner's mother and court appointed guardian, filed a request with the Director of Insurance and Financial Services for an external review of UHC's decision under the Patient's Right to Independent Review Act (PRIRA), MCL 550.1901 *et seq.*

The Petitioner receives medical and prescription drug benefits under a group plan that is underwritten by UHC. The Director immediately notified UHC of the external review request and asked for the information it used to make its final adverse determination. After a preliminary review of the material received, the Director accepted the request on May 24, 2016.

The case involves medical issues, so the Director assigned the matter to an independent review organization, which completed its review and sent its recommendation to the Director on June 7, 2016.

II. FACTUAL BACKGROUND

The Petitioner's health care benefits are described in the *UnitedHealthcare Choice Plus Certificate of Coverage* (the certificate) and its *Outpatient Prescription Drug Rider* (the drug rider).

The Petitioner was diagnosed with narcolepsy in 2012. After her diagnosis, she was started on modafinil, a drug used to treat excessive sleepiness, at a dosage of 400 mg daily. That dosage was increased to 600 mg daily in 2013. When her health care coverage changed to UHC on April 18, 2016,

her physician asked UHC to cover modafinil at the 600 mg daily dosage she was receiving. UHC denied the request, saying that dosage is unproven and exceeds UHC's quantity limit.

The Petitioner appealed UHC's denial through its internal grievance process. At the conclusion of that process, UHC issued a final adverse determination dated May 13, 2016, upholding its decision. The Petitioner now seeks a review of that final adverse determination from the Director.

III. ISSUE

Did UHC correctly deny coverage for modafinil at a dosage of 600 mg per day?

IV. ANALYSIS

Petitioner's Argument

In a May 5, 2016, letter, the Petitioner's pediatric sleep nurse and attending pediatric sleep physician from the Children's Hospital of Philadelphia wrote:

. . . [The Petitioner] is a 19 year-old female with complex partial epilepsy, learning disability, obesity, and narcolepsy with cataplexy. [She] is currently on modafinil to treat her narcolepsy with cataplexy. She is being followed by the Sleep Center at The Children's Hospital of Philadelphia.

[The Petitioner] initially presented to the Sleep Center with excessive daytime sleepiness and frequent nighttime awakenings confirmed by Actigraphy in September 2012. [She] underwent a sleep study with next-day multiple sleep latency test (MSLT) on 10/3/12 which showed [she] fell asleep on 5 out of 5 naps and had a short sleep latency with an average time to sleep onset of 1.5 minutes. It also revealed 5 episodes of sleep-onset REM. At her follow-up appointment in the Sleep Center 10/10/12, [the Petitioner] presented with a score of 23/24 on the Epworth Sleepiness Scale, demonstrating severe ongoing sleepiness. [Her] high Epworth Sleepiness Scale score, Actigraphy findings, excessive daytime sleepiness, and positive MSLT are consistent with the diagnosis of narcolepsy.

[The Petitioner] was initiated on modafinil 400mg daily immediately following her 10/3/12 sleep study / MSLT. At her follow-up appointment in the Sleep Center on 10/21/13, [her] father reported continued daytime sleepiness. Her parents had even received notes from school complaining of her excessive sleepiness during class. [She] was also taking naps for several hours in the afternoon. Because of her residual symptoms on modafinil 400mg daily, [her] modafinil was increased to 600mg daily at this appointment.

It is medically necessary for [Petitioner] to receive the increased dose of modafinil 600mg daily to treat her narcolepsy with cataplexy. Research has shown that modafinil at such dosages is successful in reducing symptoms of narcolepsy. . . .

Without modafinil 600mg, [the Petitioner] will continue to have debilitating excessive daytime sleepiness and impaired daytime functioning which will negatively impact her quality of life and education. We are requesting modafinil 600mg daily so that [she] may manage her symptoms and optimize her education and quality of life. We are requesting urgent review as [Petitioner] will be running out of her current supply of modafinil 600mg daily that she's been on for several years to treat her narcolepsy with cataplexy.
[References omitted.]

Respondent's Argument

In its final adverse determination to the Petitioner, UHC said:

The pharmacy medication being appealed denied previously because the quantity limit was exceeded. The reason was that the dose was determined not to be proven.

We looked at the appeal, the information sent, our policies, and your health plan documents to make the decision.

[A] UnitedHealthcare Pharmacist, reviewed the appeal. [The pharmacist] is trained in a similar specialty as the professional who typically manages the condition, procedure or treatment being reviewed. The doctor did not make the original decision. It was determined that your health plan does not pay for this medication.

Our decision not to cover Modafinil 200 milligrams (mg) at a dose of 600 mg per day is upheld. You are using this drug for narcolepsy. We found that our first decision to deny coverage was correct. Your UnitedHealthCare Benefit Plan and your Drug Policy do not cover drugs when their dose is determined not to be proven. A dosage of up to 400 mg will continue to be covered.

Director's Review

UHC determined that modafinil administered at a dosage of 600 mg daily is unproven. The certificate (pp. 72-73) defines "unproven service(s)" as

services, including medications, that are determined not to be effective for treatment of the medical condition and / or not to have a beneficial effect on health outcomes due to insufficient and inadequate clinical evidence from well-conducted randomized controlled trials or cohort studies in the prevailing published peer-reviewed medical literature.

In "Section 2: Exclusions" (p. 15), the drug rider has this provision, which was the basis of UHC's denial:

Exclusions from coverage listed in the *Certificate* also apply to this Rider. In addition, the exclusions listed below apply.

* * *

5. Experimental or Investigational or Unproven Services and medications; medications used for experimental indications and / or dosage regimens determined by us to be experimental, investigational or unproven.

To determine if modafinil at a dosage of 600 mg daily is unproven for use in treating the Petitioner's condition, this case was assigned to an independent review organization (IRO) as required by section 11(6) of the Patient's Right to Independent Review Act, MCL 550.1911(6).

The IRO physician reviewer is certified by the American Board of Psychiatry and Neurology with a subspecialty in sleep medicine and is in active practice. The IRO report included the following analysis and recommendation:

Reviewer's Decision and Principal Reasons for the Decision:

Is the requested dosage of the prescribed medication: Modafinil considered unproven for treatment of the enrollee's condition?

No. The requested dosage of the prescribed medication modafinil is not considered unproven for the treatment of the enrollee's condition.

Is the requested dosage of prescribed medication: Modafinil medically necessary for treatment of the enrollee's condition?

Yes. The requested dosage of the prescribed medication modafinil is medically necessary for the treatment of the enrollee's condition.

Clinical Rationale for the Decision:

The American Academy of Sleep Medicine (AASM) Practice Parameters are the "go to" resource for sleep medicine. The AASM Practice Parameters for the Treatment of Narcolepsy and other Hypersomnias of Central Origin indicate that modafinil is effective for treatment of daytime sleepiness due to narcolepsy. This recommendation is unchanged from a previous recommendation. Fourteen additional studies including four (4) level 1 studies and two (2) level 2 studies support this recommendation. The approved recommended dose of modafinil is 200 mg given once daily, but higher doses and split dose regimens have been investigated. Three (3) level 1 studies indicated that the use of a split dose strategy provides better control of daytime sleepiness than a single daily dose. One (1) of the studies demonstrated that adding a dose of modafinil 200 mg at 12:00 after a 400 mg dose at 07:00 improved late day maintenance of wakefulness test (MWT) scores relative to a single 400 mg morning dose alone. A study demonstrating the efficacy of the split dose with a total of 600 mg daily dose is cited in the Practice Parameter paper.

Modafinil is Food and Drug Administration (FDA) approved at 400 mg per day total daily dose for treatment of narcolepsy. The 600 mg daily dose is not FDA approved; however, there are several references in the AASM Practice Parameters Evidence Table that use modafinil at the 600 mg per day dose.

Alternatives to this dosing would be to change course and treat the enrollee with stimulants, which may increase her risk of seizures and may put her at risk for psychotic episodes. Overall modafinil has a higher level of recommendation (standard) versus amphetamine, methamphetamine, dextroamphetamine, and methylphenidate for treatment of daytime sleepiness due to narcolepsy (guideline), for which the practice parameter states that "These medications have a long history of effective use in clinical practice but have limited information available on benefit-to-risk ratio."

There is also literature that supports that the use of modafinil may enhance the efficiency of antiepileptic drugs. Andrade reviews the literature and finds that even at very high overdoses, there were no seizures due to modafinil. This would be important for this enrollee with a history of seizure disorder, to help to validate the safety of using a higher dose of the medication. Zolkowska et al look at the efficacy of modafinil in enhancing the anti-seizure properties of some seizure medications. It is reassuring that modafinil is being studied in this fashion, as an adjunct to seizure medication rather than a risk for inducing seizures. Given the enrollee's history of seizure disorder, modafinil is [a] safer choice for her treatment than alternatives including stimulant medications.

The 600 mg per day dose of modafinil is medically necessary, as the enrollee had residual daytime sleepiness with the 400 mg per day daily dose. The requested dosage of modafinil is not unproven, as the enrollee has taken the medication since 2013. Modafinil 600 mg per day is a valid treatment option when used with close clinical follow up. The treating physicians provide good documentation that the enrollee has received close neurological and psychological follow up along with the sleep physicians. Therefore, for the reasons noted above, Modafinil 600 mg per day is medically necessary for this enrollee.

Recommendation:

It is the recommendation of this reviewer that the denial issued by United Healthcare Insurance for 200 milligrams (mg) per day of the prescription medication modafinil at a dose of 600 mg per day be overturned. [References omitted.]

The Director is not required to accept the IRO's recommendation. *Ross v Blue Care Network of Michigan*, 480 Mich 153 (2008). However, the 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. The Director discerning no reason why the IRO's recommendation should be rejected in the present case, accepts the recommendation and finds the requested dosage of 600 mg of Modafinil is not unproven and is medically necessary for treatment of the Petitioner's condition, and therefore is a covered benefit.

V. ORDER

The Director reverses UHC's final adverse determination of May 13, 2016.

UHC shall immediately cover the requested dosage of 600 mg daily of the prescription drug modafinil for the Petitioner and shall, within seven days of providing coverage, furnish the Director with proof it has implemented this order.

To enforce this Order, the Petitioner may report any complaint regarding its implementation to the Department of Insurance and Financial Services, Health Care Appeals Section, toll free at 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 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:



Randall S. Gregg
Special Deputy Director