



UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 2270-4
Program	Prior Authorization/Medical Necessity
Medication	Qelbree (viloxazine)*
P&T Approval Date	9/1/2021, 2/2022, 6/2022, 7/2023
Effective Date	1/1/2024; Oxford only: 1/1/2024

1. Background:

Qelbree is a selective norepinephrine reuptake inhibitor indicated for the treatment of attention deficit hyperactivity disorder (ADHD) in adults and pediatric patients 6 years and older. The American Academy of Pediatrics generally recommends stimulants as first-line medications for the treatment of ADHD. Selective norepinephrine reuptake inhibitors (e.g. atomoxetine) and selective alpha-2 adrenergic agonists (e.g. clonidine extended-release, guanfacine extended-release) are also recommended, however the data are less robust.

2. Coverage Criteria^a:

<p>A. <u>Authorization</u></p> <p>1. Qelbree* will be approved based on <u>both</u> of the following:</p> <p>a. <u>One</u> of the following:</p> <p>(1) History of failure, contraindication, or intolerance to <u>both</u> of the following (document medication names and dates of trials):</p> <p>(a) a methylphenidate class stimulant (e.g. generic Concerta)</p> <p>(b) an amphetamine class stimulant (e.g. generic Adderall XR)</p> <p style="text-align: center;">-OR-</p> <p>(2) History of a substance use disorder or concern for potential misuse and/or diversion</p> <p style="text-align: center;">-AND-</p> <p>b. <u>One</u> of the following:</p> <p>(1) History of failure, contraindication, or intolerance to <u>both</u> of the following:</p> <p>(a) an alpha-2 adrenergic agonist [e.g. clonidine extended-release, guanfacine extended-release (document medication name and date of trial)].</p> <p>(b) atomoxetine [(generic Strattera) document date of trial]</p> <p style="text-align: center;">-OR-</p>
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- (2) Patient is unable to swallow a solid dosage form (i.e. an oral tablet or capsule) due to age, oral/motor difficulties, or dysphagia

Authorization will be issued for 12 months.

^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

* Qelbree is typically excluded from coverage.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Qelbree [package insert]. Rockville, MD: Supernus Pharmaceuticals, Inc; April 2022.
2. Wolraich ML. et. al. Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents. *Pediatrics*. Oct. 2019, 144 (4) 2019-2528.

Program	Prior Authorization/Medical Necessity – Qelbree (viloxazine)
Change Control	
9/2021	New program.
2/2022	Change program type from Non-Formulary (program number 1368) to Medical Necessity (program number 2270).
6/2022	Removed requirement that patient is less than 18 years old due to new FDA approval for adult patients.
7/2023	Annual review. Updated examples to generics.