Pharmacy Medical Necessity Guidelines: Pediatric Behavioral Health Medication Initiative (PBHMI) - Polypharmacy

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

The goal of the MassHealth Pediatric Behavioral Health Medication Initiative (PBHMI) is to encourage safe prescribing of behavioral health medication regimens in members less than 18 years of age. As part of the PBHMI, prior authorization is required when a child is on different behavioral health medications. The medications in the table below are included in the PBHMI. Of note, this policy addresses the polypharmacy component of the PBHMI. There are also criteria in place for age limit restrictions. That criteria can be found in the medication class's respective Medical Necessity Guideline and must be met in additional to the polypharmacy criteria listed in this policy.

Alpha-2 Agonists		
Clonidine IR/ER/patch	Guanfacine IR/ER	
Antidepressants		
Amitriptyline	Fluoxetine	Phenelzine
Amoxapine	Fluvoxamine	Proptriptyline
Bupropion	Imipramine	Selegeline*
Citalopram	Isocarboxazid	Sertraline
Clomipramine	Levomilnacipran	Tranylcypromine
Desipramine	Maprotline	Trazodone
Desvenlafaxine	Mirtazapine	Trimipramine
Doxepin	Nefazodone	Venlafaxine
Duloxetine	Nortriptyline	Vilazodone
Escitalopram	Paroxetine	Vortioxetine
Esketamine		
Mood Stabilizers		
Brivaracetam	Gabapentin	Pregabalin
Cannabidiol	Lacosamide	Primidone
Carbamazepine	Lamotrigine	Rufinamide
Cenobamate	Levetiracetam	Stiripentol
Clobazam	Lithium	Tiagabine
Divalproex	Methsuximide	Topiramate
Eslicarbazepine	Oxcarbazepine	Valproic acid
Ethosuximide	Perampanel	Vigabatrin
Ethotoin	Phenytoin	Zonisamide
Felbamate		
Stimulants and Atomoxetine**		
Amphetamine	Dexmethylphenidate	Lisdexamfetamine
Amphetamine sulfate	Dextroamphetamine	Methamphetamine
Atomoxetine	Dextroamphetamine/	Methylphenidate

	amphetamine	
Antianxiety Agents		
Alprazolam Buspirone Chlordiazepoxide Chlordiazepoxide/amitriptyline	Clonazepam Clorazepate Diazepam† Lorazepam	Meprobamate Midazolam Oxazepam
Antipsychotics		
Aripiprazole Asenapine Brexpiprazole Cariparazine Chlorpromazine Clozapine Fluphenazine Haloperidol Iloperidone	Loxapine Lumateperone Lurasidone Molindone Olanzapine Olanzapine/fluoxetine Paliperidone Perphenazine Perphenazine/amitriptyline	Pimozide Prochlorperazine Quetiapine Risperidone Thioridazine Thiothixene Trifluoroperazine Ziprasidone
Hypnotics		
Doxepin‡ Estazolam Eszopiclone Flurazepam	Lemborexant Quazepam Suvorexant Temazepam	Triazolam Zaleplon Zolpidem
Miscellaneous		
Armodafinil Atmoxetine	Donepezil Memantine	Modafinil Naltrexone†

*Emsam (selegiline) is the only selegiline formulation included in the Pediatric Behavioral Health Medication Initiative.

** Immediate-release and extended-release formulations of the same chemical entity are counted as one.

†Rectal diazepam and nasal midazolam formulations are excluded from the Pediatric Behavioral Health Medication Initiative requirements.

†Injectable naltrexone (Vivitrol) is not included.

‡Silenor (doxepin) is classified as a hypnotic agent and the Pediatric Behavioral Health Medication Initiative requirements for antidepressants do not apply. Instead, Pediatric Behavioral Health Medication Initiative requirements for hypnotics apply.

COVERAGE GUIDELINES

In addition to **medication-specific criteria** and **age limit criteria**, the Plan may authorize coverage of a preferred or non-preferred medication when the following criteria are met:

Behavioral Health Medication Polypharmacy

Pharmacy claims for any combination of four or more behavioral health medications (i.e., alpha2 agonists, antidepressants, antipsychotics, atomoxetine, benzodiazepines, buspirone, cerebral stimulants, hypnotic agents, and mood stabilizers) within a 45-day period for members less than 18 years of age

For members on ≤ 2 mood stabilizers (including regimens that do not include a mood stabilizer):

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

2. Member has all of the following:
    a. Appropriate diagnoses

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

For members on ≥ 3 mood stabilizers:

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

2. Member has all of the following:
   a. Appropriate diagnoses

   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

   AND

   d. One of the following:
      i. Member has a seizure diagnosis only

      OR

      ii. Member has an appropriate psychiatric diagnosis and one of the following:
         1. Cross-titration/taper of mood stabilizer therapy

         OR

         2. An inadequate response or adverse reaction to two monotherapy trials and/or multiple combination trials as clinically appropriate

      OR

      iii. Member has diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain) and documentation that other clinically appropriate therapies have been tried and failed; therefore, multiple mood stabilizers are needed

      OR

      iv. Member has psychiatric and comorbid diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain) and documentation that other clinically relevant therapies have been tried and failed; therefore, multiple mood stabilizers are needed, **and** one of the following
         1. Cross-titration/taper of mood stabilizer therapy

         OR

         2. Inadequate response or adverse reaction to two monotherapy trials and/or multiple combination therapy trials as clinically appropriate

Antidepressant Polypharmacy

Overlapping pharmacy claims for ≥ 2 antidepressants for at least 60 days within a 90 day period for members < 18 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

2. Member has all of the following:
   a. Appropriate psychiatric diagnosis

AND

   b. Treatment plan including names of current antidepressants and corresponding diagnoses

AND

   c. Prescriber is a psychiatrist or a consult is provided

AND

   d. One of the following:
      i. Cross-titration/taper of antidepressant therapy

OR

      ii. Inadequate response (defined as four weeks of therapy) or adverse reaction to two monotherapy trials as clinically appropriate

OR

      iii. Antidepressant polypharmacy regimen of ≤ 2 antidepressants includes one of the following: bupropion, mirtazapine, or trazodone

OR

      iv. One antidepressants in the regimen is indicated for a comorbid condition in which antidepressants may be clinically appropriate

Antipsychotic Polypharmacy

Overlapping pharmacy claims for ≥ 2 or more antipsychotics (includes 1st generation and/or 2nd generation antipsychotics) for at least 60 days within a 90 day period for members less than 18 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

2. Member has all of the following :
   a. Treatment plan include name, dose, and frequency of all current behavioral health medications, associated targeted symptom(s), and behavioral health diagnoses

AND

   b. A comprehensive behavioral health plan (i.e., non-pharmacologic interventions) is in place

AND

   c. Prescriber is a psychiatrist or consult is provided

AND

   d. Stage of treatment is acute, maintenance, or discontinuation

AND

   e. One of the following:
      i. For **acute stage** (initiation of antipsychotic treatment likely with subsequent dose adjustments to maximize response and minimize side effects), one of the following:

1. Cross-titration/taper of antipsychotic therapy

OR

2. Inadequate response or adverse reaction to two monotherapy trials as clinically appropriate

OR

ii. For **maintenance stage** (response to antipsychotic treatment with goal of remission or recovery), all of the following:
   1. Regimen is effective, therapy benefits outweigh risks, and appropriate monitoring is in place

AND

   2. If member has been on the antipsychotic regimen for the past 12 months, clinical rationale for extended therapy including at least one of the following:
      a. Previous efforts to reduce/simplify the antipsychotic regimen in the past 24 months results in symptom exacerbation

OR

      b. Family/caregiver does not support the antipsychotic regimen change at this time due to risk of exacerbation

OR

      c. Other significant barrier for antipsychotic therapy discontinuation

OR

iii. For **discontinuation stage** (clinically indicated that the antipsychotic regimen can likely be successfully tapered), cross-titration/taper of antipsychotic therapy

Benzodiazepine Polypharmacy

Overlapping pharmacy claims for two or more benzodiazepines (does not include hypnotic benzodiazepine agents and rectal diazepam) for at least 60 days within a 90 days period for members less than 18 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. Member has a seizure diagnosis only

OR

2. Member has all of the following:
   a. Appropriate diagnosis

AND

   b. Treatment plan, including names of current benzodiazepines and corresponding diagnoses

AND

   c. One of the following:
      i. Cross-titration/taper of benzodiazepine therapy

OR

      ii. Clinical rationale for use of two benzodiazepines of different chemical entities

Cerebral Stimulants

Overlapping pharmacy claims for two or more cerebral stimulants (immediate-release and extended-release formulations of the same chemical entity are counted as one) for at least 60 days within a 90-day period for members less than 18 years of age

1. Member has <u>one</u> 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

2. Member has <u>all</u> of the following:
    a. An appropriate diagnosis

AND

    b. Treatment plan, including names of current cerebral stimulants and corresponding diagnoses

AND

    c. Inadequate response (defined as more than 7 days of therapy), adverse reaction, or contraindication to monotherapy trial with methylphenidate product

AND

    d. Inadequate response (defined as more than 7 days of therapy), adverse reaction, or contraindication to monotherapy trial with an amphetamine product

AND

    e. Clinical rationale for cerebral stimulant polypharmacy

<u>Mood Stabilizer Polypharmacy</u>

Overlapping pharmacy claims for three or more mood stabilizers for at least 60 days within a 90 day period for members < 18 years old

For members with a seizure diagnosis <u>only</u>:

1. Appropriate diagnosis (seizure) without comorbid condition

For members with psychiatric diagnoses:

1. Member has <u>one</u> 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

2. Member has <u>all</u> of the following:
    a. Appropriate psychiatric diagnoses

AND

    b. Treatment plan including names of current mood stabilizers and corresponding diagnoses

AND

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

AND

    d. One of the following:
        i. Cross-titration/taper of mood stabilizer therapy

OR

ii. Inadequate response or adverse reaction to two monotherapy trials and/or multiple combination therapy trials as clinically appropriate

For members with a diagnosis in which mood stabilizers may be clinically appropriate (e.g. migraine, neuropathic pain):

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

2. Member has all of the following:
   a. Appropriate diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain)

   AND

   b. Treatment plan including names of current mood stabilizers and corresponding diagnoses

   AND

   c. Documentation that other clinically appropriate therapies have been tried and failed; therefore, multiple mood stabilizers are needed

For members with a psychiatric diagnosis and comorbid diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain)

3. 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

4. Member has all of the following:
   a. Psychiatric diagnosis and diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain)

   AND

   b. Treatment plan including names of current mood stabilizers and corresponding diagnoses

   AND

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

   AND

   d. Documentation that other clinically relevant therapies have been tried and failed; therefore, multiple mood stabilizers are needed

   AND

   e. One of the following:
      i. Cross-titration/taper of mood stabilizer therapy

      OR

      ii. Inadequate response or adverse reaction to two monotherapy trials and/or multiple combination therapy trials as clinically appropriate

LIMITATIONS

1. Individual drug prior authorization criteria must also be met, when applicable.
2. Length of approval for each medication is dependent on the length of approval outlined in the Medical Necessity Guideline for the medication's therapeutic class.
3. Age limit prior authorization criteria must also be met.
4. Requests for brand-name products, which have AB-rated generics, will be reviewed according to Non-covered Medications 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. MassHealth. Pediatric Behavioral Health Medication Initiative (PBHMI) Information. Available at: mass.gov/info-details/pediatric-behavioral-health-medication-initiative-pbhmi-information. Accessed 3 January 2020.

APPROVAL HISTORY

March 14, 2017: Reviewed by Pharmacy & Therapeutics Committee

1. May 9, 2017: Administrative update, Adding Tufts Health RITogether to the template.
2. June 12, 2018: Updated criteria for mood stabilizer polypharmacy. Updated Limitations section to indicate that length of approval is dependent on the length of approval outlined in the Medical Necessity Guideline for the medication's therapeutic class.
3. June 11, 2019: Administrative changes made to template.
4. January 14, 2020: Added brivaracetam, cannabidiol, esketamine, and stiripentol to the list of medications falling under the PBHMI polypharmacy program. Removed ezogabine from the list of medications falling under the PBHMi polypharmacy program. Specified that nasal midazolam formulations are not included in the PBHMI program.
5. July 14, 2020: Administrative update, added language regarding samples to the limitations section of the MNG.
6. September 15, 2020: Effective 1/1/2021, added the following agents to the list of medications falling under the PBHMI polypharmacy program: armodafinil, cenobamate, donepezil, lemborexant, lumateperone, memantine, modafinil, naltrexone, quazepam.

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.

Provider Services