

Sodium oxybate (Xyrem, Xywav, and Lumryz)

Coverage Criteria for Cataplexy associated with Narcolepsy:

1. Prescribed by a provider with experience in the management of narcolepsy including but not limited to, neurologist and sleep specialists; and,
2. Patient is ≥ 7 years of age; and,
3. Prescribed for the treatment of cataplexy associated with narcolepsy, confirmed with polysomnography (PSG), multiple sleep latency testing (MSLT), or cerebrospinal fluid analysis that supports the diagnosis. Submission of medical chart documentation of the test and chart notes clearly describing that the test results are indicative of the diagnosis is required; and,
4. Patient has had no improvement in symptoms despite at least two months of treatment (or medical contraindications to use) with each of the following first line therapies including:
 - a. Modafinil or armodafinil to reduce daytime sleepiness; and,
 - b. An antidepressant used in the treatment of cataplexy (such as SSRIs (e.g., fluoxetine) or TCAs (e.g., clomipramine)); and,
 - c. Sunosi; and,
 - d. Wakix (A trial with Wakix is not required for patients who are 7-17 years of age); and,
5. Sedative hypnotics will not be used concurrently; and,
6. Sodium oxybate (Xyrem, Xywav, Lumryz) and Wakix will not be used in conjunction; and,
7. For brand name requests (e.g., Xyrem, Xywav, Lumryz): patient has a medical contraindication to generic sodium oxybate; and,
8. Prescribed within the FDA approved dosing regimen.

Renewal Criteria for Cataplexy associated with Narcolepsy:

1. Patient has been seen by the prescriber in the past 12 months; and,
2. Medical chart documentation of efficacy, such as reduction in symptoms of daytime sleepiness or reduction in frequency of cataplexy attacks; and,
3. Provider attests that discontinuation or de-escalation of sodium oxybate use would be clinically inappropriate for the patient at this time; and,
4. For brand name requests (e.g., Xyrem, Xywav, Lumryz): patient has a medical contraindication to generic sodium oxybate; and,
5. Prescribed within the FDA approved dosing regimen.

Coverage Criteria for Excessive Daytime Sleepiness associated with Narcolepsy:

1. Prescribed by a provider with experience in the management of narcolepsy including but not limited to, neurologist and sleep specialists; and,
2. Patient is ≥ 7 years of age; and,
3. Prescribed for the treatment of excessive daytime sleepiness associated with narcolepsy, confirmed with polysomnography (PSG), multiple sleep latency testing (MSLT), or cerebrospinal fluid analysis that supports the diagnosis. Submission of medical chart documentation of the test and chart notes clearly describing that the test results are indicative of the diagnosis is required; and,

4. Patient has had no improvement in symptoms despite at least two months of treatment (or medical contraindications to use) with each of the following first line therapies including
 - a. Modafinil or armodafinil to reduce daytime sleepiness; and,
 - b. Sunosi; and,
 - c. Wakix (A trial with Wakix is not required for patients who are 7-17 years of age); and,
5. Sedative hypnotics will not be used concurrently; and,
6. Sodium oxybate (Xyrem, Xywav, Lumryz) and Wakix will not be used in conjunction; and,
7. For brand name requests (e.g., Xyrem, Xywav, Lumryz): patient has a medical contraindication to generic sodium oxybate; and,
8. Prescribed within the FDA approved dosing regimen.

Renewal Criteria for Excessive Daytime Sleepiness associated with Narcolepsy:

1. Patient has been seen by the prescriber in the past 12 months; and,
2. Medical chart documentation of efficacy, such as reduction in symptoms of daytime sleepiness; and,
3. Provider attests that discontinuation or de-escalation of sodium oxybate use would be clinically inappropriate for the patient at this time; and,
4. For brand name requests (e.g., Xyrem, Xywav, Lumryz): patient has a medical contraindication to generic sodium oxybate; and,
5. Prescribed within the FDA approved dosing regimen.

Coverage Criteria for Idiopathic Hypersomnia

1. Prescribed by a provider with experience in the management of narcolepsy including but not limited to, neurologist and sleep specialists; and,
2. Patient is ≥ 7 years of age; and,
3. Prescribed for the treatment of idiopathic hypersomnia, confirmed with polysomnography (PSG), multiple sleep latency testing (MSLT), or cerebrospinal fluid analysis that supports the diagnosis. Submission of medical chart documentation of the test and chart notes clearly describing that the test results are indicative of the diagnosis is required; and,
4. Patient has had no improvement in symptoms despite at least two months of treatment (or medical contraindications to use) with each of the following first line therapies including:
 - a. Modafinil or armodafinil to reduce daytime sleepiness; and,
 - b. Wakix (A trial with Wakix is not required for patients who are 7-17 years of age); and
5. Sedative hypnotics will not be used concurrently; and,
6. Sodium oxybate (Xyrem, Xywav, Lumryz) and Wakix will not be used in conjunction; and,
7. For brand name requests (e.g., Xyrem, Xywav, Lumryz): patient has a medical contraindication to generic sodium oxybate; and,
8. Prescribed within the FDA approved dosing regimen.

Renewal Criteria for Idiopathic hypersomnia:

1. Patient has been seen by the prescriber in the past 12 months; and,



2. Medical chart documentation of efficacy, such as reduction in symptoms of daytime sleepiness; and,
3. Provider attests that discontinuation or de-escalation of sodium oxybate use would be clinically inappropriate for the patient at this time; and,
4. For brand name requests (e.g., Xyrem, Xywav, Lumryz): patient has a medical contraindication to generic sodium oxybate; and,
5. Prescribed within the FDA approved dosing regimen.

Other Criteria:

Use of generic sodium oxybate is required unless the patient has a medical contraindication to its use. Patients must meet all other coverage criteria.