STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SODIUM OXYBATE-XYREM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SODIUM OXYBATE	XYREM, SODIUM OXYBATE	12346		GPI-10 (6245006020)	FORM = SOLUTION

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of idiopathic hypersomnia (IH) and the diagnosis is confirmed by **ALL** of the following criteria?
   - The patient does NOT have cataplexy
   - The patient has a Multiple Sleep Latency Test (MSLT) showing less than two sleep-onset REM sleep periods (SOREMP) OR no SOREMPs if REM sleep latency on polysomnogram is 15 minutes or less
   - The patient has one or more MSLT mean sleep latency of 8 minutes or less, OR total 24-hour sleep is 660 minutes or more on 24-hour polysomnography or by wrist actigraphy in association with a sleep log
   - The patient has had insufficient sleep syndrome ruled out, AND there is no better explanation by another sleep/medical/psychiatric disorder or use of drugs/medications, AND the patient has experienced daily periods of an irrepressible need to sleep or daytime lapses into sleep for at least 3 months

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
   - Xyrem (sodium oxybate) will NOT be used concurrently with a sedative hypnotic agent (e.g., Lunesta [eszopiclone], Ambien [zolpidem], Restoril [temazepam])
   - The patient had a trial and failure of or contraindication to armodafinil (Nuvigil) OR modafinil (Provigil)

   If yes, continue to #8.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INITIAL CRITERIA (CONTINUED)

3. 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 in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
   - Xyrem (sodium oxybate) will NOT be used concurrently with a sedative hypnotic agent (e.g., Lunesta [eszopiclone], Ambien [zolpidem], Restoril [temazepam])
   - The patient has tried TWO of the following: venlafaxine (Effexor), fluoxetine (Prozac), a TCA (tricyclic antidepressant, e.g., amitriptyline [Elavil], clomipramine [Anafranil], imipramine [Tofranil])

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #18mL per day.**
   If no, continue to #4.

4. Does the patient have a diagnosis of excessive daytime sleepiness (EDS) in narcolepsy and the narcolepsy diagnosis is confirmed by **ONE** of the following criteria?
   - The patient has a Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less AND two or more early-onset REM sleep periods (SOREMPs)
   - The patient has a Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less AND one or more early-onset REM sleep periods (SOREMPS) AND additionally one early-onset SOREMP (within approx. 15 minutes or less) on a polysomnography the night preceding the MSLT, with the polysomnography ruling 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

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INITIAL CRITERIA (CONTINUED)

5. Does the patient meet **ALL** of the following criteria?
   - The patient is 7 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
   - The patient has EDS persisting for 3 or more months
   - The patient has an Epworth Sleepiness Scale (ESS) score of more than 10
   - Xyrem (sodium oxybate) will NOT be used concurrently with a sedative hypnotic agent (e.g., Lunesta [eszopiclone], Ambien [zolpidem], Restoril [temazepam])

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

6. Is the patient 7 to 17 years of age **AND** meet the following criterion?
   - The patient had a trial and failure of or contraindication to one generic stimulant indicated for excessive daytime sleepiness (EDS) in narcolepsy (e.g., amphetamine sulfate [Evekeo], dextroamphetamine [Dexedrine], methylphenidate [Ritalin])

   If yes, continue to #8.
   If no, continue to #7.

7. Is the patient 18 years of age or older **AND** meet the following criterion?
   - The patient had a trial and failure of or contraindication to one agent from EACH of the following categories:
     - Generic typical stimulant (e.g., amphetamine sulfate [Evekeo], dextroamphetamine [Dexedrine], methylphenidate [Ritalin])
     - Armodafinil (Nuvigil) OR modafinil (Provigil)

   If yes, continue to #8.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

8. Is the request for generic sodium oxybate?

   If yes, **approve for 6 months for generic only by GPID or GPI-14 with a quantity limit of #18mL per day.**

   If no, continue to #9.

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INITIAL CRITERIA (CONTINUED)

9. Is the request for brand Xyrem **AND** the patient meets the following criterion?
   - The patient had a trial and failure of or contraindication to generic sodium oxybate

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #18mL per day.**
   If no, do not approve. **(NOTE: Please enter a proactive PA for 6 months for generic sodium oxybate by GPID or GPI-14 with a quantity limit of #18mL per day.)**

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SODIUM OXYBATE (Xyrem)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Idiopathic hypersomnia (IH: a type of sleep disorder)
      2. Cataplexy in narcolepsy (sudden and uncontrollable muscle weakness or paralysis associated with a sleep disorder)
      3. Excessive daytime sleepiness (EDS) in narcolepsy (sleep disorder)
   B. Xyrem (sodium oxybate) will NOT be used concurrently (at the same time) with a sedative hypnotic agent (drugs that make you sleepy), such as Lunesta (eszopiclone), Ambien (zolpidem), or Restoril (temazepam)
   C. **If you have idiopathic hypersomnia, approval also requires:**
      1. You are 18 years of age or older
      2. Therapy is prescribed by or in consultation with a neurologist (nerve doctor), psychiatrist (mental health doctor), or specialist in sleep medicine
      3. Your diagnosis is confirmed by ALL of the following:
         a. You do NOT have cataplexy (sudden and uncontrollable muscle weakness or paralysis associated with a sleep disorder)
         b. You have a Multiple Sleep Latency Test (MSLT) showing less than two sleep-onset REM (rapid eye movement) sleep periods (SOREMP) OR no SOREMPs if REM sleep latency on polysomnogram (type of sleep test) is 15 minutes or less
         c. You have one or more MSLT mean sleep latency of 8 minutes or less, OR total 24-hour sleep is 660 minutes or more on 24-hour polysomnography or by wrist actigraphy (device that monitors movement) in association with a sleep log
         d. You have had insufficient sleep syndrome ruled out, AND there is no better explanation by another sleep/medical/psychiatric disorder or use of drugs/medications, AND you have experienced daily periods of an irrepressible need to sleep or daytime lapses into sleep for at least 3 months

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INITIAL CRITERIA (CONTINUED)

4. You have tried and failed or have a contraindication (harmful for) to armodafinil (Nuvigil) OR modafinil (Provigil)
5. If you are requesting brand Xyrem, you have tried and failed or have a contraindication (harmful for) to generic sodium oxybate

D. **If you have cataplexy in narcolepsy, approval also requires:**
1. You are 7 years of age or older
2. Therapy is prescribed by or in consultation with a neurologist (nerve doctor), psychiatrist (mental health doctor), or specialist in sleep medicine
3. You have tried TWO of the following: venlafaxine (Effexor), fluoxetine (Prozac), a tricyclic anti-depressant (such as amitriptyline [Elavil], clomipramine [Anafranil], imipramine [Tofranil])

E. **If you have excessive daytime sleepiness in narcolepsy, approval also requires:**
1. You are 7 years of age or older
2. Therapy is prescribed by or in consultation with a neurologist (nerve doctor), psychiatrist (mental health doctor), or specialist in sleep medicine
3. You have EDS persisting for 3 or more months
4. You have an Epworth Sleepiness Scale (tool to measure sleepiness) score of more than 10
5. Your diagnosis of narcolepsy is confirmed by ONE of the following:
   a. A Multiple Sleep Latency Test (MSLT) showing both an average sleep latency of 8 minutes or less AND two or more early-onset rapid eye movement (REM) sleep test periods
   b. A Multiple Sleep Latency Test showing an average sleep latency of 8 minutes or less AND one early-onset rapid eye movement (REM) sleep test period (SOREMP) AND additionally one SOREMP (within approximately 15 minutes) on a polysomnography (type of sleep test) the night preceding the MSLT, with the polysomnography ruling out non-narcolepsy causes of excessive daytime sleepiness
   c. You have low orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay (test showing low levels of a chemical that help with staying awake)
6. If you are 7 to 17 years old, you have tried and failed or have a contraindication (harmful for) to one generic stimulant indicated for EDS in narcolepsy (such as amphetamine [Evekeo], dextroamphetamine [Dexedrine], or methylphenidate [Ritalin])
7. If you are 18 years or older, you have tried and failed or have a contraindication (harmful for) to one agent from EACH of the following categories:
   a. Generic typical stimulant (such as amphetamine sulfate [Evekeo], dextroamphetamine [Dexedrine], methylphenidate [Ritalin])
   b. Armodafinil (Nuvigil) OR modafinil (Provigil)
   c. If you are requesting brand Xyrem, you have tried and failed or have a contraindication (harmful for) to generic sodium oxybate

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SODIUM OXYBATE-XYREM

INITIAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of narcolepsy **AND** meet the following criterion?
   - Xyrem (sodium oxybate) will NOT be used concurrently with a sedative hypnotic agent (e.g., Lunesta [eszopiclone], Ambien [zolpidem], Restoril [temazepam])

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has demonstrated improvement of cataplexy symptoms compared to baseline
   - The patient has maintained an improvement in Epworth Sleepiness Scale (ESS) scores by at least 25% compared to baseline
   - The patient has demonstrated improvement in sleep latency from baseline

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #18mL per day.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

3. Does the patient have a diagnosis of idiopathic hypersomnia (IH) **AND** meet the following criterion?
   - Xyrem (sodium oxybate) will NOT be used concurrently with a sedative hypnotic agent (e.g., Lunesta [eszopiclone], Ambien [zolpidem], Restoril [temazepam])

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Does the patient meet **ONE** of the following criteria?
   - The patient has demonstrated improvement of idiopathic hypersomnia symptoms compared to baseline
   - The patient has maintained an improvement in Epworth Sleepiness Scale (ESS) scores by at least 25% compared to baseline

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #18mL per day.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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SODIUM OXYBATE-XYREM

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SODIUM OXYBATE (Xyrem)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Narcolepsy (uncontrollable daytime sleepiness)
   2. Idiopathic hypersomnia (IH: a type of sleep disorder)

B. Xyrem (sodium oxybate) will NOT be used concurrently (at the same time) with a sedative hypnotic agent (drugs that make you sleepy), such as Lunesta [eszopiclone], Ambien [zolpidem], or Restoril [temazepam]

C. **If you have narcolepsy, renewal also requires ONE of the following:**
   1. You have demonstrated improvement in cataplexy symptoms (sudden and uncontrollable muscle weakness) compared to baseline
   2. You have maintained improvement in Epworth Sleepiness Scale (tool to measure sleepiness) scores by at least 25% compared to baseline
   3. You have demonstrated improvement in sleep latency (the amount of time it takes to fall asleep)

D. **If you have idiopathic hypersomnia, renewal also requires ONE of the following:**
   1. You have demonstrated improvement of idiopathic hypersomnia symptoms compared to baseline
   2. You have maintained an improvement in Epworth Sleepiness Scale (tool to measure sleepiness) scores by at least 25% compared to baseline

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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.; April 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 06/12/23
Created: 11/13
Client Approval: 05/23
P&T Approval: 10/22