PITOLISANT

Generic	Brand	HICL	GCN	Exception/Other
PITOLISANT	WAKIX	45575		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of narcolepsy as demonstrated by cataplexy **AND** meet the following criterion?
   - Therapy is prescribed by or given in consultation with a neurologist, psychiatrist, or specialist in sleep medicine

   If yes, **approve for 6 months by HICL with a quantity limit of #2 per day.**
   APPROVAL TEXT: Renewal requires that the patient has demonstrated 25% or more improvement in Epworth Sleepiness Scale (ESS) scores compared to baseline, OR the patient has shown improvement in cataplexy compared to baseline.
   If no, continue to #2.

2. 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 #3.
   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 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 given 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 with a quantity limit of #2 per day.**
   APPROVAL TEXT: Renewal requires that the patient has demonstrated 25% or more improvement in Epworth Sleepiness Scale (ESS) scores compared to baseline, OR the patient has shown improvement in cataplexy compared to baseline.

   If no, do not approve.
   INITIAL DENIAL TEXT: The guideline named **PITOLISANT (Wakix)** requires a diagnosis of narcolepsy as demonstrated by cataplexy OR excessive daytime sleepiness (EDS) with narcolepsy. In addition, the following criteria must be met:
   For the diagnosis of narcolepsy as demonstrated by cataplexy, approval requires:
   - Therapy is prescribed by or given in consultation with a neurologist, psychiatrist, or specialist in sleep medicine

   For the diagnosis of excessive daytime sleepiness (EDS) with narcolepsy, approval requires:
   - The patient has narcolepsy that is confirmed by **ONE** of the following:
     - 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
   - 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 given 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

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PITOLISANT

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of 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, OR
   - The patient has shown improvement in cataplexy compared to baseline

   If yes, **approve for 12 months by HICL with a quantity limit of #2 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: The guideline named **PITOLISANT (Wakix)** requires a diagnosis of narcolepsy. In addition, **ONE** of the following must be met:
   - The patient has demonstrated 25% or more improvement in Epworth Sleepiness Scale (ESS) scores compared to baseline, OR
   - The patient has shown improvement in cataplexy compared to baseline

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; August 2019.

Library	Commercial	NSA
Yes	Yes	No

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