ALASKA MEDICAID
Prior Authorization Criteria

Xyrem® (Sodium Oxybate), Xywav™ (calcium, magnesium, potassium, sodium oxbates)

FDA INDICATIONS AND USAGE[1,3]

Xyrem® and Xywav™ oral solutions are a central nervous system depressant that is indicated for the treatment of cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy. Sodium oxybate (GHB) is a controlled substance that has been associated abuse and misuse.

APPROVAL CRITERIA[1,2,3]

1. Patient is 7 years of age or older **AND;**
2. Patient has a documented diagnosis supported by a letter of medical necessity for excessive daytime sleepiness in narcolepsy or cataplexy in narcolepsy **AND**;
3. Patient and provider are both enrolled in the REMS Program **AND;**
4. The medication 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, 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]

1. Failure to meet approval criteria **OR**;
2. For Xyrem® the patient has heart failure, uncontrolled hypertension or impaired renal function **OR**;
3. Patient has succinic semialdehyde dehydrogenase deficiency **OR**;
4. If being used in combination with sedative hypnotics or alcohol.

CAUTIONS[1,3]

- Xyrem® and Xywav™ can increase depression and suicidality in certain patients.
- Xyrem® and Xywav™ can cause impaired motor and cognitive function.
- Xyrem® oral solution has a high sodium content.
- Evaluate for episodes of sleepwalking.

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 mg per day

QUANTITY LIMITS

- 3 – 180ml bottles
- Doses do not exceed 9mg 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. Xywav® [Package Insert]. Palo Alto, CA: Jazz Pharmaceuticals; July 2020. Available at: https://pp.jazzpharma.com/pi/xywav.en.USPI.pdf . Accessed on October 6, 2020.