Clinical Policy: Viloxazine (Qelbree)

Reference Number: ERX. NPA.155
Effective Date: 06.01.21
Last Review Date: 05.21
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Viloxazine (Qelbree™) is a selective norepinephrine reuptake inhibitor.

FDA Approved Indication(s)
Qelbree is indicated for the treatment of attention deficit hyperactivity disorder (ADHD) in pediatric patients 6 to 17 years of age.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Qelbree is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Attention Deficit Hyperactivity Disorder (must meet all)**:**

1. Diagnosis of ADHD;
2. Age ≥ 6 years and ≤ 17 years;
3. Member meets one of the following (a or b):
   a. Failure of atomoxetine at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
   b. Documentation supports inability to swallow capsules;
4. Member meets one of the following (a or b):
   a. Member or parent/guardian of member has a history of substance abuse;
   b. Both of the following (i and ii):
      i. Failure of an amphetamine-based stimulant at up to maximally indicated doses, unless clinically significant adverse effects are experienced to any amphetamine product or all are contraindicated;
      ii. Failure of a methylphenidate-based stimulant at up to maximally indicated doses, unless clinically significant adverse effects are experienced to any methylphenidate product or all are contraindicated;
5. Dose does not exceed 400 mg per day.

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Attention Deficit Hyperactivity Disorder (must meet all)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;

2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 400 mg per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
ADHD: attention-deficit and hyperactivity disorder
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
atomoxetine (Strattera®)	≤ 70 kg: 1.2 mg/kg/day PO > 70 kg: 80 mg/day PO	≤ 70 kg: 1.4 mg/kg/day > 70 kg: 100 mg/day
Short-Acting Amphetamines		
Evekeo® (amphetamine)	Refer to prescribing information	60 mg/day
amphetamine/dextroamphetamine salts (Adderall®)		60 mg/day
dextroamphetamine (Dexedrine®, Procentra®, Zenzedi®)		40 mg/day
methamphetamine (Desoxyn®)		25 mg/day
Long-Acting Amphetamines		
Adzenys XR ODT™ (amphetamine ER)	Refer to prescribing information	12.5 mg/day
Dyanavel® XR (amphetamine ER)		20 mg/day
amphetamine/ dextroamphetamine salts ER (Adderall® XR)		20 mg/day (20-30 mg/day if ≥ 6 years)
dextroamphetamine ER (Dexedrine Spansule®)		40 mg/day
Short-Acting Methylphenidates		
dexmethylphenidate (Focalin®)	Refer to prescribing information	20 mg/day
methylphenidate (Methylin®, Ritalin®)		60 mg/day
Long-Acting Methylphenidates		
dexmethylphenidate ER (Focalin XR®)	Refer to prescribing information	40 mg/day (30 mg/day if 6-17 years)
methylphenidate ER (Aptensio XR™, Metadate CD®, QuilliChew ER®, Quillivant XR®, Ritalin LA®)		60 mg/day
methylphenidate ER (Concerta®)		72 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
atomoxetine (Strattera®)	≤ 70 kg: 1.2 mg/kg/day PO > 70 kg: 80 mg/day PO	≤ 70 kg: 1.4 mg/kg/day > 70 kg: 100 mg/day
Daytrana® (methylphenidate transdermal)		One 30 mg/9-hour patch/day
Cotempla XR-ODT® (methylphenidate ER)		51.8 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s)
  - Concomitant administration of monoamine oxidase inhibitors (MAOI), or dosing within 14 days after discontinuing an MAOI
  - Concomitant administration of sensitive CYP1A2 substrates or CYP1A2 substrates with a narrow therapeutic range
- Boxed warning(s): suicidal thoughts and behaviors

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
ADHD	Age 6 to 11 years: Initial daily dose: 100 mg. May titrate in increments of 100 mg weekly to the target daily dosage of 400 mg Age 12 to 17 years: Initial daily dose: 200 mg. After 1 week, may titrate by an increment of 200 mg to target daily dose of 400 mg Capsules may be swallowed whole or opened and the entire contents sprinkled onto applesauce	400 mg/day

VI. Product Availability

Extended-release capsules: 100 mg, 150 mg, 200 mg

VII. References

1. Qelbree Prescribing Information. Rockville, MD: Supernus Pharmaceuticals, Inc.; April 2021. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/211964s000lbl.pdf. Accessed April 16, 2021.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2021. Available at: http://www.clinicalpharmacology-ip.com/.
3. American Academy of Pediatrics subcommittee on attention-deficit/hyperactivity disorder, clinical practice guideline for the diagnosis, evaluation, and treatment of attention-deficit/hyperactivity disorder in children and adolescents. Pediatrics 2019;144(4):e20192528.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	04.19.21	05.21

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of

physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.