UnitedHealthcare Individual & Family ACA Marketplace Plans
Clinical Pharmacy Program Guidelines for Qelbree

Program	Step Therapy
Medication	Qelbree (viloxazine)
Formulary	Missouri
Issue Date	8/2022
Pharmacy and Therapeutics Approval Date	7/2023
Effective Date	9/2023

1. Background:

Qelbree is a selective norepinephrine reuptake inhibitor indicated for the treatment of attention deficit hyperactivity disorder (ADHD) in pediatric patients 6 to 17 years of age. 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., guanfacine extended-release) are also recommended, however the data are less robust.

Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. This program requires a member to try stimulant based products, atomoxetine (generic Strattera), and guanfacine extended-release (generic Intuniv) prior to receiving coverage for Qelbree.

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 (document date of trial):
(a) guanfacine extended-release (generic Intuniv)
(b) atomoxetine (generic Strattera)

-OR-

(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.

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	Step Therapy – 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).
9/2022	Removed clonidine from applicable drugs due to formulary status and removed age criteria for application to the UnitedHealthcare Value & Balance Exchange – Missouri market for 1/2023 implementation.
7/2023	Annual review. Updated examples to generics.