UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Wakix

Program	Prior Authorization
Medication	Wakix® (pitolisant)
Markets in Scope	Arizona, California, Hawaii, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	10/2019
Pharmacy and Therapeutics Approval Date	5/2020
Effective Date	7/2020

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 irrepressible 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:

1. Wakix [package insert]. Harmony Biosciences, LLC. Plymouth Meeting, PA; November 2019.
2. American Academy of Sleep Medicine. International Classification of Sleep Disorders: Diagnostic and Coding Manual. 3rd ed. Darien, IL: American Academy of Sleep Medicine; 2014.
3. Sunsoi [package insert]. Jazz Pharmaceuticals, Inc. Palo Alto, CA. June 2019.
4. Morgenthaler TI1, Kapur VK, Brown T, et al. Practice parameters for the treatment of narcolepsy and other hypersomnias of central origin. Sleep. 2007 Dec;30(12):1705-11.
5. Wise MS1, Arand DL, Auger RR, et al. Treatment of narcolepsy and other hypersomnias of central origin. Sleep. 2007 Dec;30(12):1712-27.

Change Control	
Date	Change
10/2019	New program
1/2020	Added Sunosi as a required step therapy medication.
5/2020	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.