PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	**NARCOLEPSY AGENTS**
BRAND NAME*	
(generic)	
	WAKIX
	(pitolisant)

Status: CVS Caremark Criteria
Type: Initial Prior Authorization with Quantity Limit ***Ref # 3176-C***

** Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.*

FDA-APPROVED INDICATIONS
Wakix is indicated for the treatment of excessive daytime sleepiness (EDS) in adult patients with narcolepsy.

COVERAGE CRITERIA
The requested drug will be covered with prior authorization when the following criteria are met:

- The patient has narcolepsy confirmed by sleep lab evaluation

AND

- The patient has experienced an inadequate treatment response to a central nervous system (CNS) stimulant (e.g., amphetamine, dextroamphetamine, methylphenidate)
  OR
- The patient has experienced an intolerance to a central nervous system (CNS) stimulant (e.g., amphetamine, dextroamphetamine, methylphenidate)
  OR
- The patient has a contraindication that would prohibit a trial of central nervous system (CNS) stimulants (e.g., amphetamine, dextroamphetamine, methylphenidate)

AND

- The patient has experienced an inadequate treatment response to armodafinil OR modafinil
  OR
- The patient has experienced an intolerance to armodafinil OR modafinil
  OR
- The patient has a contraindication that would prohibit a trial of ALL of the following: A) armodafinil, B) modafinil

Quantity Limits Apply.

RATIONALE
The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Wakix is indicated for the treatment of excessive daytime sleepiness (EDS) in adult patients with narcolepsy.

According to the American Academy of Sleep Medicine (AASM), successful treatment of hypersomnia of central origin requires an accurate diagnosis, individual tailoring of therapy to produce the fullest possible return of normal function, and regular follow-up to monitor response to treatment. The evaluation should include a thorough evaluation of other possible contributing causes of excessive daytime sleepiness. The International Classification of Sleep Disorders, Third Edition (ICSD-3) specifies necessary diagnostic tests and criteria for each disorder of central origin. For narcolepsy, a sleep lab evaluation consisting of an overnight polysomnography (PSG) and mean sleep latency tests (MSLT) is recommended to

confirm the diagnosis. Many other conditions produce such sleepiness and can mimic or coexist with a hypersomnia of central origin.[4]

According to AASM guidelines, modafinil is effective for the treatment of daytime sleepiness due to narcolepsy. One additional study of 196 subjects involved assessment of armodafinil (the longer half-life enantiomer of modafinil) for treatment of excessive sleepiness in patients with narcolepsy.[4] Subjects receiving armodafinil experienced significant improvement in sleepiness as measured by the Mean Wakefulness Test (MWT) mean sleep latency, and in the Clinical Global Impression of Change.[4] The guidelines also state that amphetamine, dextroamphetamine, and methylphenidate are effective for treatment of daytime sleepiness due to narcolepsy.[4] Therefore, patients who have an inadequate treatment response, intolerance, or contraindication to a CNS stimulant and either modafinil or armodafinil will be considered for approval.

The recommended dosage range of Wakix in patients with narcolepsy is 17.8 mg to 35.6 mg once daily. Dosage should be titrated, starting with 8.9 mg once daily and increasing to 17.8 mg after one week of therapy. After one week of therapy at 17.8 mg once daily, dosage may be increased to the maximum recommended dosage of 35.6 mg once daily. Patients with moderate hepatic impairment and renal impairment should initiate Wakix at 8.9 mg once daily and increase to a maximum recommended dose of 17.8 mg once daily. Wakix is available as 4.45 mg tablets and 17.8 mg tablets. Approvals will have a limit of 60 tablets per month to allow for the initial starting dose and then up to the maximum recommended daily dose of 35.6 mg.

REFERENCES

1. Wakix [package insert]. Plymouth Meeting, PA: Harmony Biosciences, LLC; August 2019.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. http://online.lexi.com/. Accessed August 2019.
3. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. http://www.micromedexsolutions.com/. Accessed August 2019.
4. Morgenthaler TI, Vishesh KK, Brown T, et al. Practice Parameters for the Treatment of Narcolepsy and other Hypersomnias of Central Origin. Sleep 2007;30(12):1705-11.
5. Epstein LJ, Kristo D, Strollo PJ et al. Clinical Guidelines for the Evaluation, Management and Long-term Care of Obstructive Sleep Apnea in Adults. J Clinical Sleep Medicine 2009:5(3):263-276.

Written by: UM Development (KC)
Date Written: 08/2019
Revised:
Reviewed: Medical Affairs (CHART) 09/05/2019
External Review: 10/2019

CRITERIA FOR APPROVAL

1	Does the patient have a diagnosis of narcolepsy confirmed by sleep lab evaluation?	Yes	No
2	Has the patient experienced an inadequate treatment response to a central nervous system (CNS) stimulant (e.g., amphetamine, dextroamphetamine, methylphenidate)? [If yes, then skip to question 5.]	Yes	No
3	Has the patient experienced an intolerance to a central nervous system (CNS) stimulant (e.g., amphetamine, dextroamphetamine, methylphenidate)? [If yes, then skip to question 5.]	Yes	No
4	Does the patient have a contraindication that would prohibit a trial of central nervous system (CNS) stimulants (e.g., amphetamine, dextroamphetamine, methylphenidate)?	Yes	No

5	Has the patient experienced an inadequate treatment response to armodafinil OR modafinil? [If yes, then skip to question 8.]	Yes	No
6	Has the patient experienced an intolerance to armodafinil OR modafinil? [If yes, then skip to question 8.]	Yes	No
7	Does the patient have a contraindication to that would prohibit a trial of ALL of the following: A) armodafinil, B) modafinil?	Yes	No
8	Does the patient require MORE than the plan allowance of 60 tablets per month? [RPh Note: If yes, then deny and enter a partial approval for 60 tablets/25 days or 180 tablets/75 days.]	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS – DO NOT USE FOR MEDICARE PART D**
1.	Go to 2	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have narcolepsy confirmed by sleep lab testing. Your request has been denied based on the information we have. [Short Description: No approvable diagnosis]
2.	Go to 5	Go to 3	
3.	Go to 5	Go to 4	
4.	Go to 5	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have tried a central nervous system (CNS) stimulant drug (e.g., amphetamine, dextroamphetamine, or methylphenidate) and it either did not work for you, or you cannot use it. Your request has been denied based on the information we have. [Short Description: No inadequate response, intolerance, or contraindication to a CNS stimulant drug]
5.	Go to 8	Go to 6	
6.	Go to 8	Go to 7	
7.	Go to 8	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have tried armodafinil or modafinil and it did not work for you, or you cannot use it. Your request has been denied based on the information we have. [Short Description: No inadequate response, intolerance, or contraindication to armodafinil or modafinil]
8.	Deny	Approve, 12 months, 60 tablets/25 days* or 180 tablets/75 days*	You have requested more than the maximum quantity allowed by your plan. Current plan approved criteria cover up to 60 tablets/month of the requested drug and strength. You have been approved for the maximum quantity that your plan covers for a duration of 12 months. Your request for additional quantities of the requested drug and strength has been denied. [Short Description: Over max quantity]

**The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.*