UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2270-6
Program	Prior Authorization/Medical Necessity
Medication	Qelbree® (viloxazine)*
P&T Approval Date	9/1/2021, 2/2022, 6/2022, 7/2023, 7/2024, 1/2025
Effective Date	4/1/2025

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]:

A. Authorization

1. **Qelbree*** will be approved based on **both** of the following:

   a. **One** of the following:

      (1) History of failure, contraindication, or intolerance to **both** of the following (document medication names and dates of trials):

         (a) a methylphenidate class stimulant (e.g. generic Concerta)
         (b) an amphetamine class stimulant (e.g. generic Adderall XR)

      -OR-

      (2) History of a substance use disorder or concern for potential misuse and/or diversion

   -AND-

   b. **One** of the following:

      (1) History of failure, contraindication, or intolerance to **both** of the following:

         (a) an alpha-2 adrenergic agonist [e.g. clonidine extended-release, guanfacine extended-release (document medication name and date of trial)].
         (b) atomoxetine [(generic Strattera) document date of trial]

      -OR-

      (2) **Both** of the following:

(a) Patient is unable to swallow a solid dosage form (i.e. an oral tablet or capsule) due to age, oral/motor difficulties, or dysphagia
(b) History of failure, contraindication, or intolerance to Onyda XR (document date of trial).

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.
7/2024	Annual review. No changes.
1/2025	Added trial of Onyda XR for patients unable to swallow solid dosage form.