PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Xyrem (sodium oxybate), Lumryz (sodium oxybate extended release) and Xywav (calcium, magnesium, potassium, and sodium oxybates)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Xyrem, Lumryz and Xywav are central nervous system depressants indicated for narcolepsy associated with cataplexy or excessive daytime sleepiness in adults. Xyrem and Xywav are also approved in patients 7 years of age and older. Additionally, Xywav is approved for idiopathic hypersomnia for adults. The exact mechanism of action is unknown, but it's hypothesized to involve activation during sleep at noradrenergic and dopaminergic neurons, as well as at thalamocortical neurons.
Narcolepsy is a chronic neurologic disorder involving dysregulation of the sleep/wake cycle. It is estimated about 50 per 100,000 people in the U.S. have narcolepsy. Idiopathic hypersomnia (IH) is a chronic neurological disorder that results in daytime sleepiness, frequently accompanied by long nocturnal or daytime sleep, unrefreshing sleep, difficulty in awakening, cognitive dysfunction, and autonomic symptoms. A less common condition than narcolepsy, there are approximately 20 to 50 cases per million of idiopathic hypersomnia.

Xyrem (sodium oxybate), Lumryz (sodium oxybate extended release) and Xywav (calcium, magnesium, potassium, and sodium oxybates) will be considered for coverage when the following criteria are met:

Idiopathic Hypersomnia – Xywav only

For **initial** authorization:

1. Member is 18 years old or older; AND
2. Medication must be prescribed by or in consultation with a neurologist or sleep specialist; AND
3. Member must have a diagnosis of idiopathic hypersomnia with the presence of at least **one** of the following:
   a) MSLT (multiple sleep latency test) showing a mean sleep latency of Ò 8 mi; OR
   b) Total 24-hour sleep time usually 12Ó16 hours in 24-hour polysomnography or by wrist actigraphy in association with a sleep log; AND
4. Member has documentation of **ALL** of the following:

a) Once nightly dosing: Initiate dosage at 3 g or less per night orally, as one dose. Titrate to effect in increments of up to 1.5g per night per week, up to 6g total nightly dose.
b) Twice nightly dosing: Initiate dosage at 4.5g or less per night orally, divided into two doses. Titrate to effect in increments of up to 1.5g per night per week, up to 9g total nightly dose.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes must show improvement or stabilized signs and symptoms of disease (ex. Improved score on the Epworth Sleepiness Scale and/or improved signs and symptoms of daytime sleepiness, etc.).

If all the above requirements are met, the medication will be approved for an additional 12 months.

Narcolepsy with Excessive Daytime Sleepiness (EDS)

For **initial** authorization:
1. For Xyrem or Xywav, member is 7 years old or older; OR
2. For Lumryz, member is 18 years old or older; AND
3. Medication must be prescribed by or in consultation with a neurologist or sleep specialist; AND
4. Member has a diagnosis of narcolepsy with EDS confirmed by sleep studies: polysomnogram and multiple sleep latency test (MSLT); AND
5. Member has documentation of baseline Epworth Sleepiness Scale (ESS); AND
6. If member is 18 years of age and older:
   a) Member has had a 30-day trial of BOTH of the following: Modafinil OR armodafinil AND Sunosi; AND
   b) Member has had a 60-day trial of Wakix; OR
7. If member is less than 18 years of age:
   a) Member has had a 30-day trial of modafinil (trial of a stimulant medication such as methylphenidate is also acceptable); AND
8. Member is not using any alcohol or sedative hypnotic agents (such as zolpidem).
9. **Dosage allowed/Quantity limit:**
   a) Xyrem and Xywav: 9g per day (4.5g per dose). QL: 540 mL/30 days
   b) Lumryz: 6 g to 9 g once per night. QL: 30 packets/30 days

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes must show improvement or stabilized signs and symptoms of disease (ex. Improved score on the Epworth Sleepiness Scale and/or improved signs and symptoms of daytime sleepiness, etc.).

If all the above requirements are met, the medication will be approved for an additional 12 months.

Narcolepsy with Cataplexy

For **initial** authorization:
1. For Xyrem or Xywav, member is 7 years old or older; OR
2. For Lumryz, member is 18 years old or older; AND
3. Medication must be prescribed by or in consultation with a neurologist or sleep specialist; AND
4. Member must have a diagnosis of narcolepsy with cataplexy confirmed by sleep studies: polysomnogram and multiple sleep latency test (MSLT); AND
5. Member has documentation of baseline Epworth Sleepiness Scale (ESS) and baseline frequency of cataplexy attacks (e.g. weekly rate); AND

10.