STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR MEDICAL SERVICES

Office of Pharmacy Services
Prior Authorization Criteria

Xyrem® (sodium oxybate)
Xywav® (oxybate salts)

Prior Authorization Request Form

Xyrem (sodium oxybate) is a central nervous system depressant indicated for the treatment of cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy.

Xywav (oxybate salts) is a central nervous system depressant indicated for the treatment of: (1) Cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy (2) Idiopathic Hypersomnia (IH) in adults

CRITERIA FOR APPROVAL:

1. The patient has a diagnosis of narcolepsy with excessive daytime sleepiness (EDS) and/or cataplexy as confirmed by a sleep study followed by multiple sleep latency testing (MSLT) or Diagnosis of idiopathic Hypersomnia (for Xywav); **AND**

2. The medication is prescribed by a sleep specialist enrolled in the Xywav and Xyrem® REMS Program; **AND**

3. The patient is enrolled in Xywav and Xyrem REMS Program; **AND**

4. The patient does not have a history or succinic semialdehyde dehydrogenase deficiency; **AND**

5. The patient is not receiving concurrent treatment with sedative hypnotics or central nervous system depressants; **AND**

6. The patient has a recent drug screen negative for benzodiazepines, opiates, and illicit drugs; **AND**

7. The patient has a documented history of alcohol abstinence; **AND**

8. The patient does not have a history of substance abuse; **AND**

9. The patient does not have a condition which would require a restricted intake of sodium such as, but not limited to, hypertension or stage 4-5 renal impairment.

For narcolepsy with daytime sleepiness, must have documented history of therapeutic failure of the following, as determined by an Epworth Sleepiness scale of greater than or equal to 10 or repeated maintenance of Wakefulness Test (MWT) or MSLT with a mean sleep latency of 8 minutes or less;

1) Modafinil or Armodafinil at maximum recommended doses; **AND**
2) Methylphenidate, methamphetamine or dextroamphetamine at maximum recommended doses; **OR**
3) Intolerance to or contraindication for the above agents

For narcolepsy with cataplexy, must have documented history of therapeutic failure, contraindication, or intolerance to:

1) Tricyclic antidepressants; **AND**
2) SSRIS and SNRIS

For Xywav: Diagnosis of Idiopathic Hypersomnia

1) The member is ≥18 years of age; **AND**
2) Diagnosis must be confirmed by supporting documentation which includes the specialist's interpretation of the Polysomnography (PSG) and Multiple Sleep Latency Test (MSLT) results; **AND**
3) The member must have a 60-day trial of at least one preferred stimulant treatment (e.g., methylphenidate or dextroamphetamine) at maximally tolerated dosage which resulted in an inadequate treatment response, unless contraindicated; **AND**
4) The member must have a 60-day trial of modafinil which resulted in an inadequate treatment response, unless contraindicated.

Xywav will only be approved upon documentation of allergy, intolerance, or contraindication to Xyrem. Requests for Xywav must be accompanied with the 2 most recent basic metabolic panel (BMP) tests.