FDA INDICATIONS AND USAGE

Xyrem® oral solution is a central nervous system depressant that is indicated for the treatment of excessive daytime sleepiness with narcolepsy and cataplexy with narcolepsy. Sodium oxybate (GHB) is a controlled substance that has been associated with abuse and misuse.

APPROVAL CRITERIA

1. Patient is 16 years of age or older AND;
2. Patient has a documented diagnosis supported by a letter of medical necessity for excessive daytime sleepiness with narcolepsy or cataplexy with narcolepsy AND;
3. Patient and provider are both enrolled in Xyrem® REMS Program AND;
4. Xyrem® is being prescribed by a sleep specialist or neurologist AND;
5. Patient is not taking/using concomitant CNS depressants (i.e. opioids, benzodiazepines, alcohol, sedative hypnotics, muscle relaxants, etc.) verified by drug screen prior to use AND;
6. Patient has been evaluated for major depressive disorder and history of substance misuse AND;
7. Patient has tried for a period of at least 30 days and failed at least one CNS stimulant drug (i.e. methylphenidate) or has a contraindication to stimulant use AND;
8. Patient has tried for a period of at least 30 days and failed at least one CNS promoting wakefulness drug (i.e. modafinil) or has a contraindication to stimulant use AND;
9. Sleep logs have been submitted for the last 30 days.

DENIAL CRITERIA

1. Patient is less than 16 years of age OR;
2. Patient does not have a documented diagnosis for excessive daytime sleepiness with narcolepsy or cataplexy with narcolepsy OR;
3. Patient and provider are not both enrolled in Xyrem® REMS Program OR;
4. Xyrem® is not being prescribed by a sleep specialist or neurologist OR;
5. Patient is taking/using concomitant CNS depressants (i.e. opioids, benzodiazepines, alcohol, sedative hypnotics, muscle relaxants, etc.) OR;
6. Patient has major depressive disorder and history of substance misuse OR;
7. Patient has not tried for at least 30 days and failed at least one CNS stimulant drug (i.e. methylphenidate) or has a contraindication to stimulant use OR;
8. Patient has not tried for at least 30 days and failed at least one CNS promoting wakefulness drug (i.e. modafinil) or has a contraindication to stimulant use OR;
9. Sleep logs have not been submitted for the last 30 days OR;
10. Patient has heart failure, hypertension, impaired renal function, or respiratory problems.

CAUTIONS

- Contraindicated in patients with succinic semialdehyde dehydrogenase deficiency and when used in combination with sedative hypnotics or alcohol.
- Xyrem® can increase depression and suicidality in certain patients.
Xyrem® can cause impaired motor and cognitive function.  
Xyrem® oral solution has a high sodium content.

DURATION OF APPROVAL

- Initial Approval: up to 3 months
- Reauthorization Approval: up to 6 months if the patient is responding positively and doses have not exceeded 9 gm per day

QUANTITY LIMITS

- 3 – 180ml bottles
- Doses do not exceed 9gm per day

REFERENCES / FOOTNOTES: