PITOLISANT

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.

CONTINUED ON NEXT PAGE
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:
     o 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)
     o 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)
     o 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

CONTINUED ON NEXT PAGE
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**

<table>
<thead>
<tr>
<th>Library</th>
<th>Commercial</th>
<th>NSA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

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