BlueCross BlueShield Federal Employee Program

QELBREE
(viloxazine extended-release capsules)

RATIONALE FOR INCLUSION IN PA PROGRAM

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).

Summary

BlueCross BlueShield
Federal Employee Program

QELBREE
(viloxazine extended-release capsules)

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.