GUIDELINES FOR USE

1. Is the patient currently on a sedative hypnotic agent (e.g., Lunesta (eszopiclone), Ambien (zolpidem), Sonata (zaleplon), estazolam, Restoril (temazepam), Halcion (triazolam), flurazepam, quazepam, Belsomra)?

   If yes, do not approve.
   **DENIAL TEXT:** See the denial text at the end of the guideline.
   If no, continue to #2.

2. Does the patient have a diagnosis of cataplexy in narcolepsy and meets the following criteria?
   - Patient age 18 years and above
   - Prescribed by or in consultation with one of the following specialists: neurologist, psychiatrist, or specialist in sleep medicine

   If yes, **approve for 12 months by HICL for #18mL per day.**
   **APPROVAL TEXT:** Please note that this drug has an important FDA safety warning.
   For more information, please ask your doctor or pharmacist.
   If no, continue to #3.

3. Does the patient have a diagnosis of excessive daytime sleepiness in narcolepsy and meets the following criteria?
   - Patient age 18 years and above
   - Patient has tried 2 of the following preferred agents (unless contraindicated to stimulants):
     - a generic stimulant (e.g., amphetamine, dextroamphetamine, or methylphenidate) **AND**
     - Provigil (modafinil) or Nuvigil (armodafinil)
   - Prescribed by or in consultation with one of the following specialists: neurologist, psychiatrist, or specialist in sleep medicine

   If yes, **approve for 12 months by HICL for #18mL per day.**
   **APPROVAL TEXT:** Please note that this drug has an important FDA safety warning.
   For more information, please ask your doctor or pharmacist.
   If no, do not approve.  (**NOTE:** Please review the request for a proactive prior authorization of modafinil and armodafinil. Please enter proactive PA if criteria is met and modify denial text as needed.)
   **DENIAL TEXT:** See the denial text at the end of the guideline.

   CONTINUED ON NEXT PAGE
GUIDELINES FOR USE

DENIAL TEXT: Our guideline for SODIUM OXYBATE requires a diagnosis of cataplexy in narcolepsy or excessive daytime sleepiness in narcolepsy. Additional guideline requirements apply.

For the diagnosis of cataplexy in narcolepsy, the following criteria must be met:

- Patient age 18 years and above
- Prescribed by or in consultation with one of the following specialists: neurologist, psychiatrist, or specialist in sleep medicine

For the diagnosis of excessive daytime sleepiness in narcolepsy, the following criteria must be met:

- Patient age 18 years and above
- Patient has tried 2 of the following preferred agents (unless contraindicated to stimulants):
  - a generic stimulant (e.g., amphetamine, dextroamphetamine, or methylphenidate)
  - AND
  - Provigil (modafinil) or Nuvigil (armodafinil) (Note: Prior authorization is required for Provigil and Nuvigil)
- Prescribed by or in consultation with one of the following specialists: neurologist, psychiatrist, or specialist in sleep medicine

This medication will not be approved for patients currently being treated with sedative hypnotic agents (e.g., Lunesta (eszopiclone), Ambien (zolpidem), Sonata (zaleplon), estazolam, Restoril (temazepam), Halcion (triazolam), flurazepam, quazepam, Belsomra).

RATIONALE
Based on recommended maximum dose of 9g daily and FDA indications.

DOSAGE
Initiate dose at 4.5 grams (g) per night administered orally in two equal, divided doses: 2.25 g at bedtime and 2.25 g taken 2.5 to 4 hours later. Titrate to effect in increments of 1.5 g per night at weekly intervals (0.75 g at bedtime and 0.75 g taken 2.5 to 4 hours later). Recommended dose range: 6 g to 9 g per night orally (2.1).

FDA APPROVED INDICATION
Xyrem is a central nervous system depressant indicated for the treatment of:

- Cataplexy in narcolepsy.
- Excessive daytime sleepiness (EDS) in narcolepsy.

Xyrem may only be dispensed to patients enrolled in the Xyrem Success Program.

CONTINUED ON NEXT PAGE
SODIUM OXYBATE

REFERENCES


<table>
<thead>
<tr>
<th>Library</th>
<th>Commercial</th>
<th>NSA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

Created: 11/13
Effective: 01/01/16
Client Approval: 11/15