



STATE OF WISCONSIN
Division of Hearings and Appeals

In the Matter of



DECISION

Case #: MPA - 200328

PRELIMINARY RECITALS

Pursuant to a petition filed on October 21, 2020, under Wis. Stat. § 49.45(5), and Wis. Admin. Code § HA 3.03(1), to review a decision by the Division of Medicaid Services regarding Medical Assistance (MA), a hearing was held on December 2, 2020, by telephone.

The issue for determination is whether the agency correctly denied the Petitioner’s prior authorization (PA) request for Xyrem.

There appeared at that time the following persons:


PARTIES IN INTEREST:

Petitioner:



Respondent:

Department of Health Services
1 West Wilson Street, Room 651
Madison, WI 53703


By:  (written appearance only)

Division of Medicaid Services
PO Box 309
Madison, WI 53701-0309

ADMINISTRATIVE LAW JUDGE:

Peter McCombs
Division of Hearings and Appeals

FINDINGS OF FACT

1. Petitioner (CARES # ) is a resident of Dodge County. She is 50 years old with diagnoses of narcolepsy without cataplexy.
2. On or about September 15, 2020, the Petitioner’s provider submitted a PA request for Xyrem

3. On October 9, 2020, the agency issued a notice to the petitioner that her PA request for Xyrem was denied.
4. On October 21, 2020, the Petitioner filed an appeal with the Division of Hearings and Appeals.

DISCUSSION

The Petitioner is a 50-year-old woman who seeks reimbursement from the medical assistance program for Xyrem to treat her narcolepsy without cataplexy. Federal law allows state MA programs to deny coverage of drugs they would otherwise cover if the drug is not prescribed for a “medically accepted indication.” 42 U.S.C § 1396r-8(d)(1)(B)(i). A medically accepted indication “means any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i).” 42 U.S.C § 1396r-8(k)(6). Those compendia are the American Hospital Formulary Service Drug Information, the United States Pharmacopeia-Drug Information (or its successor publications), and the DRUGDEX Information System.

Consistent with the federal law, Wisconsin regulations allow the department to deny payment for services that do not comply with program policies. Wis. Admin. Code, § DHS 107.02(2)(a). These policies are put in place to ensure that services comply with generic medical assistance regulations such the requirements that the services are medically necessary, appropriate, cost-effective, and of proven medical value and not experimental. Wis. Admin. Code §§ DHS 107.02(3)(e) and 101.03(96m).

The department denied the Petitioner’s request for Xyrem because the Petitioner does not meet the MA program’s clinical criteria for approval. The department notes that there is incomplete information on the PA request about the Petitioner’s diagnosis. The department also notes that the clinical criteria require a PSG sleep study and a MSLT to be performed. In addition, the provider must submit medical documentation supporting a clinical correlation between the test results and a diagnosis of narcolepsy without cataplexy. The criteria require that the PSG test results and provider documentation include findings that total sleep time is at least 360 minutes, the member experienced minimal sleep interruptions and an adequate night’s sleep was achieved. An MSLT must be conducted the morning after the PSG, and indicate an average sleep latency for all naps of eight minutes or less and that the Petitioner achieved at least two SOREMPs. The department contends these criteria were not met. See ForwardHealth Topic #16437 and ForwardHealth Update No. 2018-47 (December 2018).

The medical documentation indicates the Petitioner had an overnight PSG on May 11, 2017. The total sleep time documented was 218 minutes based upon her polysomnography. The MSLT indicates that portioner did not achieve two SOREMPs. The department asserts that because of the failure of Petitioner’s PSG to meet the 360 minute minimum of sleep and the failure of the MSLT to identify at least two SOREMPs, the Petitioner has failed to meet the criteria for approval.

The Petitioner testified at the hearing, explaining that her physician, Dr. Jack Jones, diagnosed her with narcolepsy in 2017. She has participated in multiple sleep studies, and has been taking Xyrem since 2018. She noted that Xyrem has benefited her by addressing her narcolepsy as well as her fibromyalgia. The Petitioner argues that Xyrem is appropriate for treatment of her diagnoses and has demonstrable medical value for her.

I understand why the Petitioner wants this drug and why she believes it will continue to be of value, but I have only the authority the department grants to me. This means I must follow its policies, rules and regulations. Because the clinical criteria for coverage of Xyrem to treat narcolepsy without cataplexy has not been met, I have no authority to order the department to allow coverage. Therefore, I must uphold the department’s denial of the PA request.

CONCLUSIONS OF LAW

The department correctly denied the Petitioner’s PA request because the documentation does not demonstrate that she meets the clinical criteria for coverage of Xyrem.

THEREFORE, it is ORDERED

That the Petitioner’s appeal is dismissed.

REQUEST FOR A REHEARING

You may request a rehearing if you think this decision is based on a serious mistake in the facts or the law or if you have found new evidence that would change the decision. Your request must be **received within 20 days after the date of this decision**. Late requests cannot be granted.

Send your request for rehearing in writing to the Division of Hearings and Appeals, 4822 Madison Yards Way, 5th Floor North, Madison, WI 53705-5400 **and** to those identified in this decision as "PARTIES IN INTEREST." Your rehearing request must explain what mistake the Administrative Law Judge made and why it is important or you must describe your new evidence and explain why you did not have it at your first hearing. If your request does not explain these things, it will be denied.

The process for requesting a rehearing may be found at Wis. Stat. § 227.49. A copy of the statutes may be found online or at your local library or courthouse.

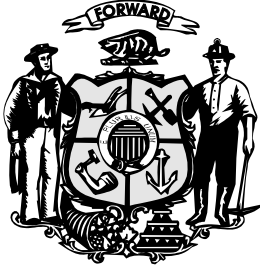
APPEAL TO COURT

You may also appeal this decision to Circuit Court in the county where you live. Appeals must be filed with the Court **and** served either personally or by certified mail on the Secretary of the Department of Health Services, 1 West Wilson Street, Room 651, **and** on those identified in this decision as “PARTIES IN INTEREST” **no more than 30 days after the date of this decision** or 30 days after a denial of a timely rehearing (if you request one).

The process for Circuit Court Appeals may be found at Wis. Stat. §§ 227.52 and 227.53. A copy of the statutes may be found online or at your local library or courthouse.

Given under my hand at the City of Madison,
Wisconsin, this 5th day of January, 2021

\s _____
Peter McCombs
Administrative Law Judge
Division of Hearings and Appeals



State of Wisconsin\DIVISION OF HEARINGS AND APPEALS

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The preceding decision was sent to the following parties on January 5, 2021.

Division of Medicaid Services