Pharmacy Medical Necessity Guidelines:
Anti-anxiety Medications (Benzodiazepines and Buspirone)

Effective: January 1, 2021

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

FDA-APPROVED INDICATIONS

Buspirone is indicated for the management of anxiety disorders or the short-term relief of the symptoms of anxiety.

Concomitant use of benzodiazepines and opioids cause increase the risk of respiratory depression. Additionally, per the Centers for Disease Control and Prevention (CDC), concomitant use of these two classes likely puts patients at increased risk for potentially fatal overdose. MassHealth's Concomitant Opioid and Benzodiazepine Initiative (COBI) focuses on the safe prescribing of opioid and benzodiazepine medications. As part of COBI, prior authorization is required when a member fills opioid and benzodiazepine medications together for at least 60 days in a 90-day period. Table 1. Outlines the medications that are included in COBI. **COBI applies to members of all ages.**

Table 1. Medications included in COBI

Benzodiazepines[1]	Opioids
• Alprazolam • Chlordiazepoxide • Chlordiazepoxide/clidinium • Clonazepam • Clorazepate • Diazepam[2] • Estazolam • Flurazepam • Lorazepam • Midazolam[2] • Oxazepam • Quazepam • Temazepam • Triazolam	• Buprenorphine[3] • Butorphanol • Codeine • Dihydrocodeine • Fentanyl • Hydrocodone • Hydromorphone • Levorphanol • Meperidine • Morphine • Oxycodone • Oxymorphone • Opioid powders • Tapentadol • Tramadol • Ziconotide

[1]Injectable benzodiazepine formulations are excluded from COBI requirements.
[2]Rectal diazepam and nasal midazolam formulations are excluded from the COBI requirements.
[3]Buprenorphine formulations used in the treatment of substance use disorder are not included in COBI.

The MassHealth Pediatric Behavioral Health Medication Initiative (PBHMI) has been implemented to encourage safe prescribing of behavioral health medication regimens in members less than 18 years of age. As part of the PBHMI, a prior authorization is required for pediatric members less than 6 years of age who are being prescribed a benzodiazepine or buspirone, regardless as to whether the medication

is preferred on the Plan's formulary. Table 2 lists the anti-anxiety medications that are included in the PBHMI. Of note, **short-acting intramuscular injectable and intravenous formulations are excluded from the Pediatric Behavioral Health Medication initiative requirements.**

Table 2. Anxiety Medications the PBHMI

Drug Name	Generic Name	For members < 6 years of age	For members ≥ 6 years of age
Alprazolam tablet	Alprazolam	PA	Covered
Alprazolam ER	Alprazolam extended-release	PA	Covered
Alprazolam Intensol	Alprazolam oral concentrate	PA	Covered
Alprazolam ODT	Alprazolam orally disintegrating tablet	PA	Covered
Buspirone	Buspirone	PA	5 mg, 7.5 mg, 10 mg, 15 mg: covered 30 mg: PA
Chlordiazepoxide	Chlordiazepoxide	PA	Covered
Chlordiazepoxide/amitriptyline	Chlordiazepoxide/amitriptyline	Not Covered	Not Covered
Clonazepam	Clonazepam	PA	Covered
Clorazepate	Clorazepate	PA	Covered
Diazepam	Diazepam	PA	Covered
Diazepam Intensol	Diazepam oral concentrate	PA	Covered
Lorazepam	Lorazepam	PA	Covered
Lorazepam Intensol	Lorazepam oral concentrate	PA	Covered
Meprobamate	Meprobamate	Not Covered	Not Covered
Midazolam	Midazolam	Not Covered	Not Covered
Oxazepam	Oxazepam	PA	Covered

COVERAGE GUIDELINES

In addition to medication-specific prior authorization criteria, the Plan may authorize coverage of a preferred or non-preferred anti-anxiety medication for Members less than 6 years of age when **all** the following criteria are met:

Age-Specific Criteria

Benzodiazepine for Members less than 6 years of age:

1. Member has one of the following:
   a) Recent psychiatric hospitalization (within the last three months)

   OR

   b) History of severe risk of harm to self or others

   OR

   c) A seizure diagnosis only

   OR

   Member has all of the following:
   a) An appropriate diagnosis

   AND

   b) Treatment plan, including the names of current behavioral health medications and corresponding indications

AND

c) Prescriber is a specialist (e.g., neurologist, psychiatrist) or a consult is provided

Concomitant Opioid and Benzodiazepine Initiative (COBI) Prior Authorization Requirements

The Plan may authorize coverage of a benzodiazepine when it has been used concomitantly with opioids for at least 60 days in a 90 days period when the following criteria are met:

1. Documentation of appropriate diagnosis of the benzodiazepine

AND

2. Documentation of appropriate diagnosis of the opioid

AND

3. Documentation of one of the following:
    a. If the benzodiazepine is being used for a psychiatric diagnosis, an inadequate response or adverse reaction to three antidepressants, or contraindication to all antidepressants

    OR

    b. If the benzodiazepine is being used for a musculoskeletal diagnosis, an inadequate response or adverse reaction to three skeletal muscle relaxants (e.g., cyclobenzaprine, chlorzoxazone, metaxalone, methocarbamol, orphenadrine) or a contraindication to all skeletal muscle relaxants

    OR

    c. If the benzodiazepine is being used for a sleep disorder, an inadequate response or adverse reaction to three non-benzodiazepine sleep medications, or a contraindication to all non-benzodiazepine sleep medications

    OR

    d. If the benzodiazepine is being used for a seizure disorder, member is stable on a non-benzodiazepine anticonvulsant

    OR

    e. Treatment plan to taper off or taper down from benzodiazepine therapy

    OR

    f. Treatment plan to taper off opioid therapy

    OR

    g. Clinical rationale for the concomitant use of opioids and benzodiazepines

AND

4. Documentation that member will be co-prescribed naloxone

Buspirone or Meprobamate for Members less than 6 years of age:

1. Member has one of the following:
    a) Recent psychiatric hospitalization (within the last three months)

    OR

    b) History of severe risk of harm to self or others

    OR

    Member has all of the following:
    a) An appropriate diagnosis

    AND

    b) Treatment plan, including the names of current behavioral health medications and corresponding diagnoses

    AND

    c) Prescriber is a specialist (e.g., neurologist, psychiatrist) or a consult is provided

Medication-Specific Criteria

The plan may authorize coverage of a non-preferred anti-anxiety medication for Members 6 years of age or older when all of the following criteria are met. If the Member is less than 6 years of age, the age-specific criteria listed above must be met first in addition to the medication-specific criteria listed below:

Buspirone 30 mg tablets:

1. The Member had an inadequate response to or the provider indicates clinical inappropriateness of therapy with two 15 mg buspirone tablets

Reauthorization Criteria for Buspirone and PBHMI Age-Limit Requests:

1. The Member had an office visit in the past year, was reassessed for the condition, and continued therapy with the medication is considered medically necessary.

LIMITATIONS

1. The length of approval for buspirone and PBHMI requests will be for 2 years.
2. The length of approval for COBI requests will be for 1 year. COBI reauthorization requests will be reviewed against the initial COBI criteria.
3. Non-covered antianxiety medications reviewed under the PBHMI criteria for members less than 6 years age will also be reviewed according to the Noncovered Medications criteria.
4. Requests for members exceeding the PBHMI polypharmacy limits will also be reviewed against the PBHMI polypharmacy criteria.
5. 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. Buspar (buspirone) [prescribing Information] Princeton, NJ; Bristol-Myers Squibb; November 2010.
2. National Collaborating Centre for Mental Health, National Collaborating Centre for Primary Care. Generalised anxiety disorder and panic disorder (with or without agoraphobia) in adults. Management in primary, secondary and community care. London, UK: National Institute for Health and Clinical Excellence (NICE); 2011.
3. Bandelow B, Sher L, Bunevicius R, Hollander E., Siegfried K. Guidelines for the pharmacological treatment of anxiety disorders, obsessive – compulsive disorder and posttraumatic stress disorder in primary care. International Journal of Psychiatry in Clinical Practice 2013: 16: 77-84.
4. Meprobamate [prescribing information]. Bridgewater, NJ: Alembic Pharmaceuticals; March 2019.
5. MassHealth. MassHealth Concomitant Opioid and Benzodiazepine Initiative. Available at: https://masshealthdruglist.ehs.state.ma.us/MHDL/pubdownloadpdfcurrent.do?id=5066. Accessed 10 June 2020.

APPROVAL HISTORY

June 9, 2015: Reviewed by Pharmacy & Therapeutics Committee; incorporated criteria for buspirone and established drug-specific criteria for meprobamate; added criteria for Members less than 6 years of age.

Subsequent endorsement date(s) and changes made:

1. September 15, 2015: Approval duration modified to life of plan for Members less than 6 years of age and for buspirone. Approval duration modified to 2 years for meprobamate.
2. January 1, 2016: Administrative change to rebranded template.
3. September 13, 2016: Modified approval criteria for members less than 6 years of age. Added benzodiazepines falling under the PBHMI to the policy.
4. May 9, 2017: Administrative update, Adding Tufts Health RITogether to the template.
5. December 12, 2017: No changes.
6. December 11, 2018: Administrative updates made to template.
7. October 15, 2019: Administrative update, added to limitations section of the MNG that requests for members exceeding the PBHMI polypharmacy limits will also be reviewed against the PBHMI polypharmacy criteria.
8. April 14, 2020: Effective July 1, 2020, removed medication-specific criteria for meprobamate from the MNG, as it is Not Covered. Clarified renewal criteria so that it applies to all agents in the MNG.
9. July 14, 2020: Administrative update, added language concerning samples to the limitations section of the MNG.
10. August 11, 2020: Effective January 1, 2021, added criteria for Concomitant Opioid and Benzodiazepine Initiative (COBI) to the MNG. Updated the title of the MNG from "Antianxiety Medications" to "Antianxiety Medications (Benzodiazepines and Buspirone)".

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.