Clinical Policy: Viloxazine (Qelbree)

Reference Number: CP.PMN.264
Effective Date: 06.01.21
Last Review Date: 05.22
Line of Business: Commercial, HIM, 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 adults and pediatric patients 6 years and older.

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.

It is the policy of health plans affiliated with Centene Corporation® 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;
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 one of the following (a or b):
   a. Pediatric members: 400 mg per day;
   b. Adults: 600 mg per day.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Currently receiving medication via Centene benefit 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 one of the following (a or b):
   a. Pediatric members: 400 mg per day;
   b. Adults: 600 mg per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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 policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid 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 for all relevant lines of business 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

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
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
Daytrana® (methylphenidate transdermal)		One 30 mg/9-hour patch/day
Cotempla XR-ODT® (methylphenidate ER)		51.8 mg/day
Adhansia XR® (methylphenidate)		6 to 17 years: 70 mg Adults: 85 mg

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 of age: 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 of age: Initial daily dose: 200 mg. After 1 week, may titrate by an increment of 200 mg to target daily dose of 400 mg Adults: Initial daily dose: 200 mg. May titrate by an increment of 200mg weekly to target daily dose of 600 mg Capsules may be swallowed whole or opened and the entire contents sprinkled onto applesauce	Pediatric members: 400 mg/day Adults: 600 mg/day

VI. Product Availability

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

VII. References

1. Qelbree Prescribing Information. Rockville, MD: Supernus Pharmaceuticals, Inc.; April 2022. Available at: https://www.supernus.com/sites/default/files/Qelbree-Prescribing-Info.pdf. Accessed May 13, 2022.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc. Updated periodically. Accessed February 7, 2022.
3. Wolraich LM, Hagan Jr JF, Allan C, et al. 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
2Q 2022 annual review: HIM line of business added; references reviewed and updated.	02.06.22	05.22
RT4: updated policy with FDA-labeled age expansion to include adults.	05.13.22	

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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.