

Texas Prior Authorization Program Clinical Criteria

Drug/Drug Class

Wakix (Pitolisant)

This criteria was recommended for review by an MCO to ensure appropriate and safe utilization

Clinical Criteria Information Included in this Document

- **Drugs requiring prior authorization:** the list of drugs requiring prior authorization for this clinical criteria
- **Prior authorization criteria logic:** a description of how the prior authorization request will be evaluated against the clinical criteria rules
- **Logic diagram:** a visual depiction of the clinical criteria logic
- **Supporting tables:** a collection of information associated with the steps within the criteria (diagnosis codes, procedure codes, and therapy codes); provided when applicable
- **References:** clinical publications and sources relevant to this clinical criteria

Note: Click the hyperlink to navigate directly to that section.

Revision Notes

Initial publication, including recommendations from the DUR Board



Wakix (Pitolisant)

Drugs Requiring Prior Authorization

The listed GCNS may not be an indication of TX Medicaid Formulary coverage. To learn the current formulary coverage, visit TxVendorDrug.com/formulary/formulary-search.

Drugs Requiring Prior Authorization	
Label Name	GCN
WAKIX 17.8 MG TABLET	45949
WAKIX 4.45 MG TABLET	45948



Wakix (Pitolisant)

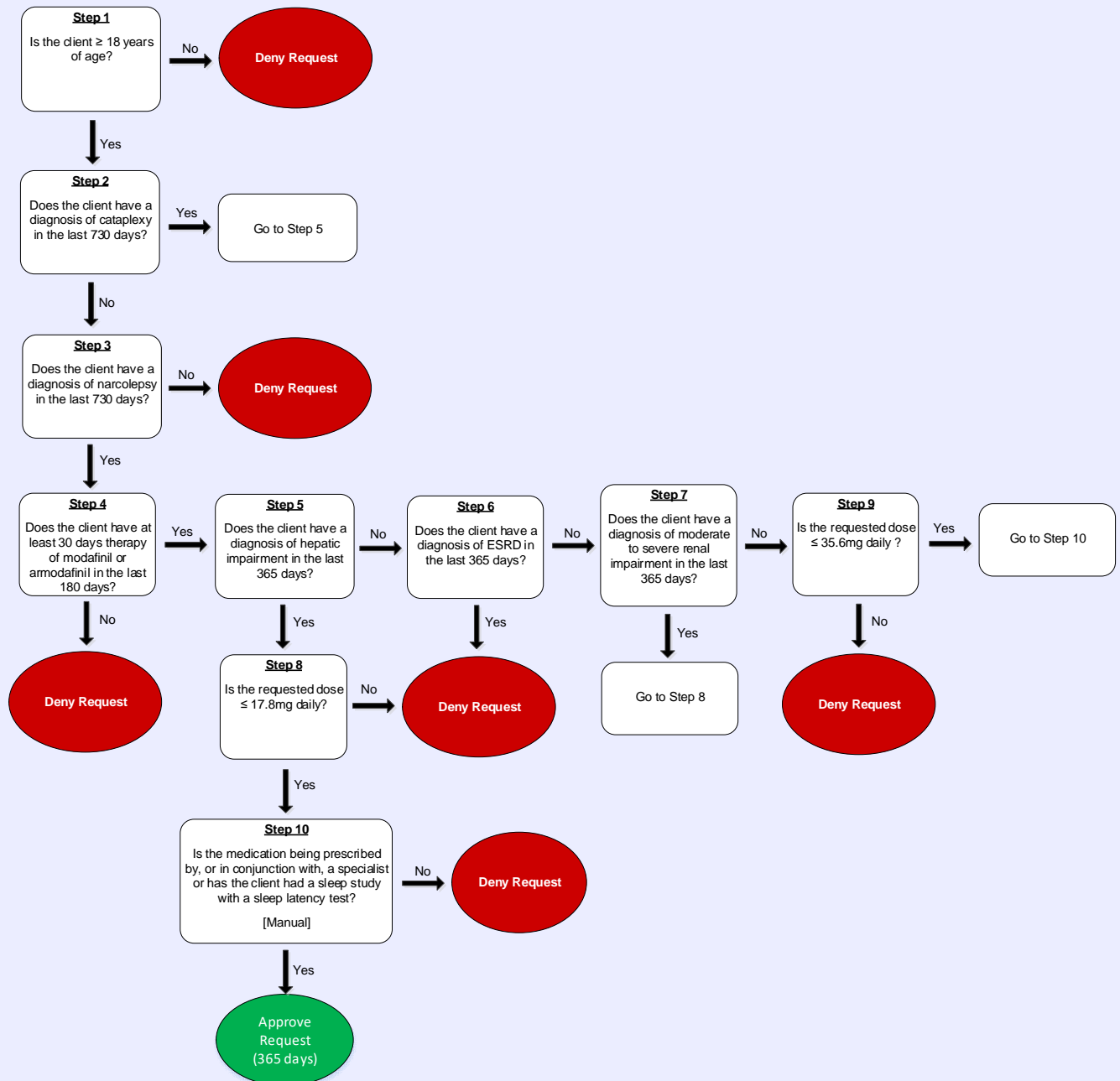
Clinical Criteria Logic

1. Is the client greater than or equal to (\geq) 18 years of age?
 Yes (Go to #2)
 No (Deny)
2. Does the client have a diagnosis of **cataplexy** in the last 730 days?
 Yes (Go to #5)
 No (Go to #3)
3. Does the client have a diagnosis of **narcolepsy** in the last 730 days?
 Yes (Go to #4)
 No (Deny)
4. Does the client have at least 30 days therapy of **modafinil or armodafinil** in the last 90 days?
 Yes (Go to #5)
 No (Deny)
5. Does the client have a diagnosis of **hepatic impairment** in the last 365 days?
 Yes (Go to #8)
 No (Go to #6)
6. Does the client have a diagnosis of **end stage renal disease (ESRD)** in the last 365 days?
 Yes (Deny)
 No (Go to #7)
7. Does the client have a diagnosis of **moderate to severe renal impairment** in the last 365 days?
 Yes (Go to #8)
 No (Go to #9)
8. Is the requested dose less than or equal to (\leq) 17.8 mg daily?
 Yes (Go to #10)
 No (Deny)
9. Is the requested dose less than or equal to (\leq) 35.6 mg daily?
 Yes (Go to #10)
 No (Deny)
10. Is the medication being requested by, or in consultation with, a specialist (psychiatrist, neurologist, sleep specialist) or has the client had a sleep study with a sleep latency test? [MANUAL]
 Yes (Approve - 365 days)
 No (Deny)



Wakix (Pitolisant)

Clinical Criteria Logic Diagram





Wakix (Pitolisant)

Clinical Criteria Supporting Tables

Step 2 (diagnosis of cataplexy) Required diagnosis: 1 Look back timeframe: 730 days	
ICD-10 Code	Description
G47411	NARCOLEPSY WITH CATAPLEXY
G47421	NARCOLEPSY IN CONDITIONS CLASSIFIED ELSEWHERE WITH CATAPLEXY

Step 3 (diagnosis of narcolepsy) Required diagnosis: 1 Look back timeframe: 730 days	
ICD-10 Code	Description
G47419	NARCOLEPSY WITHOUT CATAPLEXY
G47429	NARCOLEPSY IN CONDITIONS CLASSIFIED ELSEWHERE WITHOUT CATAPLEXY

Step 4 (claim for modafinil or armodafinil) Required claims: 1 Look back timeframe: 90 days	
GCN	Label Name
26101	PROVIGIL 100MG TABLET
26102	PROVIGIL 200MG TABLET
98591	ARMODAFINIL 50MG TABLET
98590	ARMODAFINIL 150MG TABLET
36082	ARMODAFINIL 200MG TABLET
98592	ARMODAFINIL 250MG TABLET
26101	MODAFINIL 100MG TABLET
26102	MODAFINIL 200MG TABLET
98591	NUVIGIL 50MG TABLET
98590	NUVIGIL 150MG TABLET
36082	NUVIGIL 200MG TABLET
98592	NUVIGIL 250MG TABLET

Step 4 (diagnosis of hepatic impairment)	
Required diagnosis: 1	
Look back timeframe: 365 days	
ICD-10 Code	Description
B160	ACUTE HEPATITIS B WITH DELTA-AGENT WITH HEPATIC COMA
B161	ACUTE HEPATITIS B WITH DELTA-AGENT WITHOUT HEPATIC COMA
B162	ACUTE HEPATITIS B WITHOUT DELTA-AGENT WITH HEPATIC COMA
B169	ACUTE HEPATITIS B WITHOUT DELTA-AGENT AND WITHOUT HEPATIC COMA
B170	ACUTE DELTA-(SUPER) INFECTION OF HEPATITIS B CARRIER
B1710	ACUTE HEPATITIS C WITHOUT HEPATIC COMA
B1711	ACUTE HEPATITIS C WITH HEPATIC COMA
B172	ACUTE HEPATITIS E
B178	OTHER SPECIFIED ACUTE VIRAL HEPATITIS
B179	ACUTE VIRAL HEPATITIS, UNSPECIFIED
B180	CHRONIC VIRAL HEPATITIS B WITH DELTA-AGENT
B181	CHRONIC VIRAL HEPATITIS B WITHOUT DELTA-AGENT
B182	CHRONIC VIRAL HEPATITIS C
B188	OTHER CHRONIC VIRAL HEPATITIS
B189	CHRONIC VIRAL HEPATITIS, UNSPECIFIED
B190	UNSPECIFIED VIRAL HEPATITIS WITH HEPATIC COMA
B1910	UNSPECIFIED VIRAL HEPATITIS B WITHOUT HEPATIC COMA
B1911	UNSPECIFIED VIRAL HEPATITIS B WITH HEPATIC COMA
B1920	UNSPECIFIED VIRAL HEPATITIS C WITHOUT HEPATIC COMA
B1921	UNSPECIFIED VIRAL HEPATITIS C WITH HEPATIC COMA
B199	UNSPECIFIED VIRAL HEPATITIS WITHOUT HEPATIC COMA
K700	ALCOHOLIC FATTY LIVER
K7010	ALCOHOLIC HEPATITIS WITHOUT ASCITES
K7011	ALCOHOLIC HEPATITIS WITH ASCITES
K702	ALCOHOLIC FIBROSIS AND SCLEROSIS OF LIVER
K7030	ALCOHOLIC CIRRHOSIS OF LIVER WITHOUT ASCITES
K7031	ALCOHOLIC CIRRHOSIS OF LIVER WITH ASCITES
K7040	ALCOHOLIC HEPATIC FAILURE WITHOUT COMA
K7041	ALCOHOLIC HEPATIC FAILURE WITH COMA
K709	ALCOHOLIC LIVER DISEASE, UNSPECIFIED
K710	TOXIC LIVER DISEASE WITH CHOLESTASIS
K7110	TOXIC LIVER DISEASE WITH HEPATIC NECROSIS WITHOUT COMA
K7111	TOXIC LIVER DISEASE WITH HEPATIC NECROSIS WITH COMA
K712	TOXIC LIVER DISEASE WITH ACUTE HEPATITIS
K713	TOXIC LIVER DISEASE WITH CHRONIC PERSISTENT HEPATITIS

Step 4 (diagnosis of hepatic impairment)	
Required diagnosis: 1	
Look back timeframe: 365 days	
K714	TOXIC LIVER DISEASE WITH CHRONIC LOBULAR HEPATITIS
K7150	TOXIC LIVER DISEASE WITH CHRONIC ACTIVE HEPATITIS WITHOUT ASCITES
K7151	TOXIC LIVER DISEASE WITH CHRONIC ACTIVE HEPATITIS WITH ASCITES
K716	TOXIC LIVER DISEASE WITH HEPATITIS, NOT ELSEWHERE CLASSIFIED
K717	TOXIC LIVER DISEASE WITH FIBROSIS AND CIRRHOSIS OF LIVER
K718	TOXIC LIVER DISEASE WITH OTHER DISORDERS OF LIVER
K719	TOXIC LIVER DISEASE, UNSPECIFIED
K7200	ACUTE AND SUBACUTE HEPATIC FAILURE WITHOUT COMA
K7201	ACUTE AND SUBACUTE HEPATIC FAILURE WITH COMA
K7210	CHRONIC HEPATIC FAILURE WITHOUT COMA
K7211	CHRONIC HEPATIC FAILURE WITH COMA
K7290	HEPATIC FAILURE, UNSPECIFIED WITHOUT COMA
K7291	HEPATIC FAILURE, UNSPECIFIED WITH COMA
K730	CHRONIC PERSISTENT HEPATITIS, NOT ELSEWHERE CLASSIFIED
K731	CHRONIC LOBULAR HEPATITIS, NOT ELSEWHERE CLASSIFIED
K732	CHRONIC ACTIVE HEPATITIS, NOT ELSEWHERE CLASSIFIED
K738	OTHER CHRONIC HEPATITIS, NOT ELSEWHERE CLASSIFIED
K739	CHRONIC HEPATITIS, UNSPECIFIED
K740	HEPATIC FIBROSIS
K741	HEPATIC SCLEROSIS
K742	HEPATIC FIBROSIS WITH HEPATIC SCLEROSIS
K743	PRIMARY BILIARY CIRRHOSIS
K744	SECONDARY BILIARY CIRRHOSIS
K745	BILIARY CIRRHOSIS, UNSPECIFIED
K7460	UNSPECIFIED CIRRHOSIS OF LIVER
K7469	OTHER CIRRHOSIS OF LIVER
K750	ABSCESS OF LIVER
K751	PHLEBITIS OF PORTAL VEIN
K752	NONSPECIFIC REACTIVE HEPATITIS
K753	GRANULOMATOUS HEPATITIS, NOT ELSEWHERE CLASSIFIED
K754	AUTOIMMUNE HEPATITIS
K7581	NONALCOHOLIC STEATOHEPATITIS (NASH)
K7589	OTHER SPECIFIED INFLAMMATORY LIVER DISEASES
K759	INFLAMMATORY LIVER DISEASE, UNSPECIFIED
K761	CHRONIC PASSIVE CONGESTION OF LIVER

Step 4 (diagnosis of hepatic impairment)	
Required diagnosis: 1	
Look back timeframe: 365 days	
K763	INFARCTION OF LIVER
K7689	OTHER SPECIFIED DISEASES OF LIVER
K769	LIVER DISEASE, UNSPECIFIED
K77	LIVER DISORDERS IN DISEASES CLASSIFIED ELSEWHERE

Step 6 (diagnosis of ESRD)	
Required diagnosis: 1	
Look back timeframe: 365 days	
ICD-10 Code	Description
N186	END STAGE RENAL DISEASE

Step 7 (diagnosis of moderate to severe renal impairment)	
Required diagnosis: 1	
Look back timeframe: 365 days	
ICD-10 Code	Description
N183	CHRONIC KIDNEY DISEASE, STAGE 3 (MODERATE)
N184	CHRONIC KIDNEY DISEASE, STAGE 4 (SEVERE)
N185	CHRONIC KIDNEY DISEASE, STAGE 5



Wakix (Pitolisant)

Clinical Criteria References

1. Clinical Pharmacology [online database]. Tampa, FL: Elsevier/Gold Standard, Inc.; 2020. Available at www.clinicalpharmacology.com. Accessed on October 23, 2020.
2. Micromedex [online database]. Available at www.micromedexsolutions.com. Accessed on October 23, 2020.
3. Wakix Prescribing Information. Plymouth Meeting, PA. Harmony Biosciences, LLC. November 2019.

Publication History

The Publication History records the publication iterations and revisions to this document. Notes for the *most current revision* are also provided in the **Revision Notes** on the first page of this document.

Publication Date	Notes
10/23/2020	Initial publication and presentation to DUR Board
10/28/2020	Added recommendations from the DUR Board