Clinical Pharmacy Program Guidelines for Wakix

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<th>Program</th>
<th>Prior Authorization</th>
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<tr>
<td>Medication</td>
<td>Wakix® (pitolisant)</td>
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<tr>
<td>Markets in Scope</td>
<td>Ohio</td>
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1. **Background:**

   Wakix is a histamine-3 (H3) receptor antagonist/inverse agonist indicated for the treatment of excessive daytime sleepiness (EDS) in adult patients with narcolepsy.

2. **Coverage Criteria:**
A. **Narcolepsy**

1. **Initial Authorization**

   a. **Wakix** will be approved based on **all** of the following criteria:

      (1) Submission of medical records (e.g. chart notes, lab values) documenting a diagnosis of narcolepsy with **both** of the following:

          (a) The patient has daily periods of irrepresible need to sleep or daytime lapses into sleep occurring for at least three months.

          (b) A mean sleep latency of ≤ 8 minutes and two or more sleep onset REM periods (SOREMPs) are found on a MSLT performed according to standard techniques following a normal overnight polysomnogram. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace one of the SOREMPs on the MSLT.

          -AND-

      (2) Physician attestation to the following:

          (a) Other causes of sleepiness have been ruled out or treated (including but not limited to obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications or their withdrawal, sleep phase disorder, or other sleep disorders).

          -AND-

      (3) **One** of the following:

          i. History of failure, contraindication, or intolerance to **all** of the following:

             (a) an amphetamine-based stimulant (e.g., amphetamine, dextroamphetamine) OR a methylphenidate-based stimulant

             (b) armodafinil (Nuvigil)

             (c) Sunosi (solriamfetol)

             -OR-

          ii. History of or potential for a substance abuse disorder

          -AND-
(4) Prescribed by **one** of the following:

(a) Neurologist  
(b) Psychiatrist  
(c) Sleep Medicine Specialist  

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Wakix** will be approved for continuation of therapy based on the following criterion:

(1) Reduction in symptoms of excessive daytime sleepiness associated with Wakix therapy  

Authorization will be issued for 12 months.

3. **Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.  
- Supply limits may be in place.

4. **References:**

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<th>Date</th>
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<tbody>
<tr>
<td>10/2019</td>
<td>New program</td>
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<tr>
<td>1/2020</td>
<td>Added Sunosi as a required step therapy medication.</td>
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<tr>
<td>5/2020</td>
<td>Added requirement for submission of documentation of sleep study with specific sleep study requirements. Added requirement for prescriber specialty. Changed initial authorization duration to 12 months.</td>
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