SODIUM OXYBATE

Generic	Brand	HICL	GCN	Exception/Other
SODIUM OXYBATE	XYREM	12346		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the patient currently on a sedative hypnotic agent (examples include but are not limited to: Lunesta (eszopiclone), Ambien (zolpidem), Sonata (zaleplon), estazolam, Restoril (temazepam), Halcion (triazolam), flurazepam, quazepam, or Belsomra (suvorexant))?

   If yes, do not approve.
   DENIAL TEXT: See the initial 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 meet **ALL** of the following criteria?
   - The patient is 7 years of age or older
   - Therapy is prescribed by or given in consultation with one of the following specialists: neurologist, psychiatrist, or specialist in sleep medicine
   - The patient has tried **TWO** of the following: venlafaxine, TCA (e.g., amitriptyline, clomipramine), duloxetine

   If yes, **approve for 6 months by HICL with a quantity limit of #18mL per day.**
   APPROVAL TEXT: Renewal requires physician attestation of sustained improvement of cataplexy symptoms compared to baseline.

   If no, continue to #3.

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SODIUM OXYBATE

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of excessive daytime sleepiness (EDS) in narcolepsy and meets **ALL** of the following criteria?
   - The patient is 7 years of age or older
   - Therapy is prescribed by or given in consultation with one of the following specialists: neurologist, psychiatrist, or specialist in sleep medicine
   - The patient has an Epworth Sleepiness Scale (ESS) score of more than 10, persisting for 3 or more months, at baseline
   - Narcolepsy diagnosis as confirmed by **ONE** of the following:
     - The patient has a Multiple Sleep Latency Test (MSLT) showing a mean sleep latency of 8 minutes or less and **ONE** of the following:
       - 2 or more early-onset REM sleep periods (SOREMPs) during a single MSLT session, **OR**
       - 1 or more early-onset REM sleep periods (SOREMPS) during a single MSLT session **AND** 1 early-onset SOREMP (within approx. 15 minutes or less) on a polysomnography the night preceding the MSLT **AND** polysomnography has ruled out non-narcolepsy causes of EDS
         [**Note to pharmacist:** Multiple Sleep Latency Test (MSLT) is a guideline-supported instrument for assessing the severity and likelihood of narcolepsy, which consists of five 20-minute nap periods spread throughout *a single test* day at 2-hour intervals]
     - The patient has low Orexin/Hypocretin levels on CSF assay
   - The patient had a trial of or contraindication to **ONE** amphetamine derivative (e.g., amphetamine sulfate, methylphenidate, etc.) **AND** modafinil, armodafinil, solriamfetol, or pitolisant

     If yes, **approve for 6 months by HICL with a quantity limit of #18mL per day.**
     APPROVAL TEXT: Renewal requires physician attestation of sustained improvement in Epworth Sleepiness Scale (ESS) scores by at least 25% compared to baseline.

     If no, do not approve.
     DENIAL TEXT: See the initial denial text at the end of the guideline.

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SODIUM OXYBATE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **SODIUM OXYBATE (Xyrem)** requires a diagnosis of cataplexy in narcolepsy or excessive daytime sleepiness in narcolepsy. In addition, the following must be met:

For the diagnosis of cataplexy in narcolepsy, approval requires:

- The patient is 7 years of age or older
- Therapy is prescribed by or given in consultation with one of the following specialists: neurologist, psychiatrist, or specialist in sleep medicine
- The patient has tried **TWO** of the following: venlafaxine, TCA (e.g., amitriptyline, clomipramine), duloxetine

For the diagnosis of excessive daytime sleepiness in narcolepsy, approval requires:

- The patient is 7 years of age or older
- Therapy is prescribed by or given in consultation with one of the following specialists: neurologist, psychiatrist, or specialist in sleep medicine
- The patient has an Epworth Sleepiness Scale (ESS) score of more than 10, persisting for 3 or more months, at baseline
- Narcolepsy diagnosis as confirmed by **ONE** of the following:
  - The patient has a Multiple Sleep Latency Test (MSLT) showing a mean sleep latency of 8 minutes or less and **ONE** of the following:
    - 2 or more early-onset REM sleep periods (SOREMPs) during a single MSLT session, **OR**
    - 1 or more early-onset REM sleep periods (SOREMPS) during a single MSLT session **AND** 1 early-onset SOREMP (within approx. 15 minutes or less) on a polysomnography the night preceding the MSLT **AND** polysomnography has ruled out non-narcolepsy causes of EDS
  - The patient has low Orexin/Hypocretin levels on CSF assay
- The patient had a trial of or contraindication to **ONE** amphetamine derivative (e.g., amphetamine sulfate, methylphenidate, etc.) **AND** modafinil, armodafinil, solriamfetol, or pitolisant

This medication will not be approved for patients currently being treated with sedative hypnotic agents (examples include but are not limited to: Lunesta (eszopiclone), Ambien (zolpidem), Sonata (zaleplon), estazolam, Restoril (temazepam), Halcion (triazolam), flurazepam, quazepam, or Belsomra (suvorexant)).

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SODIUM OXYBATE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of narcolepsy and meet **ONE** of the following criteria?
   - Physician attestation of sustained improvement of cataplexy symptoms compared to baseline
   - Physician attestation of sustained improvement in Epworth Sleepiness Scale (ESS) scores by at least 25% compared to baseline

   If yes, **approve for 12 months by HICL with a quantity limit of #18mL per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: The guideline named **SODIUM OXYBATE (Xyrem)** requires a diagnosis of narcolepsy. In addition, **ONE** of the following must be met:
   - Physician attestation of maintained improvement in cataplexy symptoms compared to baseline
   - Physician attestation of sustained improvement in Epworth Sleepiness Scale (ESS) scores by at least 25% compared to baseline

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Xyrem.

REFERENCES

- Xyrem [Prescribing Information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; October 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/21/19
Created: 11/13
Client Approval: 10/19
P&T Approval: 07/19