



STANDARD COMMERCIAL DRUG FORMULARY  
PRIOR AUTHORIZATION GUIDELINES

PITOLISANT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PITOLISANT HCL	WAKIX	45575		GPI-10 (6145007010)	

**GUIDELINES FOR USE**

**INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)**

1. Does the patient have a diagnosis of excessive daytime sleepiness (EDS) with narcolepsy and narcolepsy 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** 2 or more early-onset rapid eye movement (REM) sleep test periods (SOREMPs)
  - The patient has a Multiple Sleep Latency Test (MSLT) showing both a mean 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 the night preceding the MSLT, with the polysomnography ruling out non-narcolepsy causes of excessive daytime sleepiness (EDS)
  - The patient has low orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay

If yes, continue to #2.

If no, continue to #3.

2. Does the patient meet **ALL** of the following criteria?
  - The patient has excessive daytime sleepiness (EDS) persisting for at least 3 months and Epworth Sleepiness Scale (ESS) score of more than 10
  - Therapy is prescribed by or in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
  - The patient had a trial of or contraindication to one generic typical stimulant (e.g., amphetamine sulfate, methylphenidate, etc.) **AND** solriamfetol, armodafinil, or modafinil

If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 per day.**

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 with narcolepsy and meet **ALL** of the following criteria?
- Therapy is prescribed by or in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
  - The patient has tried **TWO** of the following: venlafaxine, fluoxetine or a TCA (e.g., clomipramine, imipramine)

If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 per day.**

If no, do not approve.

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

A. You have one of the following:

1. Excessive daytime sleepiness (EDS) with narcolepsy (sleep disorder with extreme drowsiness)
2. Narcolepsy as demonstrated by cataplexy (sleep disorder with extreme drowsiness with sudden and uncontrollable muscle weakness)

B. **If you have excessive daytime sleepiness with narcolepsy, approval also requires:**

1. You have narcolepsy that is confirmed by **ONE** of the following:
  - a. A Multiple Sleep Latency Test showing a 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 both 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 you have low levels of a chemical that helps with staying awake)
2. You have excessive daytime sleepiness (EDS) lasting for at least 3 months and Epworth Sleepiness Scale (type of sleepiness test) score of more than 10
3. Therapy is prescribed by or in consultation with a neurologist (nerve doctor), psychiatrist (mental health doctor), or specialist in sleep medicine
4. You had a trial of one generic typical stimulant (such as amphetamine sulfate, methylphenidate, etc.) **AND** solriamfetol, armodafinil, or modafinil, unless there is a medical reason why you cannot (contraindication)

***(Initial denial text continued on next page)***

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INITIAL CRITERIA (CONTINUED)

C. If you have cataplexy with narcolepsy, approval also requires:

1. Wakix is prescribed by or in consultation with a neurologist (nerve doctor), psychiatrist (mental health doctor), or specialist in sleep medicine
2. You have tried TWO of the following: venlafaxine, fluoxetine, or a TCA (tricyclic antidepressant such as clomipramine, imipramine)

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 excessive daytime sleepiness (EDS) with narcolepsy or cataplexy with narcolepsy and meet **ONE** of the following criteria?
  - The patient has demonstrated 25% or more improvement in Epworth Sleepiness Scale (ESS) scores compared to baseline
  - The patient has shown improvement in cataplexy symptoms compared to baseline
  - The patient has demonstrated improvement in sleep latency from baseline

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**

If no, do not approve.

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

A. You have ONE of the following:

1. Excessive daytime sleepiness (EDS) with narcolepsy (sleep disorder with extreme drowsiness)
2. Narcolepsy as demonstrated by cataplexy (sleep disorder with extreme drowsiness with sudden and uncontrollable muscle weakness)

B. You meet ONE of the following:

1. You have demonstrated 25% or more improvement in Epworth Sleepiness Scale (type of sleepiness test) scores compared to baseline
2. You have shown improvement in cataplexy (sudden and uncontrollable muscle weakness) symptoms compared to baseline
3. You have demonstrated improvement in sleep latency (the amount of time it takes to fall asleep) from baseline

***(Renewal denial text continued on next page)***

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RENEWAL 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.

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**RATIONALE**

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

**REFERENCES**

- Wakix [Prescribing Information]. Plymouth Meeting, PA: Harmony Biosciences, LLC; October 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 01/01/23

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