ALASKA MEDICAID
Prior Authorization Criteria

Xyrem® (Sodium Oxybate)

FDA INDICATIONS AND USAGE[1]

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 abuse and misuse.

APPROVAL CRITERIA[1,2,3,4]

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[1,2,3,4]

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[1]

- 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:

1. Xyrem® [Package Insert]. Palo Alto, CA: Jazz Pharmaceuticals; April 2015. Available at: http://pp.jazzpharma.com/pi/xyrem.en.USPI.pdf. Accessed on October 12, 2018.
2. Wise MS, Arand DL, Auger R, et al. Treatment of narcolepsy and other hypersomnias of central origin. An American Academy of Sleep Medicine Review. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2276130/. Accessed on October 12, 2018.
3. Barateu L, Lopez R, Franchi JA, Dauvilliers Y. Hypersomnolence, Hypersomnia, And Mood Disorders. Current Psychiatry Rep. 2017 Feb; 19(2):13.
4. Lehert P, Falissard B. Multiple Treatment Comparison in Narcolepsy: a Network Meta-analysis. Sleep. 2018 Sept 19. Available at: https://doi.org/10.1093/sleep/zsy185. Accessed on October 31, 2018