STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SODIUM OXYBATE-LUMRYZ

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

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the patient concurrently on a sedative hypnotic agent (e.g., Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, 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 in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
   - The patient had a trial of TWO of the following: venlafaxine (Effexor), fluoxetine (Prozac), TCA (tricyclic antidepressant, e.g., amitriptyline [Elavil], clomipramine [Anafranil], imipramine [Tofranil])
   - The patient had a trial of generic sodium oxybate

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #1 per day.**
   If no, continue to #3.

3. 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 #4.
   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)

4. 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 excessive daytime sleepiness (EDS) persisting for 3 or more months
   - The patient has an Epworth Sleepiness Scale (ESS) score of more than 10
   - The patient had a trial, failure, or contraindication to generic sodium oxybate

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

5. Is the patient 7 to 17 years of age **AND** meets the following criterion?
   - The patient had a trial, failure, or contraindication to a generic typical stimulant (e.g., amphetamine [Evekeo], dextroamphetamine [Dexedrine], methylphenidate [Ritalin])

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #1 per day.**
   If no, continue to #6.

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

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SODIUM OXYBATE-LUMRYZ

INITIAL CRITERIA (CONTINUED)

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 (LUMRYZ)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Cataplexy in narcolepsy (sudden and uncontrollable muscle weakness or paralysis associated with a sleep disorder)
   2. Excessive daytime sleepiness (EDS) in narcolepsy (sleep disorder)

B. You are NOT concurrently (at the same time) on a sedative hypnotic agent (drugs that make you sleepy), such as Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant]

C. **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 had a trial of generic sodium oxybate
   4. You had a trial of TWO of the following: venlafaxine (Effexor), fluoxetine (Prozac), TCA (tricyclic antidepressant, such as amitriptyline [Elavil], clomipramine [Anafranil], imipramine [Tofranil])

D. **If you have excessive daytime sleepiness (EDS) 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. Your diagnosis of narcolepsy is confirmed by ONE of the following:
      a. A Multiple Sleep Latency Test (MLST) showing both an average sleep latency of 8 minutes or less AND 2 or more early-onset rapid eye movement (REM) sleep test periods
      b. A Multiple Sleep Latency Test (MSLT) 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 before 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 you have low levels of a chemical that helps with staying awake)

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SODIUM OXYBATE-LUMRYZ

INITIAL CRITERIA (CONTINUED)

4. You have excessive daytime sleepiness (EDS) persisting for 3 or more months
5. You have an Epworth Sleepiness Scale (ESS: questionnaire used to assess daytime sleepiness) score of more than 10
6. You had a trial, failure (drug did not work), or contraindication (harmful for) to generic sodium oxybate
7. If you are 7 to 17 years old, you had a trial, failure (drug did not work), or contraindication (harmful for) to a generic typical stimulant (such as amphetamine [Evekeo], dextroamphetamine [Dexedrine], methylphenidate [Ritalin])
8. If you are 18 years or older, you had a trial, failure (drug did not work), or contraindication (harmful for) to one agent from EACH of the following categories:
   a. Generic typical stimulant (such as amphetamine [Evekeo], dextroamphetamine [Dexedrine], or methylphenidate [Ritalin])
   b. Armodafinil (Nuvigil) or modafinil (Provigil)

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

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of narcolepsy and 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 #1 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-LUMRYZ

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 (LUMRYZ)** requires the following rule(s) be met for renewal:

A. You have narcolepsy (uncontrollable daytime sleepiness)
B. You are NOT concurrently (at the same time) on a sedative hypnotic agent (drugs that make you sleepy), such as Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant]
C. You meet 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 (ESS: questionnaire used to assess daytime sleepiness) scores by at least 25% compared to baseline
   3. You have demonstrated improvement in sleep latency (the amount of time it takes you to fall asleep)

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 Lumryz.

REFERENCES

- Lumryz [Prescribing Information]. Chesterfield, MO: Avadel CNS Pharmaceuticals, LLC; May 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/28/23
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