

## Texas Prior Authorization Program Clinical Criteria

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### Drug/Drug Class

## Provigil and Nuvigil

### Clinical Criteria Information Included in this Document

#### Provigil (Modafinil)

- **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.

#### Nuvigil (Armodafinil)

- **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

Updated to include formulary statement (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](http://TxVendorDrug.com/formulary/formulary-search).) on each 'Drug Requiring PA' table



## Provigil

### 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](http://TxVendorDrug.com/formulary/formulary-search).

Drugs Requiring Prior Authorization	
Label Name	GCN
MODAFINIL 100 MG TABLET	26101
MODAFINIL 200 MG TABLET	26102
PROVIGIL 100 MG TABLET	26101
PROVIGIL 200 MG TABLET	26102

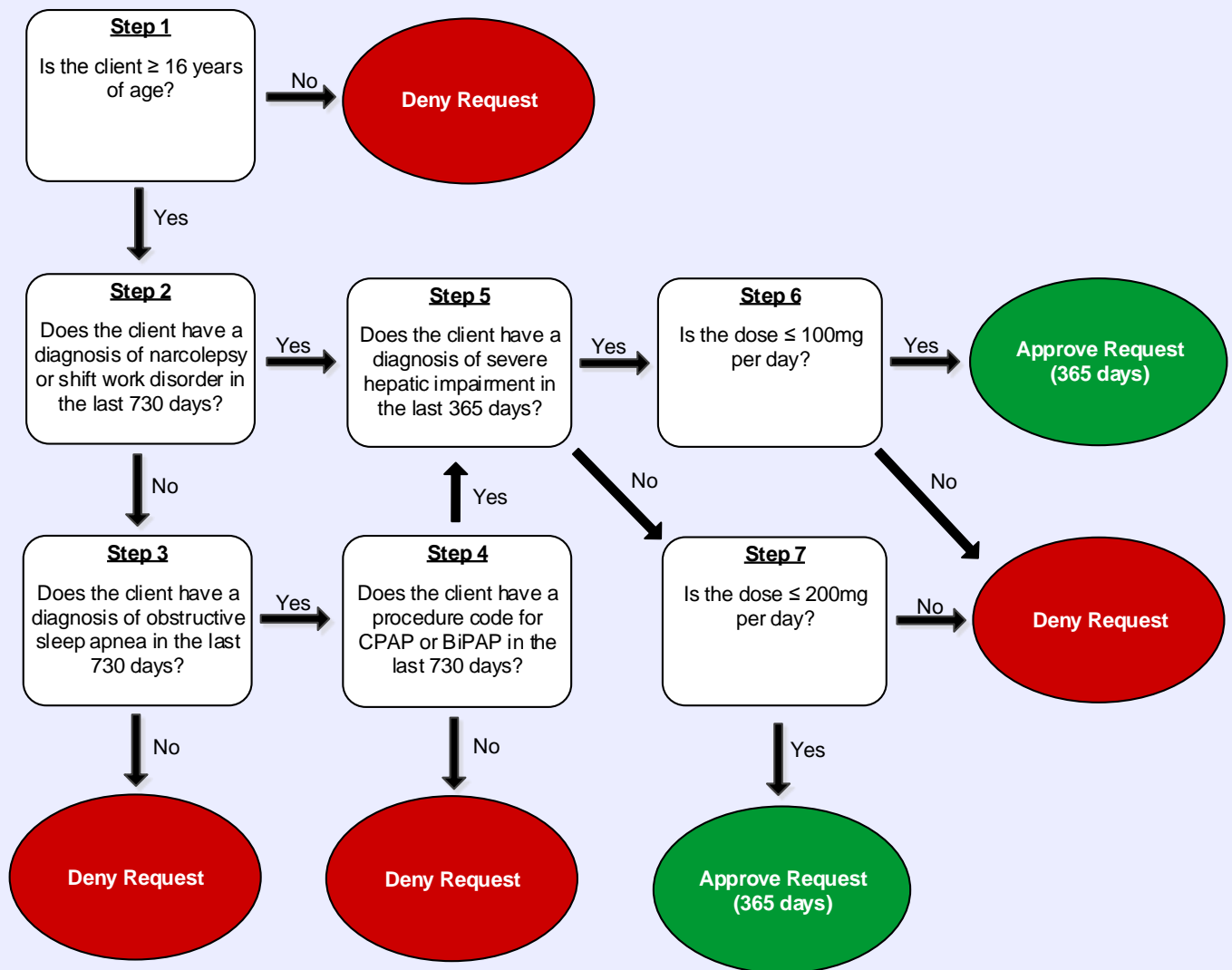
**Provigil****Clinical Criteria Logic**

1. Is the client greater than or equal to ( $\geq$ ) 16 years of age?  
 Yes (Go to #2)  
 No (Deny)
2. Does the client have a diagnosis of narcolepsy or shift work disorder in the last 730 days?  
 Yes (Go to #5)  
 No (Go to #3)
3. Does the client have a diagnosis of obstructive sleep apnea in the last 730 days?  
 Yes (Go to #4)  
 No (Deny)
4. Does the client have a procedure code for CPAP or BiPAP in the last 730 days?  
 Yes (Go to #5)  
 No (Deny)
5. Does the client have a diagnosis of severe hepatic impairment in the past 365 days?  
 Yes (Go to #6)  
 No (Go to #7)
6. Is the dose less than or equal to ( $\leq$ ) 100mg per day?  
 Yes (Approve – 365 days)  
 No (Deny)
7. Is the dose less than or equal to ( $\leq$ ) 200mg per day?  
 Yes (Approve – 365 days)  
 No (Deny)



# Provigil

## Clinical Criteria Logic Diagram




**Provigil**
**Clinical Criteria Supporting Tables**

<b>Step 2 (diagnosis of narcolepsy or shift work disorder)</b>	
<b>Required diagnosis: 1</b>	
<b>Look back timeframe: 730 days</b>	
<b>ICD-10 Code</b>	<b>Description</b>
F518	OTHER SLEEP DISORDERS NOT DUE TO A SUBSTANCE OR KNOWN PHYSIOLOGICAL CONDITION
G4726	CIRCADIAN RHYTHM SLEEP DISORDER, SHIFT WORK TYPE
G47411	NARCOLEPSY WITH CATAPLEXY
G47419	NARCOLEPSY WITHOUT CATAPLEXY
G47421	NARCOLEPSY IN CONDITIONS CLASSIFIED ELSEWHERE WITH CATAPLEXY
G47429	NARCOLEPSY IN CONDITIONS CLASSIFIED ELSEWHERE WITHOUT CATAPLEXY

<b>Step 3 (diagnosis of obstructive sleep apnea)</b>	
<b>Required diagnosis: 1</b>	
<b>Look back timeframe: 730 days</b>	
<b>ICD-10 Code</b>	<b>Description</b>
G4730	SLEEP APNEA, UNSPECIFIED
G4733	OBSTRUCTIVE SLEEP APNEA (ADULT) (PEDIATRIC)

<b>Step 4 (procedure code for CPAP or BiPAP)</b>	
<b>Required procedure: 1</b>	
<b>Look back timeframe: 730 days</b>	
<b>CPT Code</b>	<b>Description</b>
9390	CONTINUOUS POSITIVE AIRWAY PRESSURE (CPAP)
94660	CPAP INITIATION AND MANAGEMENT
95811	SLEEP STAGING WITH INITIATION OF CPAP
E0601	CPAP DEVICE
E0470	CPAP WITH BI-LEVEL FAILURE
E0471	CPAP WITH BI-LEVEL FAILURE
E0472	CPAP WITH BI-LEVEL FAILURE

<b>Step 5 (diagnosis of clinically-significant hepatic impairment)</b>	
<b>Required diagnosis: 1</b>	
<b>Look back timeframe: 365 days</b>	
<b>ICD-10 Code</b>	<b>Description</b>
B150	HEPATITIS A WITH HEPATIC COMA
B159	HEPATITIS A WITHOUT HEPATIC COMA
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
B251	CYTOMEGALOVIRAL HEPATITIS
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

<b>Step 5 (diagnosis of clinically-significant hepatic impairment)</b>	
<b>Required diagnosis: 1</b>	
<b>Look back timeframe: 365 days</b>	
<b>ICD-10 Code</b>	<b>Description</b>
K7111	TOXIC LIVER DISEASE WITH HEPATIC NECROSIS, WITH COMA
K712	TOXIC LIVER DISEASE WITH ACUTE HEPATITIS
K713	TOXIC LIVER DISEASE WITH CHRONIC PERSISTENT HEPATITIS
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
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
K7581	NONALCOHOLIC STEATOHEPATITIS (NASH)
K7589	OTHER SPECIFIED INFLAMMATORY LIVER DISEASES



<b>Step 5 (diagnosis of clinically-significant hepatic impairment)</b>	
<b>Required diagnosis: 1</b>	
<b>Look back timeframe: 365 days</b>	
<b>ICD-10 Code</b>	<b>Description</b>
K759	INFLAMMATORY LIVER DISEASE, UNSPECIFIED
K760	FATTY (CHANGE OF) LIVER, NOT ELSEWHERE CLASSIFIED
K761	CHRONIC PASSIVE CONGESTION OF LIVER
K763	INFARCTION OF LIVER
K764	PELIOSIS HEPATIS
K765	HEPATIC VENO-OCCLUSIVE DISEASE
K766	PORTAL HYPERTENSION
K767	HEPATORENAL SYNDROME
K7689	OTHER SPECIFIED DISEASES OF LIVER
K769	LIVER DISEASE, UNSPECIFIED
K77	LIVER DISORDERS IN DISEASES CLASSIFIED ELSEWHERE



## Nuvigil

### 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](http://TxVendorDrug.com/formulary/formulary-search).

Drugs Requiring Prior Authorization	
Label Name	GCN
ARMODAFINIL 50MG TABLET	98591
ARMODAFINIL 150MG TABLET	98590
ARMODAFINIL 200MG TABLET	36082
ARMODAFINIL 250MG TABLET	98592
NUVIGIL 50MG TABLET	98591
NUVIGIL 150MG TABLET	98590
NUVIGIL 200MG TABLET	36082
NUVIGIL 250MG TABLET	98592

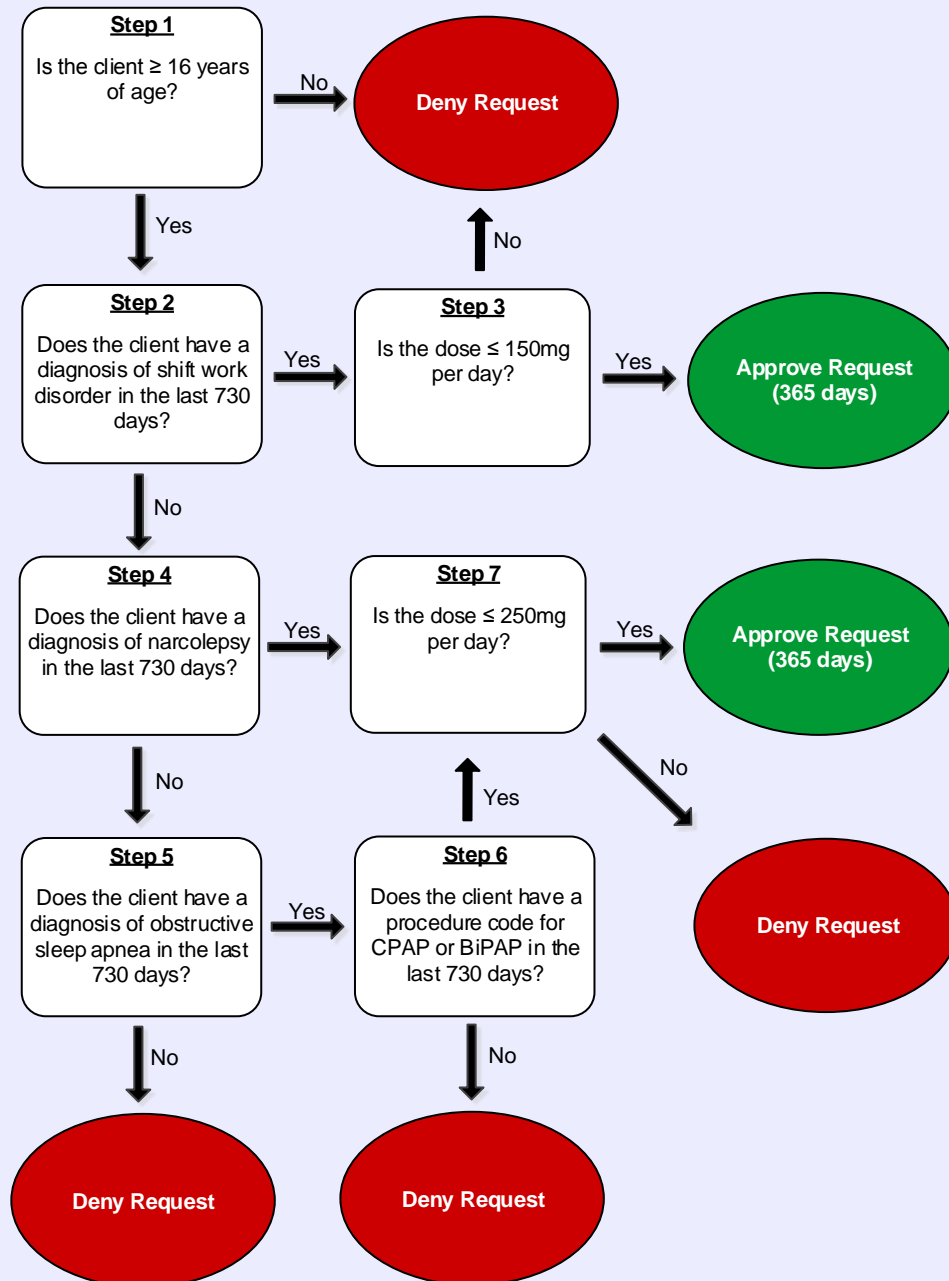
**Nuvigil****Clinical Criteria Logic**

1. Is the client greater than or equal to ( $\geq$ ) 16 years of age?  
 Yes (Go to #2)  
 No (Deny)
2. Does the client have a diagnosis of shift work disorder in the last 730 days?  
 Yes (Go to #3)  
 No (Go to #4)
3. Is the dose less than or equal to ( $\leq$ ) 150mg per day?  
 Yes (Approve – 365 days)  
 No (Deny)
4. Does the client have a diagnosis of narcolepsy in the last 730 days?  
 Yes (Go to #7)  
 No (Go to #5)
5. Does the client have a diagnosis of obstructive sleep apnea in the last 730 days?  
 Yes (Go to #6)  
 No (Deny)
6. Does the client have a procedure code for CPAP or BiPAP in the last 730 days?  
 Yes (Go to #7)  
 No (Deny)
7. Is the dose less than or equal to ( $\leq$ ) 250mg per day?  
 Yes (Approve – 365 days)  
 No (Deny)



**Nuvigil**

**Clinical Criteria Logic Diagram**





Nuvigil

## Clinical Criteria Supporting Tables

<b>Step 2 (diagnosis of shift work disorder)</b> <b>Required diagnosis: 1</b> <b>Look back timeframe: 730 days</b>	
ICD-10 Code	Description
F518	OTHER SLEEP DISORDERS NOT DUE TO A SUBSTANCE OR KNOWN PHYSIOLOGICAL CONDITION
G4726	CIRCADIAN RHYTHM SLEEP DISORDER, SHIFT WORK TYPE

<b>Step 4 (diagnosis of narcolepsy)</b> <b>Required diagnosis: 1</b> <b>Look back timeframe: 730 days</b>	
ICD-10 Code	Description
G47411	NARCOLEPSY WITH CATAPLEXY
G47419	NARCOLEPSY WITHOUT CATAPLEXY
G47421	NARCOLEPSY IN CONDITIONS CLASSIFIED ELSEWHERE WITH CATAPLEXY
G47429	NARCOLEPSY IN CONDITIONS CLASSIFIED ELSEWHERE WITHOUT CATAPLEXY

<b>Step 5 (diagnosis of obstructive sleep apnea)</b> <b>Required quantity: 1</b> <b>Look back timeframe: 730 days</b>	
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For the list of diagnosis codes that pertain to this step, see the [Obstructive Sleep Apnea](#) table in the previous "Supporting Tables" section.

**Note:** Click the hyperlink to navigate directly to the table.

<b>Step 6 (procedure code for CPAP or BiPAP)</b> <b>Required quantity: 1</b> <b>Look back timeframe: 730 days</b>	
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For the list of procedure codes that pertain to this step, see the [CPAP/BiPAP](#) table in the previous "Supporting Tables" section.

**Note:** Click the hyperlink to navigate directly to the table.



## Provigil and Nuvigil

### Clinical Criteria References

1. Ballon JS, Feifel D. A systematic review of modafinil: Potential clinical uses and mechanisms of action. *J Clin Psychiatry* 2006;67:554-66.
2. Psychopharmacologic Drugs Advisory Committee, United States Food and Drug Administration. March 23, 2006. Meeting minutes available at: <http://www.fda.gov/ohrms/dockets/ac/06/minutes/2006-4212m1.pdf>. Accessed on August 11, 2008.
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## 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
01/31/2011	Initial publication and posting to website
04/13/2012	Added a new section to specify the drugs requiring prior authorization In the "Clinical Edit Supporting Tables" section, revised tables to specify the diagnosis codes pertinent to steps 2, 3 and 4 of the logic diagram In the "Clinical Edit Supporting Tables" section, revised table to specify the procedure codes pertinent to step 5 of the logic diagram
10/26/2012	Added Modafinil 100mg and 200mg tablets to table of drugs requiring prior authorization
04/03/2015	Updated to include ICD-10s
10/05/2017	Annual review by staff Added dose check for modafinil to logic and diagram, pages 4-5 Added armodafinil to clinical edit Added criteria logic and diagram for armodafinil, pages 13-14 Updated references, page 17
03/29/2019	Updated to include formulary statement (The listed GCNS may not be an indication of TX Medicaid Formulary coverage. To learn the current formulary coverage, visit <a href="http://TxVendorDrug.com/formulary/formulary-search">TxVendorDrug.com/formulary/formulary-search</a> .) on each 'Drug Requiring PA' table