Reference number(s)
4681-A

Initial Prior Authorization
Qelbree

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Qelbree	viloxazine extended-release

Indications

FDA-approved Indications

Qelbree is indicated for the treatment of Attention-Deficit Hyperactivity Disorder (ADHD) in adults and pediatric patients 6 years and older.

Coverage Criteria

Attention-Deficit/Hyperactivity Disorder (ADHD) or Attention Deficit Disorder (ADD)

Authorization may be granted when the patient has a diagnosis of Attention-Deficit/Hyperactivity Disorder (ADHD) or Attention Deficit Disorder (ADD) when ALL of the following criteria are met:

- The diagnosis has been appropriately documented (e.g., evaluated by a complete clinical assessment, using DSM-5, standardized rating scales, interviews/questionnaires.)
- The patient will be monitored closely for suicidal thinking or behavior, clinical worsening, and unusual changes in behavior.

- The patient meets ONE of the following:
  - The patient has experienced an inadequate treatment response to Strattera (atomoxetine).
  - The patient has experienced an intolerance to Strattera (atomoxetine).
  - The patient has a contraindication that would prohibit a trial of Strattera (atomoxetine).
  - The patient has difficulty swallowing oral capsules.

Continuation of Therapy

Attention-Deficit/Hyperactivity Disorder (ADHD) or Attention Deficit Disorder (ADD)

Authorization may be granted when the patient has a diagnosis of Attention-Deficit/Hyperactivity Disorder (ADHD) or Attention Deficit Disorder (ADD) when ALL of the following criteria are met:

- The patient has achieved or maintained improvement in their signs and symptoms of ADHD/ADD from baseline.
- The patient's need for continued therapy has been assessed within the previous year.
- The patient will continue to be monitored closely for suicidal thinking or behavior, clinical worsening, and unusual changes in behavior.

Duration of Approval (DOA)

- 4681-A: DOA: 12 months

References

1. Qelbree [package insert]. Rockville, MD: Supernus Pharmaceuticals, Inc.; April 2022.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed November 6, 2024.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 11/6/2024).
4. American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition Text Revision. Arlington, Virginia. American Psychiatric Association; 2022.
5. Wolraich ML, Hagan JF, Allan C, et al. AAP Subcommittee On Children And Adolescents With Attention-Deficit/Hyperactive Disorder. Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents. Pediatrics. 2019;144(4):e20192528.

Reference number(s)
4681-A

Document History

Written by: UM Development (RP)

Date Written: 04/2021

Revised: (RZ) 11/2021 (no clinical changes), 05/2022 (updated indication to include adult patients); (ASA) 11/2022 (added COT criteria, added criteria for prescriber to confirm diagnosis by appropriate tests and evaluations, and removed age from indication question), 11/2023 (no clinical changes); (MRS) 11/2024 (no clinical changes)

Reviewed: Medical Affairs (CHART) 04/22/2021, 12/02/2021, 05/19/2022, 12/01/2022, 11/30/2023, 11/21/2024

External Review: 05/2021, 02/2022, 06/2022 (FYI), 02/2023, 02/2024, 02/2025

CRITERIA FOR APPROVAL

1	Does the patient have a diagnosis of Attention-Deficit/Hyperactivity Disorder (ADHD) or Attention Deficit Disorder (ADD)? [If Yes, then go to 2. If No, then no further questions.]	Yes	No
2	Is this request for continuation of therapy? [If Yes, then go to 3. If No, then go to 6.]	Yes	No
3	Has the patient achieved or maintained improvement in their signs and symptoms of ADHD/ADD (Attention-Deficit/Hyperactivity Disorder or Attention Deficit Disorder) from baseline? [If Yes, then go to 4. If No, then no further questions.]	Yes	No
4	Has the patient's need for continued therapy been assessed within the previous year? [If Yes, then go to 5. If No, then no further questions.]	Yes	No
5	Will the patient continue to be monitored closely for suicidal thinking or behavior, clinical worsening, and unusual changes in behavior? [No further questions]	Yes	No
6	Has the diagnosis been appropriately documented (e.g., evaluated by a complete clinical assessment, using DSM-5, standardized rating scales, interviews/questionnaires)? [If Yes, then go to 7. If No, then no further questions.]	Yes	No
7	Will the patient be monitored closely for suicidal thinking or behavior, clinical worsening, and unusual changes in behavior?	Yes	No

	[If Yes, then go to 8. If No, then no further questions.]		
8	Has the patient experienced an inadequate treatment response to Strattera (atomoxetine)? [If Yes, then no further questions. If No, then go to 9.]	Yes	No
9	Has the patient experienced an intolerance to Strattera (atomoxetine)? [If Yes, then no further questions. If No, then go to 10.]	Yes	No
10	Does the patient have a contraindication that would prohibit a trial of Strattera (atomoxetine)? [If Yes, then no further questions. If No, then go to 11.]	Yes	No
11	Does the patient have difficulty swallowing oral capsules? [No further questions]	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS**
1.	Go to 2	Deny	Your plan only covers this drug when it is used for certain health conditions. Covered uses are Attention-Deficit/Hyperactivity Disorder (ADHD) and Attention Deficit Disorder (ADD). Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Diagnosis]
2.	Go to 3	Go to 6	
3.	Go to 4	Deny	Your plan only covers this drug if it works well for you. We have denied your request because the drug did not work well for you. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria.

			You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Continuation - Efficacy]
4.	Go to 5	Deny	Your plan only covers this drug when your doctor has reviewed your therapy within the last year and you still have a need for it. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Continuation - Reassessment]
5.	Approve, 12 Months	Deny	Your plan only covers this drug when your doctor will watch for unusual changes in your mood. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Monitoring for Behavioral Changes]
6.	Go to 7	Deny	Your plan only covers this drug when you have an assessment that shows you have Attention-Deficit/Hyperactivity Disorder (ADHD) or Attention Deficit Disorder (ADD). We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Positive Assessment]
7.	Go to 8	Deny	Your plan only covers this drug when your doctor will watch for unusual changes in your mood. We reviewed the information we

			had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Monitoring for Behavioral Changes]
8.	Approve, 12 Months	Go to 9	
9.	Approve, 12 Months	Go to 10	
10.	Approve, 12 Months	Go to 11	
11.	Approve, 12 Months	Deny	Your plan only covers this drug if you have tried Strattera (atomoxetine), and it did not work well for you. We have denied your request because: A) You have not tried it, and B) You do not have a medical reason not to take it. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Step therapy]