Reference number(s)
4681-A

Initial Prior Authorization
Qelbree

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Qelbree	viloxazine extended-release

Indications

FDA-approved Indications

Qelbree is indicated for the treatment of Attention-Deficit Hyperactivity Disorder (ADHD) in adults and pediatric patients 6 years and older.

Coverage Criteria

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

Authorization may be granted when the patient has a diagnosis of Attention-Deficit/Hyperactivity Disorder (ADHD) or Attention Deficit Disorder (ADD) when ALL of the following criteria are met:

- The diagnosis has been appropriately documented (e.g., evaluated by a complete clinical assessment, using DSM-5, standardized rating scales, interviews/questionnaires).
- The patient will be monitored closely for suicidal thinking or behavior, clinical worsening, and unusual changes in behavior.
- The patient meets ONE of the following:
    - The patient has experienced an inadequate treatment response to ONE of the following: Strattera (atomoxetine), an amphetamine product (e.g., amphetamine, amphetamine-

dextroamphetamine, dextroamphetamine, methamphetamine, lisdexamfetamine), a methylphenidate product (e.g., methylphenidate, dexmethylphenidate).
- The patient has experienced an intolerance to ONE of the following: Strattera (atomoxetine), an amphetamine product (e.g., amphetamine, amphetamine-dextroamphetamine, dextroamphetamine, methamphetamine, lisdexamfetamine), a methylphenidate product (e.g., methylphenidate, dexmethylphenidate).
- The patient has a contraindication that would prohibit a trial of ALL of the following: Strattera (atomoxetine), an amphetamine product (e.g., amphetamine, amphetamine-dextroamphetamine, dextroamphetamine, methamphetamine, lisdexamfetamine), a methylphenidate product (e.g., methylphenidate, dexmethylphenidate).
- The patient has difficulty swallowing oral capsules.

Continuation of Therapy

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

Authorization may be granted when the patient has a diagnosis of Attention-Deficit/Hyperactivity Disorder (ADHD) or Attention Deficit Disorder (ADD) when ALL of the following criteria are met:

- The patient has achieved or maintained improvement in their signs and symptoms of ADHD/ADD from baseline.
- The patient's need for continued therapy has been assessed within the previous year.
- The patient will continue to be monitored closely for suicidal thinking or behavior, clinical worsening, and unusual changes in behavior.

Duration of Approval (DOA)

- 4681-A: DOA: 12 months

References

1. Qelbree [package insert]. Rockville, MD: Supernus Pharmaceuticals, Inc.; April 2022.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed November 6, 2024.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 11/6/2024).
4. American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition Text Revision. Arlington, Virginia. American Psychiatric Association; 2022.
5. Wolraich ML, Hagan JF, Allan C, et al. AAP Subcommittee On Children And Adolescents With Attention-Deficit/Hyperactive Disorder. Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents. Pediatrics. 2019;144(4):e20192528.