Pharmacy Medical Necessity Guidelines: Attention Deficit Hyperactivity Disorder (ADHD) Medications – Non-Stimulants

Effective: June 1, 2024

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Clonidine extended-release is indicated for the treatment of attention deficit hyperactivity disorder (ADHD) as monotherapy or as adjunctive therapy to stimulant medications.

Qelbree (viloxazine extended-release) capsule is a selective norepinephrine reuptake inhibitor indicated for the treatment of attention deficit hyperactivity (ADHD) in patients 6 years of age and older.

Atomoxetine (Strattera) is a selective norepinephrine reuptake inhibitor approved for the treatment of ADHD. Atomoxetine is covered without prior authorization for Tufts Health RITogether.

COVERAGE GUIDELINES

The plan may authorize coverage for a nonpreferred non-stimulant ADHD medication for Members when the following criteria are met:

Clonidine extended-release tablet

1. The Member has a documented diagnosis of attention deficit hyperactivity disorder (ADHD)

AND

2. The Member had an inadequate response, intolerance, or contraindication to ONE of the following: clonidine immediate-release, guanfacine immediate-release, guanfacine extended-release

Qelbree (viloxazine) capsule

1. The Member has a documented diagnosis of attention deficit hyperactivity disorder (ADHD)

AND

2. The Member is 6 years of age or older

AND

3. The Member had an inadequate response, intolerance, or contraindication to atomoxetine and one additional generic medication used for the treatment of ADHD

LIMITATIONS

1. Quantity limits apply as follows:

Medication Name	Quantity Limit
clonidine extended-release tablet	four tablets per day
atomoxetine capsule	two capsules per day
viloxazine capsule	100 mg: 1 capsule per day 150 mg: 2 capsules per day 200 mg: 3 capsules per day

2. Requests for brand-name products, with AB-rated generics, will be reviewed according to Brand Name criteria.
3. Samples, free goods, or similar offerings of the requested medication do not qualify for an established clinical response or exception, but will be considered on an individual basis for prior authorization.

CODES

None

REFERENCES

1. American Psychiatric Association: Diagnostic and Statistical Manual of Mental Disorders, 5th edition. Arlington, VA., American Psychiatric Association, 2013.
2. Cantwell DP. Attention deficit disorder: A review of the past 10 years. *J Am Acad Child Adolesc Psychiatry*. 1996;35:978-87.
3. Dulcan M. Practice parameters for the assessment and treatment of children, adolescents, and adults with attention deficit/hyperactivity disorder. American Academy of Child and Adolescent Psychiatry. *J Am Acad Child Adolesc Psychiatry*. 1997;36(10 Suppl):85S-121S.
4. Gibbons, C, Weiss, M. Clinical recommendations in current practice guidelines for diagnosis and treatment of ADHD in adults. *Curr Psychiatry Rep*. 2007 Oct;9(5):420-6.
5. Kapvay (clonidine) [prescribing information]. Dublin 9, Ireland: Concordia Pharmaceuticals Inc.; February 2020.
6. Pliszka S; AACAP Work Group on Quality Issues. Practice parameter for the assessment and treatment of children and adolescents with attention-deficit/hyperactivity disorder. *J Am Acad Child Adolesc Psychiatry*. 2007;46(7):894-921.
7. Qelbree (viloxazine extended-release) [prescribing information]. Rockville, MD: Supernus Pharmaceuticals, Inc; April 2022.
8. The American Academy of Pediatrics: Subcommittee on Attention-Deficit/Hyperactivity Disorder and Committee on Quality Improvement. Clinical practice guideline: treatment of the school-aged child with attention-deficit/hyperactivity disorder. Pediatrics. 2001 Oct;108(4):1033-44.
9. The American Academy Of Pediatrics: Subcommittee On Attention-Deficit/Hyperactivity Disorder, Steering Committee On Quality Improvement And Management ADHD: Clinical Practice Guideline for the diagnosis, evaluation, and treatment of attention-deficit/hyperactivity disorder in children and adolescents. Pediatrics. 2011 Nov;128(5):1-16.

APPROVAL HISTORY

October 11, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. July 11, 2023: Effective August 1, 2023, updated criteria for clonidine extended-release to include guanfacine immediate-release and extended-release formulations and previous trial options.
2. May 14, 2024: Effective June 1, 2024, updated RxUM fax number.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.