Letter of Medical Necessity Template

[To be placed on physician/provider letterhead]

To: **[Medical Director]**
[Insurance Company]
[Address]
[City, State, ZIP]

RE: **[Patient Name]**
[Policy ID Number]
[Policy Group]
[Patient Date of Birth]

Dear Dr. [Last Name]:

I am writing this letter to appeal the prior authorization denial for my patient, **[insert patient name]**, for treatment with XYREM® (sodium oxybate) oral solution, 0.5 g/mL, to treat **[insert diagnosis]**. Your organization cited **[enter reason for denial]** as the reason for the denial.

[Optional] I also request that my appeal be reviewed by
- A physician adviser not involved in the original decision
- A board-certified physician in sleep medicine

XYREM is indicated for the treatment of cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy.[1]

Treatment of **[insert patient name]** with XYREM is medically appropriate and necessary. This letter outlines the patient's medical history, prognosis, and treatment rationale.

1) Medical History and Prognosis

- **[Patient's diagnosis, condition, and history]**
- **[Previous therapies for the symptoms associated with the patient's condition and the patient's response to these therapies]**
- **[Brief description of the patient's recent symptoms and conditions]**

2) Rationale for Treatment

- **[Summary of why, based on your clinical judgment, your patient requires treatment with XYREM]**

[Optional] Based on current evidence, the American Academy of Sleep Medicine (AASM) recommends that the Multiple Sleep Latency Test (MSLT) report should not be the sole criterion for determining sleepiness or for certifying a diagnosis or response to treatment. Interpretation of test results should be made within the context of the individual patient history and as part of other medical information and testing.[2-4]

Please call my office at **[insert telephone number]** if I can provide you with any additional information. I look forward to receiving your timely response and approval.

Sincerely,

[Insert health care provider name and participating provider number]

Enclosures (as appropriate): Prior Authorization Denial Letter, Prior Authorization Form, Office Notes, Documentation of Prior Medication History, MSLT, Clinical Peer-reviewed Literature, XYREM Package Insert.

References: 1. XYREM [package insert]. Palo Alto, CA: Jazz Pharmaceuticals, Inc. **2.** Morgenthaler TI, Kapur VK, Brown T, et al. Practice parameters for the treatment of narcolepsy and other hypersomnias of central origin. *Sleep.* 2007;30(12):1705-1711. **3.** Wise MS. Objective measures of sleepiness and wakefulness: application to the real world? *J Clin Neurophysiol*. 2006;(23)1:39-49. **4.** Littner MR, Kushida C, Wise M, et al. Practice parameters for clinical use of the multiple sleep latency test and the maintenance of wakefulness test. *Sleep*. 2005;28(1):113-121.

Please see the next page for Important Safety Information and click here for full Prescribing Information, including BOXED Warning.

XYREM® (sodium oxybate) oral solution CIII

Jazz Pharmaceuticals

Indications and Usage

XYREM is indicated for the treatment of cataplexy or EDS in patients 7 years of age and older with narcolepsy.

Important Safety Information

WARNING: CENTRAL NERVOUS SYSTEM DEPRESSION and ABUSE AND MISUSE.

• Central Nervous System Depression

XYREM is a Central Nervous System (CNS) depressant. In clinical trials at recommended doses, obtundation and clinically significant respiratory depression occurred in adult patients treated with XYREM. Many patients who received XYREM during clinical trials in narcolepsy were receiving CNS stimulants.

• Abuse and Misuse

XYREM is the sodium salt of gamma-hydroxybutyrate (GHB). Abuse or misuse of illicit GHB, either alone or in combination with other CNS depressants, is associated with CNS adverse reactions, including seizure, respiratory depression, decreases in the level of consciousness, coma, and death.

Because of the risks of CNS depression and abuse and misuse, XYREM is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the XYWAV and XYREM REMS.

Contraindications

XYREM is contraindicated for use in combination with sedative hypnotics or alcohol and in patients with succinic semialdehyde dehydrogenase deficiency.

Warnings and Precautions

- CNS Depression: Use caution when considering the concurrent use of XYREM with other CNS depressants. If concurrent use is required, consider dose reduction or discontinuation of one or more CNS depressants (including XYREM). Consider interrupting XYREM treatment if short-term opioid use is required. After first initiating treatment and until certain that XYREM does not affect them adversely, caution patients against hazardous activities requiring complete mental alertness or motor coordination such as operating hazardous machinery, including automobiles or airplanes. Also caution patients against these hazardous activities for at least 6 hours after taking XYREM. Patients should be queried about CNS depression-related events upon initiation of XYREM therapy and periodically thereafter.
- Abuse and Misuse: XYREM is a Schedule III controlled substance. The rapid onset of sedation, coupled with the amnestic features of XYREM, particularly when combined with alcohol, has proven to be dangerous for the voluntary and involuntary user (eg, assault victim).
- Respiratory Depression and Sleep-Disordered Breathing: XYREM may impair respiratory drive, especially in patients with compromised respiratory function. In overdoses, life-threatening respiratory depression has been reported. Prescribers should be aware that increased central apneas and clinically relevant desaturation events have been observed with XYREM administration in adult and pediatric patients. Sleep-related breathing disorders tend to be more prevalent in obese patients, in men, in postmenopausal women not on hormone replacement therapy and among patients with narcolepsy.
- Depression and Suicidality: In adult clinical trials in patients with narcolepsy (n=781), depression was reported by 7% of XYREM-treated patients, with four patients (<1%) discontinuing because of depression. In the pediatric clinical trial in patients with narcolepsy (n=104), one patient experienced suicidal ideation and two patients reported depression while taking XYREM. Monitor patients for emergent or increased depression and/or suicidality, which require careful and immediate evaluation.
- Other Behavioral or Psychiatric Adverse Reactions: Monitor patients for impaired motor/cognitive function or the emergence of or increase in anxiety and/or confusion. The emergence or increase in the occurrence of behavioral or psychiatric events in adult and pediatric patients taking XYREM should be carefully monitored.
- Parasomnias: Episodes of sleepwalking should be fully evaluated and appropriate interventions considered. Five instances of significant injury or potential injury were associated with sleepwalking during a clinical trial of XYREM in adult patients with narcolepsy. Parasomnias, including sleepwalking, also have been reported in the pediatric clinical trial and in postmarketing experience with XYREM.
- Patients Sensitive to High Sodium Intake: XYREM has a high salt content. In patients sensitive to salt intake (eg, those with heart failure, hypertension, or renal impairment), consider the amount of daily sodium intake in each dose of XYREM.

Most Common Adverse Reactions

In three controlled adult clinical trials in patients with narcolepsy, the most common adverse reactions (incidence ≥5% and twice the rate of placebo) in XYREM-treated patients were nausea, dizziness, vomiting, somnolence, enuresis, and tremor. In the pediatric clinical trial in patients 7 years of age and older with narcolepsy, the most common adverse reactions (≥5%) were nausea (20%), enuresis (19%), vomiting (18%), headache (17%), weight decreased (13%), decreased appetite (9%), dizziness (8%) and sleepwalking (6%).

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