Washington State Health Care Authority

ADHD/Anti-Narcolepsy: Non-Stimulants – Viloxazine (Qelbree®)

Medical policy no. 61.35.40.AA-1 Effective Date: April 1, 2023

Note: *New-to-market drugs included in this class based on the Apple Health Preferred Drug List are non-preferred and subject to this prior authorization (PA) criteria. Non-preferred agents in this class require an inadequate response or documented intolerance due to severe adverse reaction or contraindication to at least TWO preferred agents. If there is only one preferred agent in the class documentation of inadequate response to ONE preferred agent is needed. If a drug within this policy receives a new indication approved by the Food and Drug Administration (FDA), medical necessity for the new indication will be determined on a case-by-case basis following FDA labeling.*

To see the list of the current Apple Health Preferred Drug List (AHPDL), please visit: https://www.hca.wa.gov/assets/billers-and-providers/apple-health-preferred-drug-list.xlsx

Background:

Viloxazine is a selective norepinephrine reuptake inhibitor (SNRI) indicated for the treatment of attention deficit hyperactivity disorder (ADHD).

Medical necessity

Drug	Medical Necessity
Viloxazine **(QELBREE)**	Viloxazine may be considered medically necessary in patients who meet the criteria described in the clinical policy below. If all criteria are not met, but there are documented medically necessary or situational circumstances, based on the professional judgement of the clinical reviewer, requests may be approved on a case-by-case basis up to the initial or reauthorization duration. Clients new to Apple Health or new to an MCO, who are requesting regimens for continuation of therapy should be reviewed following the reauthorization criteria listed below.

Clinical policy:

Clinical Criteria	
Attention Deficit Hyperactivity Disorder (ADHD)	Viloxazine may be authorized when **ALL** of the following are met: 1. Clients 17 years of age or younger may require a second opinion review with the agency-designated mental health specialist from the Second Opinion Network (SON), in addition to the following criteria; **OR** 2. Diagnosis of ADHD; **AND** 3. History of failure, contraindication, or intolerance to the following: a. Atomoxetine; **OR** b. One preferred amphetamine-based stimulant **AND** one preferred methylphenidate-based stimulant If all criteria are met, the request will be approved for **12 months.**

	Criteria (Reauthorization)
	Viloxazine may be reauthorized when **ALL** of the following are met: 1. Clients 17 years of age or younger may require a second opinion review with the agency-designated mental health specialist from the Second Opinion Network (SON), in addition to the following criteria; **AND** 2. Documentation is submitted demonstrating improvement or stabilization in signs and symptoms of ADHD (e.g., inattention, hyperactivity, behavior) If all criteria are met, the request will be approve for **12 months.**

Dosage and quantity limits

Drug	Indication	FDA Approved Dosing	Dosage Form and Quantity Limit
QELBREE	ADHD	600 mg once daily	• 100 mg capsule: #60 capsules per 30 days • 150 mg capsule: #60 capsules per 30 days • 200 mg capsule: #90 capsules per 30 days

References

Qelbree. Package insert. Supernus Pharmaceuticals Inc; 2022

History

Date	Action and Summary of Changes
5/24/2023	Updated the AND to OR between criteria #1 and #2
01/09/2023	Version 1: New policy created