

**Texas Prior Authorization Program
Clinical Criteria**

Drug/Drug Class

Qelbree (Viloxazine)

Clinical Criteria Information Included in this Document

Qelbree (Viloxazine)

- **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)
- **References:** clinical publications and sources relevant to this clinical criteria

Revision Notes

Initial publication and presentation to DUR Board



Qelbree (Viloxazine)

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
QELBREE 100 MG CAPSULE	PENDING
QELBREE 150 MG CAPSULE	PENDING
QELBREE 200 MG CAPSULE	PENDING



Qelbree (Viloxazine)

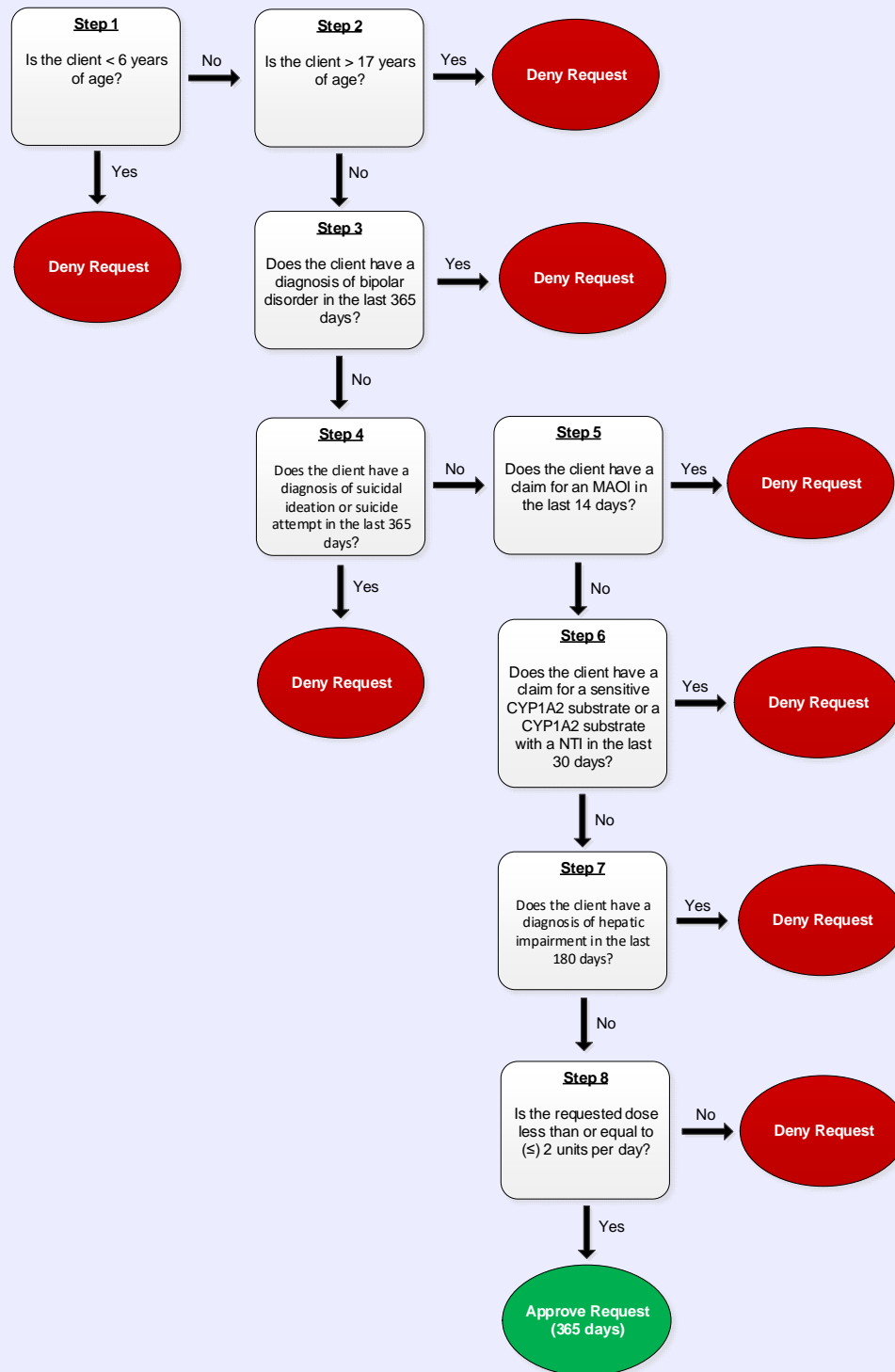
Clinical Criteria Logic

1. Is the client less than (<) 6 years of age?
 Yes – Deny
 No – Go to #2
2. Is the client greater than (>) 17 years of age?
 Yes – Deny
 No – Go to #3
3. Does the client have a **diagnosis of bipolar disorder** in the last 365 days?
 Yes – Deny
 No – Go to #4
4. Does the client have a **diagnosis of suicidal ideation or suicide attempt** in the last 180 days?
 Yes – Deny
 No – Go to #5
5. Does the client have a claim for an **MAO inhibitor** in the last 14 days?
 Yes – Deny
 No – Go to #6
6. Does the client have a claim for a **sensitive CYP1A2 substrate or a CYP1A2 substrate with a narrow therapeutic index** in the last 30 days?
 Yes – Deny
 No – Go to #7
7. Does the client have a diagnosis of **hepatic impairment** in the last 180 days?
 Yes – Deny
 No – Go to #8
8. Is the requested dose less than or equal to (\leq) 2 units per day?
 Yes – Approve (365 days)
 No – Deny



Qelbree (Viloxazine)

Clinical Criteria Logic Diagram





Qelbree (Viloxazine)

Clinical Criteria Supporting Tables

Step 3 (diagnosis of bipolar disorder) Required quantity: 1 Look back timeframe: 365 days	
ICD-10 Code	Description
F310	BIPOLAR DISORDER, CURRENT EPISODE HYPOMANIC
F3110	BIPOLAR DISORDER, CURRENT EPISODE MANIC WITHOUT PSYCHOTIC FEATURES UNSPECIFIED
F3111	BIPOLAR DISORDER, CURRENT EPISODE MANIC WITHOUT PSYCHOTIC FEATURES MILD
F3112	BIPOLAR DISORDER, CURRENT EPISODE MANIC WITHOUT PSYCHOTIC FEATURES MODERATE
F3113	BIPOLAR DISORDER, CURRENT EPISODE MANIC WITHOUT PSYCHOTIC FEATURES SEVERE
F312	BIPOLAR DISORDER, CURRENT EPISODE MANIC SEVERE WITH PSYCHOTIC FEATURES
F3130	BIPOLAR DISORDER, CURRENT EPISODE DEPRESSED, MILD OR MODERATE SEVERITY UNSPECIFIED
F3131	BIPOLAR DISORDER, CURRENT EPISODE DEPRESSED, MILD
F3132	BIPOLAR DISORDER, CURRENT EPISODE DEPRESSED, MODERATE
F314	BIPOLAR DISORDER, CURRENT EPISODE DEPRESSED, SEVERE, WITHOUT PSYCHOTIC FEATURES
F315	BIPOLAR DISORDER, CURRENT EPISODE DEPRESSED, SEVERE, WITH PSYCHOTIC FEATURES
F3160	BIPOLAR DISORDER, CURRENT EPISODE MIXED UNSPECIFIED
F3161	BIPOLAR DISORDER, CURRENT EPISODE MIXED MILD
F3162	BIPOLAR DISORDER, CURRENT EPISODE MIXED MODERATE
F3163	BIPOLAR DISORDER, CURRENT EPISODE MIXED SEVERE, WITHOUT PSYCHOTIC FEATURES
F3164	BIPOLAR DISORDER, CURRENT EPISODE MIXED SEVERE, WITH PSYCHOTIC FEATURES
F3170	BIPOLAR DISORDER, CURRENTLY IN REMISSION MOST RECENT EPISODE UNSPECIFIED
F3171	BIPOLAR DISORDER, IN PARTIAL REMISSION, MOST RECENT EPISODE HYPOMANIC
F3172	BIPOLAR DISORDER, IN FULL REMISSION, MOST RECENT EPISODE HYPOMANIC
F3173	BIPOLAR DISORDER, IN PARTIAL REMISSION, MOST RECENT EPISODE MANIC
F3174	BIPOLAR DISORDER, IN FULL REMISSION, MOST RECENT EPISODE MANIC
F3175	BIPOLAR DISORDER, IN PARTIAL REMISSION, MOST RECENT EPISODE DEPRESSED

Step 3 (diagnosis of bipolar disorder)	
Required quantity: 1	
Look back timeframe: 365 days	
ICD-10 Code	Description
F3176	BIPOLAR DISORDER, IN FULL REMISSION, MOST RECENT EPISODE DEPRESSED
F3177	BIPOLAR DISORDER, IN PARTIAL REMISSION, MOST RECENT EPISODE MIXED
F3178	BIPOLAR DISORDER, IN FULL REMISSION, MOST RECENT EPISODE MIXED
F3181	BIPOLAR II DISORDER
F3189	OTHER BIPOLAR DISORDER
F319	BIPOLAR DISORDER, UNSPECIFIED

Step 4 (diagnosis of suicidal ideation or suicide attempt)	
Required quantity: 1	
Look back timeframe: 365 days	
ICD-10 Code	Description
R45851	SUICIDAL IDEATIONS
T1491XA	SUICIDE ATTEMPT INITIAL ENCOUNTER
T1491XD	SUICIDE ATTEMPT SUBSEQUENT ENCOUNTER
T1491XS	SUICIDE ATTEMPT SEQUELA

Step 5 (claim for an MAOI)	
Required days supply: 1	
Look back timeframe: 14 days	
GCN	Label Name
27081	AZILECT 0.5 MG TABLET
24654	AZILECT 1 MG TABLET
26614	EMSAM 12MG/24 HOURS PATCH
26612	EMSAM 6MG/24 HOURS PATCH
26871	LINEZOLID 100MG/5ML SUSP
26870	LINEZOLID 600MG TABLET
26873	LINEZOLID 600MG/300ML IV SOLN
16416	MARPLAN 10 MG TABLET
16417	NARDIL 15 MG TABLET
16418	PARNATE 10 MG TABLET
16417	PHENELZINE SULFATE 15 MG TAB
27081	RASAGILINE MESYLATE 0.5 MG TAB
24654	RASAGILINE MESYLATE 1 MG TAB

Step 5 (claim for an MAOI) Required days supply: 1 Look back timeframe: 14 days	
15603	SELEGILINE 5MG CAPSULE
15600	SELEGILINE 5MG TABLET
16418	TRANLYCYPROMINE 10MG TABLET
22783	ZELAPAR 1.25MG ODT TABLET
26871	ZYVOX 100 MG/5 ML SUSPENSION
26870	ZYVOX 600 MG TABLET
26873	ZYVOX 600 MG/300 ML IV SOLN

Step 6 (claim for a sensitive CYP1A2 substrate or a CYP1A2 substrate with a NTI) Required days supply: 1 Look back timeframe: 30 days	
GCN	Label Name
21422	ALOSETRON HCL 0.5 MG TABLET
41607	ALOSETRON HCL 1 MG TABLET
25792	COUMADIN 1 MG TABLET
25790	COUMADIN 10 MG TABLET
25791	COUMADIN 2 MG TABLET
25794	COUMADIN 2.5 MG TABLET
25796	COUMADIN 3 MG TABLET
25797	COUMADIN 4 MG TABLET
25793	COUMADIN 5 MG TABLET
25798	COUMADIN 6 MG TABLET
25795	COUMADIN 7.5 MG TABLET
23161	CYMBALTA 20 MG CAPSULE
23162	CYMBALTA 30 MG CAPSULE
23164	CYMBALTA 60 MG CAPSULE
23161	DULOXETINE HCL DR 20 MG CAP
23162	DULOXETINE HCL DR 30 MG CAP
23164	DULOXETINE HCL DR 60 MG CAP
00352	ELIXOPHYLLINE 80 MG/ 15 ML ELIX
36068	HETLIOZ 20 MG CAPSULE
25792	JANTOVEN 1 MG TABLET
25790	JANTOVEN 10 MG TABLET
25791	JANTOVEN 2 MG TABLET
25794	JANTOVEN 2.5 MG TABLET
25796	JANTOVEN 3 MG TABLET

**Step 6 (claim for a sensitive CYP1A2 substrate or
a CYP1A2 substrate with a NTI)**

Required days supply: 1

Look back timeframe: 30 days

25797	JANTOVEN 4 MG TABLET
25793	JANTOVEN 5 MG TABLET
25798	JANTOVEN 6 MG TABLET
25795	JANTOVEN 7.5 MG TABLET
21422	LOTRONEX 0.5 MG TABLET
41607	LOTRONEX 1 MG TABLET
25202	RAMELTEON 8 MG TABLET
25202	ROZEREM 8 MG TABLET
00324	THEO-24 ER 100 MG CAPSULE
00325	THEO-24 ER 200 MG CAPSULE
00326	THEO-24 ER 300 MG CAPSULE
00323	THEO-24 ER 400 MG CAPSULE
01080	THEOPHYLLINE 80 MG/15 ML SOLN
00410	THEOPHYLLINE ER 100 MG TABLET
00411	THEOPHYLLINE ER 200 MG TABLET
00413	THEOPHYLLINE ER 300 MG TAB
00415	THEOPHYLLINE ER 400 MG TABLET
00416	THEOPHYLLINE ER 450 MG TAB
00417	THEOPHYLLINE ER 600 MG TABLET
24433	TIZANIDINE HCL 2 MG CAPSULE
14690	TIZANIDINE HCL 2 MG TABLET
24434	TIZANIDINE HCL 4 MG CAPSULE
14693	TIZANIDINE HCL 4 MG TABLET
24435	TIZANIDINE HCL 6 MG CAPSULE
25792	WARFARIN SODIUM 1 MG TABLET
25790	WARFARIN SODIUM 10 MG TABLET
25791	WARFARIN SODIUM 2 MG TABLET
25794	WARFARIN SODIUM 2.5 MG TABLET
25796	WARFARIN SODIUM 3 MG TABLET
25797	WARFARIN SODIUM 4 MG TABLET
25793	WARFARIN SODIUM 5 MG TABLET
25798	WARFARIN SODIUM 6 MG TABLET
25795	WARFARIN SODIUM 7.5 MG TABLET

Step 7 (diagnosis of hepatic impairment)	
Required quantity: 1	
Look back timeframe: 180 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 7 (diagnosis of hepatic impairment)	
Required quantity: 1	
Look back timeframe: 180 days	
ICD-10 Code	Description
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 7 (diagnosis of hepatic impairment)	
Required quantity: 1	
Look back timeframe: 180 days	
ICD-10 Code	Description
K763	INFARCTION OF LIVER
K7689	OTHER SPECIFIED DISEASES OF LIVER
K769	LIVER DISEASE, UNSPECIFIED
K77	LIVER DISORDERS IN DISEASES CLASSIFIED ELSEWHERE



Attention Deficit Disorder (ADD) / Attention Deficit Hyperactivity Disorder (ADHD)

Clinical Criteria References

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3. 2021 ICD-10-CM Diagnosis Codes. 2021. Available at www.icd10data.com. Accessed on July 23, 2021.
4. Qelbree Prescribing Information. Rockville, MD. Supernus Pharmaceuticals, Inc. April 2021.

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
07/23/2021	Initial publication and presentation to DUR Board