

Protocol for Qelbree® (viloxazine)**Approved July 2024**

Background: Attention deficit hyperactivity disorder (ADHD) is a widely diagnosed neurodevelopmental disorder giving rise to symptoms of hyperactivity, impulsivity, and inattentiveness that can impair daily functioning. Stimulants, such as methylphenidate and amphetamines, are the mainstay of treatment for ADHD.

Non-Preferred Agent:

Qelbree

The patient is unable to take two (2) formulary alternatives for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication. Documentation is required for approval.

Criteria for approval:

1. Patient is of the appropriate age based on FDA labeling or pharmaceutical compendia
2. Patient has a diagnosis of attention deficit hyperactivity disorder (ADHD)
3. ONE of the following:
 - a. Patient has a history of trial and failure, intolerance, or contraindication to the use of at least one stimulant indicated for the treatment of ADHD **OR**
 - b. Patient has a history of substance use disorder (SUD)
4. Patient will be monitored closely for suicidal thinking or behavior, clinical worsening, and unusual changes in behavior
5. Patient's heart rate and blood pressure is assessed prior to initiating treatment and periodically reassessed while on treatment
6. Medication is prescribed in accordance with a Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with a medically appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence

Continuation of Therapy:

1. There is improvement from baseline

Approval Duration: 12 months**Quantity Level Limit:** Reference Formulary for drug specific quantity level limits**References**

1. Qelbree [package insert]. : Supernus Pharmaceuticals, Inc. Rockville, MD. April 2022
2. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2022. Updated periodically
3. Robinson CL, Parker K, Kataria S, Downs E, Supra R, Kaye AD, Viswanath O, Urits I. Viloxazine for the Treatment of Attention Deficit Hyperactivity Disorder. Health Psychol Res. 2022 Sep 23;10(3):38360. doi: 10.52965/001c.38360. PMID: 36168642; PMCID: PMC9501833.