

**STATE OF MICHIGAN**  
**DEPARTMENT OF INSURANCE AND FINANCIAL SERVICES**  
**Before the Director of Insurance and Financial Services**

In the matter of:

██████████,  
Petitioner,

v

Health Alliance Plan of Michigan,  
Respondent.

File No. 154291-001

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Issued and entered  
this 26<sup>th</sup> day of July 2016  
by Randall S. Gregg  
Special Deputy Director

**ORDER**

**I. BACKGROUND**

██████████ (Petitioner) was denied coverage for a prescription drug by his health plan, Health Alliance Plan of Michigan (HAP), a health maintenance organization.

On June 23, 2016, ██████████, M.D., the Petitioner's authorized representative, filed a request with the Director of Insurance and Financial Services for an external review of that denial under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.*

The Petitioner receives health care benefits, including prescription drug coverage, through HAP. The Director immediately notified HAP of the external review request and asked for the information used to make its final adverse determination. HAP responded on June 24, 2016. After a preliminary review of the information submitted, the Director accepted the request on June 30, 2016.

Because the case involves medical issues, it was assigned to an independent medical review organization, which provided its analysis and recommendation to the Director on July 13, 2016.

**II. FACTUAL BACKGROUND**

The Petitioner's health care benefits are described in HAP's *HMO Group Subscriber Contract* (the contract).

The Petitioner, has narcolepsy with cataplexy. His physician prescribed the drug Xyrem to treat his condition. When HAP was asked to authorize coverage for the drug, it denied the request.

The Petitioner appealed the denial through HAP's expedited internal grievance process. At the conclusion of that process, HAP issued a final adverse determination dated June 20, 2016 affirming its denial. The Petitioner now seeks the Director's review of that final adverse determination.

### III. ISSUE

Did HAP properly deny prescription drug coverage for Xyrem?

### IV. ANALYSIS

#### Petitioner's Argument

In a letter dated June 22, 2016, the Petitioner's authorized representative wrote:

I have been treating [the Petitioner] for narcolepsy with cataplexy for the past few years, [he] has done wonderful on Xyrem. He is able to work and support his family. He has not been doing well since the discontinuation of Xyrem because of [HAP's] insurance policy coverage. He has failed several medications and keeps trying different medications. The trial and error of these medications has predisposed him to potential side effects that could be harmful end serious. I encourage approving his Xyrem so he can go back to his regular function and production at work and In the community. . . .

#### Respondent's Argument

HAP initially informed the Petitioner of its denial on May 24, 2016:

The formulary is a list of drugs covered by your Commercial Plan Prescription Drug Benefit and any applicable restrictions. According to your plan's Formulary Policy, medications with restrictions are covered after specific criteria have been met. In addition, formulary medications may have specific quantity limit restrictions. Our records show these criteria have not been met and, therefore, coverage of the requested drug is denied.

Xyrem (sodium oxybate) is included on the Formulary with both prior authorization criteria and quantity limits. For the diagnosis of narcolepsy with cataplexy, the criteria are (1) documented failure of ALL of the following stimulant products (amphetamine, amphetamine /

dextroamphetamine, dextroamphetamine, methylphenidate) AND modafinil and (2) in combination with anti-depressant products, at least one drug from each of these three classes: SSRI (example: sertraline, citalopram); SNRI (example: venlafaxine, duloxetine) and TCA (example: amitriptyline) at the highest FDA labeled dose. Documentation must show an adequate trial on each stimulant and anti-depressant and reasons for failure. Our records show these criteria have not been met. Specifically, based on your records you have not tried and failed an adequate trial of an amphetamine, dextroamphetamine, an SNRI and a TCA.

In its final adverse determination, HAP told the Petitioner:

. . . After considering all available evidence, previous decisions and your medication history, HAP's Pharmacy Care Management (PCM) is upholding the denial for Xyrem. Per PCM's review, you have not tried amphetamine and dextroamphetamine, as well as, combinations of SNRI, and TCA (anti-depressants) agents. Documentation must show an adequate trial on each stimulant and anti-depressant and reasons for failure. Therefore, the denial is upheld for the requested medication as the coverage criteria have not been met.

#### Director's Review

Xyrem is on HAP's Commercial Formulary (January 1, 2016) but it must be authorized in advance. HAP requires that certain criteria be met before it is authorized. HAP denied coverage because the Petitioner did not meet its criteria, i.e., he has not tried and failed HAP's other approved narcolepsy drugs.

The question of whether HAP used the appropriate criteria to determine if Xyrem was medically necessary to treat the Petitioner 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 physician reviewer is board certified in neurology and sleep medicine, is familiar with the medical management of patients with the Petitioner's condition, and has been in active practice for more than 12 years. The IRO report included the following recommendation and analysis:

#### **Recommended Decision:**

The MAXIMUS physician consultant determined that Xyrem is medically necessary for treatment of the member's condition.

#### **Rationale:**

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The MAXIMUS physician consultant indicated that the member's medical records contain documentation of trial and failure of Nuvigil, methylphenidate (both IR and ER), and mixed amphetamine salts. However the records do not indicate a trial of dextroamphetamine, a tricyclic antidepressant and a serotonin and norepinephrine reuptake inhibitor as required by the plan. The physician consultant noted that given the lack of documented trials / failures of these three drugs, the plan criteria for coverage have not been met.

The physician consultant explained that the use of central nervous system (CNS) stimulants have traditionally been used in the clinical management of excessive daytime sleepiness due to narcolepsy. The consultant indicated that there is also a well-documented history on the use of serotonin and norepinephrine reuptake inhibitors (SNRIs) and tricyclic antidepressants (TCAs) for the management of cataplexy. The consultant also indicated that the use of these drugs are all mentioned within the current practice parameters published by the American Academy of Sleep Medicine on the pharmacological management of hypersomnia. The physician consultant explained that in that regard, the Health Plan's pharmacy policy for Xyrem does partially reflect the current standards of care.

The current practice parameters of the American Academy of Sleep Medicine (AASM) categorize their recommendations on three levels: "Standard," "Guideline" and "Option." Guideline is defined as "This is a generally accepted patient-care strategy that reflects a high degree of clinical certainty. The term standard generally implies the use of level 1 evidence, which directly addresses the clinical issue, or overwhelming level 2 evidence." Standard is defined as: "This is a patient-care strategy that reflects a moderate degree of clinical certainty. The term guideline implies the use of level 2 evidence or a consensus of level 3 evidence." The AASM guidelines state: "Sodium oxybate is effective for treatment of cataplexy, daytime sleepiness, and disrupted sleep due to narcolepsy (Standard)." The use of other CNS stimulants (e.g. methylphenidate, amphetamine and dextroamphetamine) for excessive daytime sleepiness were only given a rating of "guideline." The use of TCAs and SNRIs as anti-cataplectic agents were also rated as "guidelines." Current guidelines from the European Federation of the Neurological Societies (EFNS) make similar categorizations. The physician consultant indicated that taking both the AASM and EFNS guidelines into consideration, the Health Plan's pharmacy policy for Xyrem partially represents the standard of care in the treatment of narcolepsy. The Health Plan's policy does list the use of drugs that are generally recommended for use.

However, the physician consultant explained that where the plan's policy

deviates from the AASM and EFNS guidelines is that both guidelines recommend the use of sodium oxybate as first line therapy in type 1 narcolepsy (formerly known as "Narcolepsy with Cataplexy"). The AASM guidelines recommend the use of Xyrem with a higher level of evidence than other CNS stimulants (for excessive daytime sleepiness) and TCAs or SNRIs (for cataplexy). The EFNS guidelines state when modafinil is unsuccessful: "when excessive daytime somnolence coexists with cataplexy and poor sleep, sodium oxybate may be prescribed, based on its well - evidenced efficacy on the three symptoms." It should be noted that Nuvigil was not approved in the European Union at the time of those guidelines. The physician consultant explained that in that regard both guidelines appear to recommend sodium oxybate as a first line therapy for type 1 narcolepsy.

The consultant indicated that in applying the recommendations from practice guidelines to the information in this case, the member is noted to have had a trial and adverse effect with Nuvigil (armodafinil). The medical record dated 1/11/16 states that Nuvigil led to tachycardia, resulting in a cardiology visit and subsequent discontinuation of the medication. Nuvigil (armodafinil) contains the "active ingredient" or R-enantiomer of modafinil. Provgil (modafinil) is a racemic mixture of R/S modafinil (with only the R having pharmacologic effects). The physician consultant explained that given that the member had a contraindication to the use of Nuvigil, modafinil would not be indicated for use in this patient.

The physician consultant explained that on the basis of the EFNS guidelines, the member's clinical presentation would support the use of Xyrem for his condition. The consultant also explained that similarly, given the higher level of evidence rating within the AASM guidelines for the use of Sodium Oxybate over CNS stimulants and antidepressants, current guidelines would also support the continuation of Xyrem therapy in this case. Therefore, the consultant indicated that it can be determined that the use of Xyrem would be medically necessary in this case on the basis of current practice guidelines and literature.

Pursuant to the information set forth above and available documentation, the MAXIMUS physician consultant determined that Xyrem is medically necessary for treatment of the member's condition. [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 IRO 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 can discern no reason why the IRO's analysis and recommendation should be rejected. In addition, the IRO's recommendation is not contrary to any provision of HAP's *Group Subscriber Contract*. MCL 550.1911(15). The Director accepts the IRO's recommendation and finds the prescription drug Xyrem is medically necessary to treat the Petitioner's condition and is, therefore, a covered benefit under the terms of the contract.

**V. ORDER**

The Director reverses Health Alliance Plan of Michigan's June 20, 2016 final adverse determination.

HAP shall immediately cover the prescription drug Xyrem 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, at this toll free telephone number: (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 Michigan 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