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Section:	Prescription Drugs	**Effective Date:**	October 1, 2024
Subsection:	Central Nervous System Drugs	**Original Policy Date:**	April 30, 2021
Subject:	Qelbree	**Page:**	1 of 5

Last Review Date: September 6, 2024

Qelbree

Description

Qelbree (viloxazine extended-release capsules)

Background
Qelbree (viloxazine) selectively inhibits the reuptake of norepinephrine. The mechanism of action of Qelbree in the treatment of ADHD is unclear but is thought to be due to its effect on norepinephrine reuptake (1).

Regulatory Status
FDA-approved indication: 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 (1).

Qelbree has a boxed warning regarding suicidal thoughts and behaviors. In clinical trials, higher rates of suicidal thoughts and behavior were reported in patients treated with Qelbree than in patients treated with placebo. Patients should be closely monitored for worsening and emergence of suicidal thoughts and behaviors (1).

Qelbree is contraindicated in patients: (1)

- receiving concomitant treatment with monoamine oxidase inhibitors (MAOI), or within 14 days following discontinuing an MAOI, because of an increased risk of hypertensive crisis.
- receiving concomitant administration of sensitive CYP1A2 substrates or CYP1A2 substrates with a narrow therapeutic range.

Qelbree can also cause an increase in heart rate and diastolic blood pressure. Heart rate and blood pressure should be assessed prior to initiating treatment with Qelbree, following increases in dosage, and periodically while on therapy. Qelbree affected heart rate and diastolic blood pressure parameters in about 20-30% of study participants while atomoxetine affected a much lower percentage (about 5-10%) of study participants (1-2).

The safety and effectiveness of Qelbree in pediatric patients less than 6 years of age have not been established (1).

Related policies

Amphetamines, Methylphenidates, Provigil-Nuvigil

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Qelbree may be considered **medically necessary** if the conditions indicated below are met.

Qelbree may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 6 years of age or older

Diagnosis

Patient must have the following:

Attention Deficit Hyperactivity Disorder (ADHD)

AND ALL of the following:

a. Patient has had an inadequate treatment response, intolerance, or contraindication to at least **ONE** of the following:
   i. Guanfacine extended-release
   ii. Atomoxetine
   iii. Clonidine extended-release
b. Prescriber agrees to monitor the patient for clinical worsening or for emergence of suicidal thoughts and behaviors

c. Prescriber agrees to monitor heart rate, blood pressure, and cardiac risk factors every 3 months during therapy and agrees to discontinue therapy if there is a clinical contraindication
d. **NO** concomitant use of a MAOI (monoamine oxidase inhibitor) (must be >14 days post discontinuing therapy) (e.g., isocarboxazid, rasagiline, selegiline)
e. **NO** concomitant use of sensitive CYP1A2 substrates or CYP1A2 substrates with a narrow therapeutic range (e.g., alosetron, duloxetine, theophylline)

Prior – Approval *Renewal* Requirements

Age 6 years of age or older

Diagnosis

Patient must have the following:

Attention Deficit Hyperactivity Disorder (ADHD)

AND ALL of the following:

a. Prescriber agrees to monitor the patient for clinical worsening or for emergence of suicidal thoughts and behaviors
b. Prescriber agrees to monitor heart rate, blood pressure, and cardiac risk factors every 3 months during therapy and agrees to discontinue therapy if there is a clinical contraindication
c. **NO** concomitant use of a MAOI (monoamine oxidase inhibitor) (must be >14 days post discontinuing therapy) (e.g., isocarboxazid, rasagiline, selegiline)
d. **NO** concomitant use of sensitive CYP1A2 substrates or CYP1A2 substrates with a narrow therapeutic range (e.g., alosetron, duloxetine, theophylline)

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity

Strength	Daily Dosing Limits

Qelbree 100 mg Qelbree 150 mg Qelbree 200 mg	**Age 6-17:** 400 mg per day **Age 18+:** 600 mg per day

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Qelbree (viloxazine) selectively inhibits the reuptake of norepinephrine. The mechanism of action of Qelbree in the treatment of ADHD is unclear but is thought to be due to its effect on norepinephrine reuptake. The safety and effectiveness of Qelbree in pediatric patients less than 6 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Qelbree while maintaining optimal therapeutic outcomes.

References

1. Qelbree [package insert]. Rockville, MD: Supernus Pharmaceuticals Inc.; April 2022.
2. Atomoxetine [package insert]. Telangana, India: Annora Pharma Pvt. Ltd.; March 2021.

Policy History

Date	Action
April 2021	Addition to PA
September 2021	Annual review. Per SME: revised regulatory status to include data about Atomoxetine, added Clonidine extended-release as an option to t/f, and changed monitoring of HR, BP, and cardiac risk factors every 3 months and discontinue if there is a clinical contraindication
March 2022	Annual review
May 2022	Per PI update, age limit revised to include adults age 18 and older
June 2022	Annual review
March 2023	Annual review. Changed policy number to 5.60.050
December 2023	Annual review
September 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 6, 2024 and is effective on October 1, 2024.