

Texas Prior Authorization Program Clinical Criteria

Drug/Drug Class

Zurzuvae (Zuranolone)

This criteria was recommended for review by the Texas Medicaid Vendor Drug Program to ensure appropriate and safe utilization

Clinical 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



Zurzuvae (Zuranolone)

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
ZURZUVAE 20 MG CAPSULE	43601
ZURZUVAE 25 MG CAPSULE	45723
ZURZUVAE 30 MG CAPSULE	48261



Zurzuvae (Zuranolone)

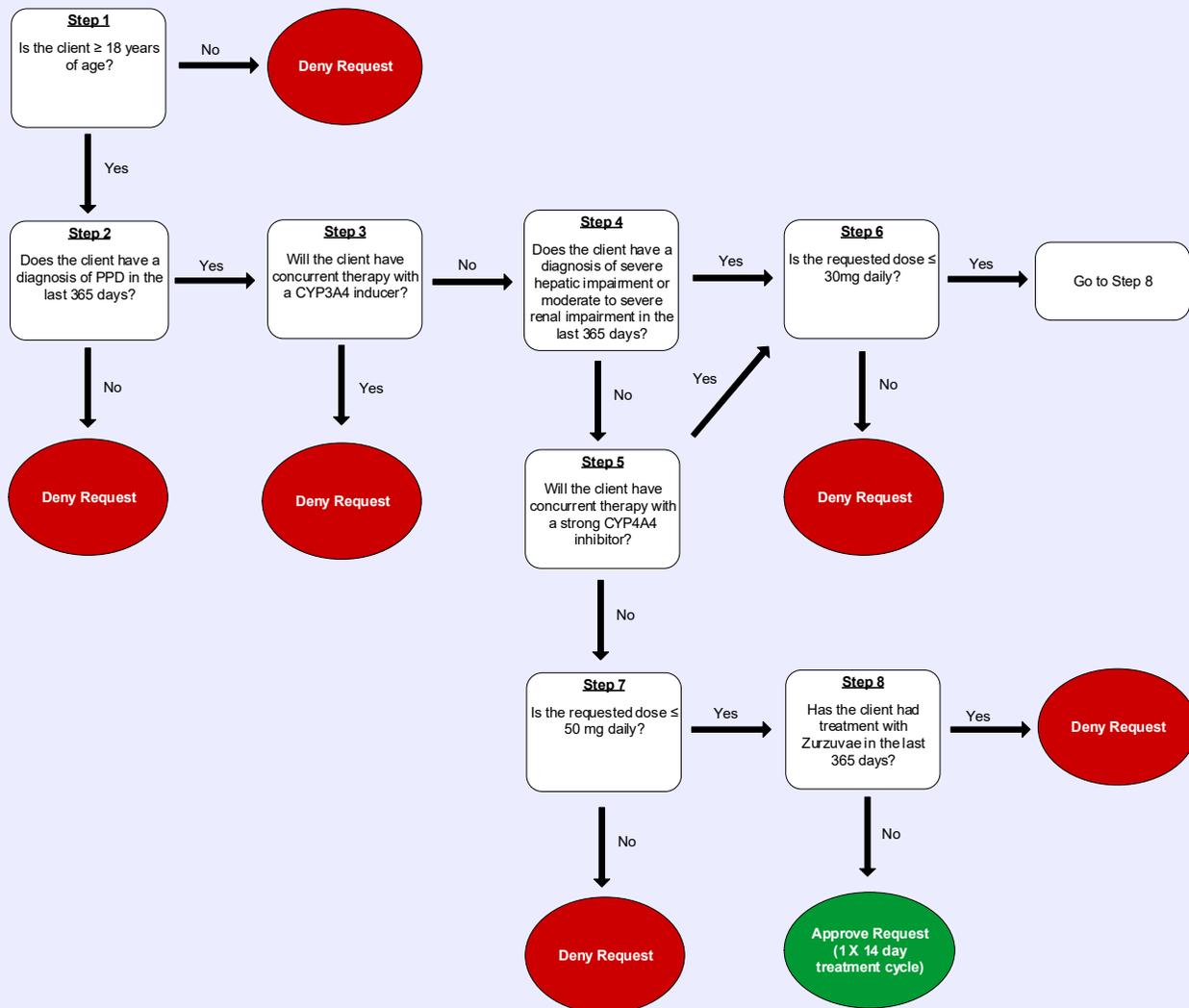
Clinical Criteria Logic

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 **postpartum depression (PPD)** in the last 365 days?
 Yes (Go to #3)
 No (Deny)
3. Will the client have concurrent therapy with a **CYP3A4 inducer**?
 Yes (Deny)
 No (Go to #4)
4. Does the client have a diagnosis of **severe hepatic impairment or moderate to severe renal impairment** in the last 365 days?
 Yes (Go to #6)
 No (Go to #5)
5. Will the client have concurrent therapy with a **strong CYP3A4 inhibitor**?
 Yes (Go to #6)
 No (Go to #7)
6. Is the requested dose less than or equal to (\leq) 30 mg daily?
 Yes (Go to #8)
 No (Deny)
7. Is the requested dose less than or equal to (\leq) 50 mg daily?
 Yes (Go to #8)
 No (Deny)
8. Has the client had treatment with Zurzuvae in the last 365 days?
 Yes (Deny)
 No (Approve – 1 X 14 day treatment cycle)



Zurzuvae (Zuranolone)

Clinical Criteria Logic Diagram





Zurzuvae (Zuranolone)

Clinical Criteria Supporting Tables

Step 2 (diagnosis of PPD)	
Required diagnosis: 1	
Look back timeframe: 365 days	
ICD-10 Code	Description
F530	POSTPARTUM DEPRESSION
F531	PUERPERAL PSYCHOSIS

Step 3 (concurrent therapy with CYP3A4 inducer)	
Label Name	GCN
BEXAROTENE 75 MG CAPSULE	92373
BEXAROTENE 75 MG CAPSULE	92373
CARBAMAZEPINE 100 MG TAB CHEW	17460
CARBAMAZEPINE 100 MG/5 ML SUSP	47500
CARBAMAZEPINE 200 MG TABLET	17450
CARBAMAZEPINE ER 100 MG CAP	23934
CARBAMAZEPINE ER 100 MG TAB	27820
CARBAMAZEPINE ER 200 MG CAP	23932
CARBAMAZEPINE ER 200 MG TABLET	27821
CARBAMAZEPINE ER 300 MG CAP	23933
CARBAMAZEPINE ER 400 MG TABLET	27822
CARBATROL ER 100 MG CAPSULE	23934
CARBATROL ER 200 MG CAPSULE	23932
CARBATROL ER 300 MG CAPSULE	23933
DILANTIN 100 MG CAPSULE	17700
DILANTIN 125 MG/5 ML SUSP	17241
DILANTIN 30 MG CAPSULE	17701
DILANTIN 50 MG INFATAB	17250
EPITOL 200 MG TABLET	17450
EQUETRO 100 MG CAPSULE	13781
EQUETRO 200 MG CAPSULE	13805
EQUETRO 300 MG CAPSULE	13818
LYSODREN 500 MG TABLET	37810
MYSOLINE 250 MG TABLET	17321
MYSOLINE 50 MG TABLET	17322
ORKAMBI 100-125 MG GRANULE PKT	36937

Step 3 (concurrent therapy with CYP3A4 inducer)	
Label Name	GCN
ORKAMBI 100-125 MG TABLET	42366
ORKAMBI 150-188 MG GRANULE PKT	42848
ORKAMBI 200-125 MG TABLET	39008
PHENOBARBITAL 100 MG TABLET	12975
PHENOBARBITAL 130 MG/ML VIAL	12892
PHENOBARBITAL 15 MG TABLET	12971
PHENOBARBITAL 16.2 MG TABLET	97706
PHENOBARBITAL 20 MG/5 ML ELIX	12956
PHENOBARBITAL 30 MG TABLET	12973
PHENOBARBITAL 32.4 MG TABLET	97965
PHENOBARBITAL 60 MG TABLET	12972
PHENOBARBITAL 64.8 MG TABLET	97966
PHENOBARBITAL 65 MG/ML VIAL	12894
PHENOBARBITAL 97.2 MG TABLET	97967
PHENYTEK 200 MG CAPSULE	15038
PHENYTEK 300 MG CAPSULE	15037
PHENYTOIN 125 MG/5 ML SUSP	17241
PHENYTOIN 50 MG TABLET CHEW	17250
PHENYTOIN 50 MG/ML VIAL	17200
PHENYTOIN SOD EXT 100 MG CAP	17700
PHENYTOIN SOD EXT 200 MG CAP	15038
PHENYTOIN SOD EXT 300 MG CAP	15037
PRIMIDONE 250 MG TABLET	17321
PRIMIDONE 50 MG TABLET	17322
RIFADIN 150 MG CAPSULE	41260
RIFADIN 300 MG CAPSULE	41261
RIFADIN IV 600 MG VIAL	41470
RIFAMATE CAPSULE	89800
RIFAMPIN 150 MG CAPSULE	41260
RIFAMPIN 300 MG CAPSULE	41261
RIFAMPIN IV 600 MG VIAL	41470
RIFATER TABLET	14142
TEGRETOL 100 MG/5 ML SUSP	47500
TEGRETOL 200 MG TABLET	17450
TEGRETOL XR 100 MG TABLET	27820
TEGRETOL XR 200 MG TABLET	27821
TEGRETOL XR 400 MG TABLET	27822
XTANDI 40 MG CAPSULE	33183

Step 4 (Severe Hepatic Impairment or Moderate to Severe Renal Impairment)	
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
K714	TOXIC LIVER DISEASE WITH CHRONIC LOBULAR HEPATITIS
K7150	TOXIC LIVER DISEASE WITH CHRONIC ACTIVE HEPATITIS WITHOUT ASCITES

Step 4 (Severe Hepatic Impairment or Moderate to Severe Renal Impairment)	
ICD-10 Code	Description
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
K763	INFARCTION OF LIVER
K7689	OTHER SPECIFIED DISEASES OF LIVER
K769	LIVER DISEASE, UNSPECIFIED
K77	LIVER DISORDERS IN DISEASES CLASSIFIED ELSEWHERE

Step 4 (Severe Hepatic Impairment or Moderate to Severe Renal Impairment)	
ICD-10 Code	Description
N1830	CHRONIC KIDNEY DISEASE, STAGE 3 UNSPECIFIED (eGFR 59-30 mL/min)
N1831	CHRONIC KIDNEY DISEASE, STAGE 3A (eGFR 59-45 mL/min)
N1832	CHRONIC KIDNEY DISEASE, STAGE 3B (eGFR 44-30 mL/min)
N184	CHRONIC KIDNEY DISEASE, STAGE 4 (SEVERE) (eGFR 29-15 mL/min)
N185	CHRONIC KIDNEY DISEASE, STAGE 5 (eGFR < 15 mL/min)
N186	END STAGE RENAL DISEASE

Step 5 (CYP3A4 Inhibitors)	
GCN	Label Name
19952	ATAZANAVIR SULFATE 150MG CAP
19953	ATAZANAVIR SULFATE 200MG CAP
97430	ATAZANAVIR SULFATE 300MG CAP
11670	CLARITHROMYCIN 125 MG/5 ML SUS
48852	CLARITHROMYCIN 250 MG TABLET
11671	CLARITHROMYCIN 250 MG/5 ML SUS
48851	CLARITHROMYCIN 500 MG TABLET
48850	CLARITHROMYCIN ER 500 MG TAB
26820	CRIXIVAN 200 MG CAPSULE
26822	CRIXIVAN 400 MG CAPSULE
37797	EVOTAZ 300-150MG TABLET
40092	GENVOYA TABLET
23952	INVIRASE 500 MG TABLET
49100	ITRACONAZOLE 10 MG/ML SOLUTION
49101	ITRACONAZOLE 100 MG CAPSULE
99101	KALETRA 100-25 MG TABLET
25919	KALETRA 200-50 MG TABLET
31782	KALETRA 400-100/5 ML ORAL SOLU
42590	KETOCONAZOLE 200 MG TABLET
31485	KORLYM 300 MG TABLET
64269	LANSOPRAZOL-AMOXICIL-CLARITHRO
16406	NEFAZODONE 100MG TABLET
16407	NEFAZODONE 150MG TABLET
16408	NEFAZODONE 200MG TABLET
16409	NEFAZODONE 250MG TABLET
16404	NEFAZODONE 50MG TABLET

Step 5 (CYP3A4 Inhibitors)	
GCN	Label Name
40309	NORVIR 100 MG POWDER PACKET
28224	NORVIR 100 MG TABLET
26810	NORVIR 80 MG/ML SOLUTION
26502	NOXAFIL 40 MG/ML SUSPENSION
35649	NOXAFIL DR 100 MG TABLET
32137	OMECLAMOX-PAK COMBO PACK
37367	PREZCOBIX 800-150MG TABLET
31201	PREZISTA 100MG/ML SUSPENSION
23489	PREZISTA 150MG TABLET
99434	PREZISTA 600MG TABLET
16759	PREZISTA 75MG TABLET
33723	PREZISTA 800MG TABLET
19952	REYATAZ 150MG CAPSULE
19953	REYATAZ 200MG CAPSULE
97430	REYATAZ 300MG CAPSULE
36647	REYATAZ 50MG POWDER PACK
28224	RITONAVIR 100 MG TABLET
49100	SPORANOX 10 MG/ML SOLUTION
49101	SPORANOX 100 MG CAPSULE
33130	STRIBILD TABLET
43968	SYMTUZA 800-150-200-10 MG TAB
45848	TOLSURA 65 MG CAPSULE
36468	TYBOST 150MG TABLET
17498	VFEND 200 MG TABLET
21513	VFEND 40 MG/ML SUSPENSION
17497	VFEND 50 MG TABLET
17499	VFEND IV 200 MG VIAL
37614	VIEKIRA PAK
40312	VIRACEPT 250 MG TABLET
19717	VIRACEPT 625 MG TABLET
17498	VORICONAZOLE 200 MG TABLET
17499	VORICONAZOLE 200 MG VIAL
21513	VORICONAZOLE 40 MG/ML SUSP
17497	VORICONAZOLE 50 MG TABLET
36884	ZYDELIG 100MG TABLET
36885	ZYDELIG 150MG TABLET



Zurzuvae (Zuranolone)

Clinical Criteria References

1. 2024 ICD-10-CM Diagnosis Codes. 2024. Available at www.icd10data.com. Accessed on July 26, 2024.
2. Clinical Pharmacology [online database]. Tampa, FL: Elsevier/Gold Standard, Inc.; 2024. Available at www.clinicalpharmacology.com. Accessed on July 26, 2024.
3. Micromedex [online database]. Available at www.micromedexsolutions.com. Accessed on July 26, 2024.
4. Zurzuvae Prescribing Information. Lexington, MA. Sage Therapeutics, Inc. August 2023.

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
07/26/2024	<ul style="list-style-type: none">Initial publication and presentation to the DUR Board