Introduction

Excessive daytime sleepiness is a common complaint among those with sleep-related problems. Excessive daytime sleepiness itself is not a disorder. However, it can be a symptom caused by other medical problems. These are conditions like narcolepsy, obstructive sleep apnea, and Parkinson disease. People with daytime sleepiness describe feeling drowsy or sluggish most of the time. These symptoms can interfere with work or school. They also can increase the risk of accidents on the road or at work. The first step in treating daytime sleepiness is evaluating its underlying cause. In some cases, medication may be an appropriate treatment. This policy describes when medications may be medically necessary for specific types of sleep disorders and excessive daytime sleepiness.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
<table>
<thead>
<tr>
<th>Drug</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Xyrem® (sodium oxybate)</td>
<td>Xyrem® (sodium oxybate) may be considered medically necessary for the following labeled indications:</td>
</tr>
<tr>
<td></td>
<td>• Treatment of cataplexy in narcolepsy patients 7 years and older when diagnosis of narcolepsy* has been documented by a sleep study</td>
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<tr>
<td></td>
<td>OR</td>
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<td></td>
<td>• Treatment of excessive daytime sleepiness (recurrent periods within the same day of an irrepressible need to sleep, lapsing into sleep, or napping, that have been occurring at least 3 times per week over at least the previous 3 months) in narcolepsy patients, when ALL of the following conditions are met:</td>
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<tr>
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<td>o Diagnosis of narcolepsy* has been documented by a sleep study</td>
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<td></td>
<td>AND</td>
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<td>o Prior therapy with a stimulant medication (eg, methylphenidate) was ineffective, not tolerated or contraindicated</td>
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<tr>
<td></td>
<td>AND</td>
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<td></td>
<td>o Prior therapy with modafinil (Provigil®) or armodafinil (Nuvigil®) was ineffective, not tolerated or contraindicated</td>
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*Diagnosis of narcolepsy is defined as recurrent periods of excessive daytime sleepiness (recurrent periods within the same day of an irrepressible need to sleep, lapsing into sleep, or napping, that have been occurring at least 3 times per week over at least the previous 3 months), and at least one of the following:  
• Episodes of cataplexy  
OR  
• Nocturnal sleep polysomnography (PSG) showing rapid eye movement (REM) sleep latency ≤ 15 minutes  
OR  
• Multiple sleep latency (MSLT) showing a mean sleep latency ≤ 8 minutes and 2 or more sleep onset REM periods
### Drug | Medical Necessity

**Medical records showing diagnosis suggestive of narcolepsy is not considered diagnostic of narcolepsy.**

**Note:** Requirement trial with a stimulant and modafinil/armodafinil may be waived if medical records show symptoms consistent with cataplexy.

**Note:** An adequate trial of a medication means:

- A therapeutic dose of the medication (ie, a dose that usually works) is taken for a period that is long enough to get a positive response. A trial that was stopped because medication was not tolerated due to a severe adverse response is considered adequate, regardless of whether or not the medicine was taken for the recommended length of time to get a positive response.

- Medication dosage and duration to achieve a therapeutic response while taking a trial of medication will vary based on the specific medication, the condition being treated and the age and/or size of the patient in some cases.

<table>
<thead>
<tr>
<th>Sunosi™ (solriamfetol)</th>
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<td>Treatment of excessive daytime sleepiness (recurrent periods within the same day of an irrepressible need to sleep, lapsing into sleep, or napping, that have been occurring at least 3 times per week over at least the previous 3 months) in adult patients with narcolepsy or obstructive sleep apnea, when ALL of the following conditions are met:</td>
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<td>o Diagnosis of narcolepsy or obstructive sleep apnea has been documented by a sleep study</td>
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**Drug** | **Medical Necessity**
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*Diagnosis of narcolepsy is defined as recurrent periods of excessive daytime sleepiness (recurrent periods within the same day of an irrepressible need to sleep, lapsing into sleep, or napping, that have been occurring at least 3 times per week over at least the previous 3 months), and at least one of the following:*  
- Episodes of cataplexy  
  OR  
- Nocturnal sleep polysomnography (PSG) showing rapid eye movement (REM) sleep latency ≤ 15 minutes  
  OR  
- Multiple sleep latency (MSLT) showing a mean sleep latency ≤ 8 minutes and 2 or more sleep onset REM periods

**Diagnosis of obstructive sleep apnea in adults is defined as:**  
- The apneic/hypopneic index (AHI) is ≥ 15 events per hour, including a minimum of 30 events documented per sleep study  
  OR  
- The AHI is ≥ 5 events per hour and < 15 events per hour, including a minimum of 10 events documented per sleep study, AND documentation of:  
  - History of stroke; OR  
  - Hypertension (systolic blood pressure > 140 mg Hg and/or diastolic blood pressure > 90 mm Hg); OR  
  - Ischemic heart disease; OR  
  - Symptoms of impaired cognition, mood disorders, or insomnia; OR  
  - Excessive daytime sleepiness (documented by either Epworth Sleepiness Scale > 10 or MSLT < 6); OR  
  - Greater than 20 episodes of desaturation (ie, oxygen saturation of less than 85%) during a full night sleep study, or any 1 episode of oxygen desaturation (ie, oxygen saturation of less than 70%); OR  
  - Obesity (BMI > 35)

Medical records showing diagnosis suggestive of narcolepsy or obstructive sleep apnea are not considered diagnostic.
### Drug Medical Necessity

**Note:** An adequate trial of a medication means:

- A therapeutic dose of the medication, (ie, a dose that usually works) is taken for a period that is long enough to get a positive response. A trial that was stopped because medication was not tolerated due to a severe adverse response is considered adequate, regardless of whether or not the medicine was taken for the recommended length of time to get a positive response.

- Medication dosage and duration to achieve a therapeutic response while taking a trial of medication will vary based on the specific medication, the condition being treated and the age and/or size of the patient in some cases.

### Investigational

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<td><em>Xyrem®</em> (sodium oxybate), <em>Sunosi™</em> (solriamfetol)</td>
<td>All other uses of <em>Xyrem®</em> (sodium oxybate) or <em>Sunosi™</em> (solriamfetol) for conditions not outlined in this policy are considered investigational.</td>
</tr>
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### Length of Approval

<table>
<thead>
<tr>
<th>Approval</th>
<th>Criteria</th>
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<tr>
<td><strong>Initial authorization</strong></td>
<td><em>Xyrem®</em> (sodium oxybate) and <em>Sunosi™</em> (solriamfetol) may be approved up to 1 year.</td>
</tr>
</tbody>
</table>
| **Re-authorization criteria** | Future re-authorization of *Xyrem®* (sodium oxybate) may be approved up to 1 year in duration when documentation provided at the time of re-authorization show:
  - Diagnosis of narcolepsy has been documented by a sleep study performed prior to starting *Xyrem®*
    - **Note:** This requirement only applies to patients started on *Xyrem®* with a prior insurer or for patients who had grandfathering for *Xyrem®* removed
  - **AND**
    - Documentation of continued clinical response
  - **AND**
    - Dose prescribed is ≤ 9 grams per day |
Length of Approval

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<tr>
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<tr>
<td>Future re-authorization of Sunosi™ (solriamfetol) may be approved up to 1 year in duration when documentation provided at the time of re-authorization show:</td>
<td></td>
</tr>
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<td>- Diagnosis of narcolepsy or obstructive sleep apnea has been documented by a sleep study performed prior to starting Sunosi™</td>
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Drug Dosage and Quantity Limit

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<tr>
<td>Xyrem® (sodium oxybate)</td>
<td>- Xyrem 0.5 g per mL, quantity limit of 270 grams (540 mL; 3 bottles) per 30 days</td>
</tr>
<tr>
<td></td>
<td>- Doses greater than 9 grams per day are not supported by clinical evidence and therefore are considered not medically necessary.</td>
</tr>
<tr>
<td>Sunosi™ (solriamfetol)</td>
<td>- Sunosi™ 75 mg tablet, quantity limit of 60 tablets per 30 days</td>
</tr>
<tr>
<td></td>
<td>- Sunosi™ 150 mg tablet, quantity limit of 30 tablets per 30 days</td>
</tr>
<tr>
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<td>- Doses greater than 150 mg once daily are not supported by clinical evidence and therefore are considered not medically necessary.</td>
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Documentation Requirements

The patient’s medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following:

- Office visit notes that contain the relevant history, diagnosis and medication history
  - AND
- Documented sleep study results
Consideration of Age

The ages noted in the policy statement for Xyrem® (sodium oxybate) and Sunosi™ (solriamfetol) are based on FDA approval.

Benefit Application

This policy is managed through the pharmacy benefit.

Background

Excessive daytime sleepiness (EDS) is defined as the inability to stay awake and alert during usual waking hours that occurs almost daily and persists for at least three months. Among obstructive sleep apnea (OSA) patients, men are twice as likely as women to suffer from EDS. Approximately 7.5 million Americans suffer from EDS due to OSA or narcolepsy. EDS puts patients at increased risk of impaired cognitive functioning and accidental injuries, as well as decreased work productivity and quality of life. Tiredness, fatigue, and lack of energy are common complaints. The potential causes of EDS are numerous and fall under several general classifications: central disorders (eg, narcolepsy), breathing disorders (eg, OSA), circadian rhythm issues (eg, jet lag), movement disorders (eg, restless leg syndrome), psychiatric disorders, substance abuse, and various diseases (eg, Parkinson).
Summary of Evidence

*Xyrem® (sodium oxybate)*

*Xyrem®* (sodium oxybate) is a CNS depressant. The mechanism of action of Xyrem in the treatment of narcolepsy is unknown. Sodium oxybate is the sodium salt of gamma hydroxybutyrate (GHB), an endogenous compound and metabolite of the neurotransmitter GABA. Abuse or misuse of illicit GHB is associated with CNS adverse reactions, including seizure, respiratory depression, decreased consciousness, coma and death. It is hypothesized that the therapeutic effects of Xyrem on cataplexy and excessive daytime sleepiness are mediated through GABA-B actions at noradrenergic and dopaminergic neurons, as well as at thalamocortical neurons. Xyrem is a Schedule III controlled substance. Because of its abuse/diversion potential, it is only available from a single pharmacy through a limited distribution scheme, the Xyrem Success Program. Both prescribers and patients must be registered in this program to obtain the drug. Serious side effects observed in patients taking Xyrem include hallucinations, agitation, severe confusion, abnormal thinking, sleep disturbances and depression.

The efficacy of Xyrem in the treatment of cataplexy was evaluated in two 4-week randomized, double-blind, placebo-controlled, multicenter, parallel-group trials, n=136 and 55 respectively. The high percentages of concomitant stimulant use in these studies make it impossible to assess the efficacy and safety independent of stimulant use. Doses of 6-9 g per night resulted in statistically significant reductions in frequency of cataplexy attacks. The 3 g per night dose had little effect. Overall, the evidence supporting this indication is of low quality.

The efficacy of Xyrem in the treatment of excessive daytime sleepiness in patients with narcolepsy was evaluated in an 8-week randomized, double-blind, placebo-controlled trial, n=228. Most of these patients were also being treated with CNS stimulants. Statistically significant improvements in Epworth Sleepiness Scores (ESS) were seen with 6 and 9 g doses. A second multicenter randomized, double-blind, placebo-controlled, parallel-group trial evaluated 222 patients on modafinil at baseline, who were randomized to placebo, Xyrem, modafinil, or Xyrem plus modafinil. Xyrem dose was 6g per night for 4 weeks, followed by 9g per night for 4 weeks. Modafinil was continued in the modafinil groups at the patient’s prior dose. A statistically significant improvement in in the Maintenance of Wakefulness Test (MWT) score from baseline at Week 8 was seen in the Xyrem and Xyrem plus modafinil groups compared to placebo. The trial was not designed to compare Xyrem with modafinil.

Studies have been conducted to demonstrate the efficacy of Xyrem in fibromyalgia patients; however, all of these have been placebo-controlled. In 2010, FDA rejected an application for use...
in fibromyalgia. FDA panel members expressed serious concerns about the potential for abuse and diversion of sodium oxybate. This concern was felt to outweigh any benefits that might accrue, and is supported by the lack of any head-to-head comparison with alternative treatments for fibromyalgia, none of which have the level of abuse potential seen with Xyrem.

**Sunosi™ (solriamfetol)**

The mechanism of action of Sunosi™ (solriamfetol) is unclear; however, it’s efficacy could be mediated through its activity as a dopamine and norepinephrine reuptake inhibitor. The published pivotal trials evaluating the efficacy and safety of Sunosi in excessive daytime sleepiness (EDS) are referred to as the TONES trials (Treatment of OSA and Narcolepsy Excessive Sleepiness). TONES 2 is a fair quality, unpublished, randomized controlled trial (RCT) that enrolled 239 adults with narcolepsy and EDS. Maintenance of Wakefulness Test (MWT) was improved in all Sunosi groups compared to placebo, but these differences were statistically significant in only the 300mg and 150mg groups (12.3 and 9.8 vs. 2.1, p<0.05). It is uncertain if this 7.7 to 10.2 minute increase in sleep latency is clinically meaningful. Sunosi improved Epworth Sleepiness Score (ESS) compared to placebo, but only the 300mg group had both a statistically and clinically significant treatment effect (-6.4 vs. -1.6, p<0.05). There was a clear dose-response relationship seen in both MWT and ESS.

TONES 3&4 are two fair quality, published, RCTs that enrolled 648 adults with OSA and EDS. In TONES 3 all doses of Sunosi (37.5mg-300mg) improved ESS and MWT compared to placebo (p<0.05). MWT scores showed a dose-response, with treatment effect values ranging from 4.5 to 12.8 (low dose to high dose Sunosi). The placebo-adjusted change in ESS was clinically meaningful in only the 300mg and 150mg groups (-4.7 and -4.5, respectively). There was a dose-response between high and low dose groups, however, the benefit appeared to plateau at 150mg. In TONES 4 the end of treatment differences between Sunosi (pooled data of all doses) and placebo were statistically significant for MWT (12.1), ESS (-4.4), and Functional Outcomes of Sleep Questionnaire-10 (1.0). The magnitude of benefit in ESS was clinically meaningful, but the observed treatment effect on functional score (Functional Outcomes of Sleep Questionnaire-10) was not clinically meaningful.

Available safety data are limited to 8-12 weeks of observation in the pivotal trials described above. Serious adverse events (SAEs) were few and none were deemed related to treatment. Most adverse events were mild to moderate in nature and resolved without intervention. The most common AEs across trials were headache, nausea, decreased appetite, and anxiety. A human use liability (HAL) study in 43 adult recreational drug users showed Sunosi was similar in abuse potential to phenteramine, a stimulant assigned to Schedule IV, and greater than that of
placebo. Of note, this study included doses of Sunosi that were up to four times greater than those studied in pivotal trials.

**Ongoing and Unpublished Clinical Trials**

An unpublished meta-analysis of six randomized control trials involving subjects with obstructive sleep apnea (OSA) and excessive daytime sleepiness (EDS) showed there was no clinically meaningful difference in Epworth Sleepiness Score (ESS) outcomes between Sunosi 150mg daily and modafinil 200mg or 400mg daily [-1.7 (95% CI -3.3, -0.01) and -1.7 (-3.3, -0.04), respectively]. The forty-minute Maintenance of Wakefulness Test (MWT) results were not shown for modafinil, so could not be compared to Sunosi trial results.

**References**


17. Weaver TE, Crosby RD, Bron M, et al. Using multiple anchor-based and distribution-based estimates to determine the minimal important difference (MID) for the FOSQ-10. Sleep 2018;41(suppl 1):A227.

### History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>06/01/19</td>
<td>New policy, approved May 14, 2019. Xyrem® (sodium oxybate) moved from policy 5.01.605. Criteria added for Sunosi™ (solriamfetol).</td>
</tr>
</tbody>
</table>

**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.

**Scope:** Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply.
Discrimination is Against the Law

Premera Blue Cross complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

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  - Qualified sign language interpreters
  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provides free language services to people whose primary language is not English, such as:
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If you need these services, contact the Civil Rights Coordinator.

If you believe that Premera has failed to provide these services or discriminated in any other way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:
Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-4535, Fax 425-918-5592. TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

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U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

Getting Help in Other Languages

This Notice has Important Information.

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Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross.

There may be key dates in this notice. You may need to take action before a date to keep your health insurance or cost assistance. You have the right to get this information and help in your language at no cost.
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