

Drug Policy

Policy:	Qelbree (viloxazine)	Annual Review Date: 08/24/2023 Last Revised Date: 08/24/2023
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OVERVIEW

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.

POLICY STATEMENT

This policy involves the use of Qelbree. Prior authorization is recommended for pharmacy benefit coverage of Qelbree. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Qelbree as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Qelbree be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Qelbree is recommended in those who meet the following criteria:

1. Attention Deficit Hyperactivity Disorder (ADHD)

Criteria. *Patient must meet the following criteria*

- A. The patient is 6 years of age or older; AND
- B. The patient meets one of the following:
 - a. The patient has tried at least one generic stimulant (examples include methylphenidate, amphetamine, etc.); OR
 - b. The patient cannot use stimulants due to a history of drug addiction, decreased appetite in children, growth restriction/suppression in children, unexplained/unexpected weight loss, etc.; AND
- C. The patient meets one of the following:
 - a. The patient has tried at least one generic non-stimulant medication (examples include atomoxetine, guanfacine ER, clonidine ER); OR
 - b. The patient has a documented inability to swallow tablets/capsules **[documentation required]**

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Initial Approval/ Extended Approval.

A) *Initial Approval:* 1 year

B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Qelbree has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Qelbree [prescribing information]. Rockville, MD: Supernus Pharmaceuticals, Inc.; April 2022.
2. Viloxazine. In: Lexi-Drugs. Lexicomp. Wolters Kluwer Clinical Drug Information, Inc.; Riverwoods, IL. Available at: <http://www.online.lexi.com>. Last updated 9 August 2022. Accessed 14 August 2022.
3. Viloxazine. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 7 March 2023. Accessed on 8 August 2023.