Pharmacy Medical Necessity Guidelines: Clonidine Extended-Release

Effective: July 20, 2020

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:

Commercial Products

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:
RXUM: 617.673.0988

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).

COVERAGE GUIDELINES

The plan may authorize coverage of clonidine extended-release when the following criteria are met:

1. Documented diagnosis of attention deficit hyperactivity disorder (ADHD)

AND

2. Documented failure of a course of therapy with immediate-release clonidine

LIMITATIONS

1. The coverage of clonidine ER tablet is limited to two tablets 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. Intuniv (guanfacine) [prescribing information]. Wayne, PA: Shire Pharmaceuticals; December 2019.
6. Kapvay (clonidine) [prescribing information]. St Michael, Barbados BB: Concordia Pharmaceuticals Inc.; August 2016.
7. 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.
8. Strattera (atomoxetine) [prescribing information]. Indianapolis, IN: Lilly USA, LLC; May 2017.

9. 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.
10. 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

April 14, 2015: Reviewed by Pharmacy & Therapeutics Committee; consolidated separate non-stimulant ADHD criteria; added criteria specific for Members 3 years of age and younger.

Subsequent endorsement date(s) and changes made:
1. January 1, 2016: Administrative change to rebranded template.
2. March 8, 2016: Approval duration extended to life of plan. Administrative update to remove Limitation "Requests for quantities that exceed the quantity limit will be reviewed according to the Quantity Limit criteria."
3. September 13, 2016: Added clonidine immediate release tablets, clonidine patch and guanfacine immediate release to the policy with criteria for Members 3 years of age. Updated PBHMI age limit for atomoxetime from 3 years of age to 6 years of age. Adjusted criteria for alpha agonists and Strattera for members less than 3 years and 6 years of age, respectively.
4. May 9, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether. Removed Pediatric Behavioral Health Medication Initiative (PBHMI) criteria.
5. December 12, 2017: No changes.
6. December 11, 2018: Administrative changes made to template.
7. March 12, 2019: Effective 4/1/2019, updated criteria to reflect that atomoxetine and guanfacine ER are now covered. Changed titled from "ADHD – Non-Stimulant Medications" to "Clonidine Extended-Release"
8. February 22, 2020: No changes.
9. July 14, 2020: Administrative update, added language regarding samples to the limitation section of the MNG.

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.