BOSTON MEDICAL CENTER HEALTHNet PLAN

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Pharmacy Policy

Pediatric Behavioral Health Medication Initiative

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Product Applicability	☐ **All Plan+ Products**
Well Sense Health Plan	**Boston Medical Center HealthNet Plan**
☐ New Hampshire Medicaid	☒ MassHealth - MCO
	☒ MassHealth - ACO
	☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct
	☐ Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Policy Summary

The Plan will authorize coverage of specific behavioral health medications for pediatric use when appropriate criteria are met.

Description of Item or Service

As part of the Pediatric Behavioral Health Medication (PBHM) Initiative, prior authorization is required for pediatric members (i.e. members less than 18 years old) for a select number of behavioral health medication classes where there is insufficient evidence for effectiveness and safety in the pediatric population. Evidence-based and age appropriate psychosocial treatments should be tried prior to psychopharmacologic treatments in pediatric patients as clinically appropriate. Pharmacological treatments should be limited to patients who have not responded to psychological treatment and if benefits outweigh the risks associated with treatment.

+ *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

Approval Criteria: **New Start or Continuation of Therapy Request for Antipsychotic polypharmacy** *(overlap of 60 days or more of ≥2 antipsychotics excluding short-acting injectable formulations within a 90 day period)*	Prescriber provides of documentation of **ONE** of the following: a. **ALL** of the following: 1. Treatment plan including name, dose and frequency of all current behavioral health medications, associated target symptom(s), and behavioral health diagnoses 2. Comprehensive behavioral health plan (i.e. non-pharmacologic interventions) is in place 3. Prescriber is a psychiatrist or psychiatry consult was provided 4. **ONE** of the following stages of treatment: a. **Acute:** initiation of antipsychotic treatment likely with subsequent dose adjustments to maximize response and minimize side effects b. **Maintenance:** response to antipsychotic treatment with goal of remission or recovery c. **Discontinuation:** clinically indicated that the antipsychotic regimen can likely be successfully tapered. 5. **If acute stage**, **ONE** of the following: a. Cross-titration/taper of antipsychotic therapy b. Inadequate response or adverse reaction to two monotherapy trials as clinically appropriate (include trial duration with dates of use as documented on request or in claims history, if available. 6. **If maintenance stage**, regimen is effective, therapy benefits outweigh risks, and appropriate monitoring is in place. i. **If member has been on the antipsychotic regimen for the past 12 months,** clinical rationale for extended therapy to include at least **ONE** of the following: a. Previous efforts to reduce/simplify the antipsychotic regimen in the past 24 months resulted in symptom exacerbation b. Family/caregiver does not support the antipsychotic regimen change at this time due to risk of exacerbation c. Other significant barrier for antipsychotic therapy discontinuation 7. **If discontinuation stage**, cross-titration or taper of antipsychotic therapy b. ***If above criteria is not met and the prescriber documents a recent psychiatric hospitalization (within the last 3 months) OR history of severe risk of harm to self or others,** please APPROVE the antipsychotic regimen (without any other requirements) for **3 months (or for duration requested if shorter)** *Notes:* • *Member needs to meet all criteria for the requested agent as specified in the respective medication class guideline, if applicable.* • *New Start defined as: antipsychotic naïve, antipsychotic for a new psychiatric*

	episode, switch to a different antipsychotic therapy • *Continuation of Therapy defined as: member new to MassHealth and continuing therapy from a previous insurer, extension of therapy past the acute phase of treatment*
Approval Criteria: **Antidepressant polypharmacy** *(overlap of 60 days or more of ≥2 antidepressants within a 90 day period; excludes esketamine) Please note, a regimen of 2 antidepressants in which one or both are bupropion, mirtazapine, or trazodone does not require PA for polypharmacy under the PBHMI. Any regimen of three or more antidepressants will require PA.*	Prescriber provides of documentation of **ONE** of the following: a. **ALL** of the following: 1. Psychiatric diagnosis(es) including treatment-resistant conditions 2. Treatment plan including names of current antidepressants and corresponding diagnoses 3. Prescriber is a psychiatrist or psychiatry consult was provided 4. **ONE** of the following: a. Cross-titration/taper of antidepressant therapy b. Inadequate response (defined as 4 weeks of therapy) or adverse reaction to two monotherapy trials as clinically appropriate (include trial duration with dates of use as documented on request or in claims history, if available) c. One antidepressant in the regimen is indicated for a comorbid condition (e.g., migraines [TCAs, venlafaxine], neuropathic pain [duloxetine, TCAs, venlafaxine], obsessive compulsive disorder [clomipramine], refractory enuresis [imipramine]) b. ******If above criteria is not met and the prescriber documents a recent psychiatric hospitalization (within the last 3 months) OR history of severe risk of harm to self or others,*** please APPROVE the antidepressant regimen (without any other requirements) for **3 months (or for duration requested if shorter)** *Notes:* • *Member needs to meet all criteria for the requested agent as specified in the respective medication class guideline, if applicable.* • *Please note a regimen of 2 antidepressants in which one or both are bupropion, mirtazapine, or trazodone does not require PA for polypharmacy under the PBHMI. Any regimen of three or more antidepressants will require PA. Please see appendix for details.* • *A regimen containing an oral antidepressant plus Spravato® (esketamine) will not require PA for polypharmacy. Spravato® (esketamine) is indicated to be used in conjunction with an oral antidepressant. Member needs to meet all criteria for the requested agent as specified in the respective medication class guideline.*

Approval Criteria: **Cerebral Stimulant polypharmacy** *(overlap of 60 days or more of ≥2 stimulants [immediate-release and extended-release formulations of the same chemical entity are counted as one] within a 90 day period)*	Prescriber provides documentation of **ONE** of the following: a. **ALL** of the following: 1. Diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) or hyperactivity associated with Autism Spectrum Disorder (ASD) 2. Treatment plan including names of current cerebral stimulants and corresponding diagnoses 3. **ALL** of the following: 1. Inadequate response (defined as ≥7 days of therapy in all claims history), adverse reaction, or contraindication to methylphenidate monotherapy 2. Inadequate response (defined as ≥7 days of therapy in all claims history), adverse reaction, or contraindication to amphetamine monotherapy 3. Rationale for cerebral stimulant polypharmacy (use of a methylphenidate agent in combination with an amphetamine agent) b. ***** If above criteria is not met and prescriber documents a recent psychiatric hospitalization (within last the 3 months) OR history of severe risk of harm to self or others,** please APPROVE the stimulant regimen (without any other requirements) for **3 months (or for duration requested if shorter)** *Notes:* • *Member needs to meet all criteria for the requested agent as specified in the respective medication class guideline, if applicable.* • *Please refer to Appendix Table II for additional information regarding which stimulants are considered immediate-release and extended-release formulations of the same chemical entity.*
Approval Criteria: **Mood stabilizer (lithium, anticonvulsants) polypharmacy** *(overlap of 60 days or more of ≥3 mood stabilizers [does not include nasal diazepam, rectal diazepam, or nasal midazolam] within a 90 day period)*	Prescriber provides documentation of **ONE** of the following: a. Member has **ONE** of the following: a. **If the member has a seizure diagnosis only**, then all requested mood stabilizer(s) may be approved b. **If the member has a psychiatric diagnosis only,** then review the medication regimen with the criteria listed in section A below c. **If the member has only a diagnosis in which mood stabilizer(s) may be clinically appropriate (e.g., migraine, neuropathic pain),** then review the medication regimen with the criteria listed in section B below d. **If the member has a seizure diagnosis AND a psychiatric diagnosis**, then subtract one anticonvulsant* from the total mood stabilizer regimen if it is listed under the column "Seizure Indications" in Appendix Table I: i. If the mood stabilizer total is ≤2, then all requested mood stabilizer(s) may be approved ii. If the mood stabilizer total is ≥3, then review the medication regimen with the criteria listed in section A below e. **If the member has a seizure diagnosis AND a diagnosis in which mood**

stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain), then subtract one anticonvulsant* from the total mood stabilizer regimen if it is listed under the column "Seizure Indications" in Appendix Table I:

i. If the mood stabilizer total is ≤2, then all requested mood stabilizer(s) may be approved
ii. If the mood stabilizer total is ≥3, then review the medication regimen with the criteria listed in section B below

f. **If the member has a psychiatric diagnosis AND a diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain)**, then review the medication regimen with the criteria listed in sections A and B below

g. **If the member has a seizure AND psychiatric diagnosis AND a diagnosis in which a mood stabilizer may be clinically appropriate (e.g., migraine, neuropathic pain)**, then subtract one anticonvulsant* from the total mood stabilizer regimen if it is listed under the column "Seizure Indications" in Appendix Table I:

i. If the mood stabilizer total is ≤2, then all requested mood stabilizer(s) may be approved
ii. If the mood stabilizer total is ≥3, then review the medication regimen with the criteria listed in sections A and B below

b. ***** If above criteria is not met and prescriber documents a recent psychiatric hospitalization (within the last 3 months) OR history of severe risk of harm to self or others,** please APPROVE the mood stabilizer regimen (without any other requirements) for **3 months (or for duration requested if shorter)**

**This anticonvulsant will not be included in the behavioral health medication total, which identifies polypharmacy (claims for 4 or more behavioral health medications in the last 45 days).*

Section A: Criteria for psychiatric diagnoses

Prescriber provides documentation of **ALL** of the following:

1. Treatment plan including names of current mood stabilizers and corresponding diagnoses
2. Prescriber is a specialist (e.g., psychiatrist, neurologist) or specialist consult was provided
3. **ONE** of the following:
    a. Cross-titration/taper of mood stabilizer therapy
    b. Inadequate response or adverse reaction to two monotherapy trials and/or multiple combination therapy trials as clinically appropriate (include trial duration with dates of use as documented on request or in claims history, if available)

	<u>Section B: Criteria for diagnoses in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain)</u> Prescriber provides documentation of **ALL** of the following: 1. Treatment plan including names of current mood stabilizers and corresponding diagnoses 2. **The mood stabilizer total is ≥3** and the prescriber provides documentation that other clinically relevant therapies for the diagnosis (e.g., migraine, neuropathic pain) have been tried and failed; therefore, multiple mood stabilizers are needed to treat the member's condition ○ *Notes:* • *If the member has a comorbid seizure diagnosis, and the prescriber documents that multiple mood stabilizers are specifically being used for seizure control, then the mood stabilizer regimen may be approved.* • *If the member has a comorbid psychiatric diagnosis and other diagnoses in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain), the request may be approved if member meets the requirements of the criteria listed in section A or B above, if clinically appropriate. Please review these requests on a case-by –case basis and/or consult with a clinical reviewer.* • *Member needs to meet all criteria for the requested agent as specified in the respective medication class guideline, if applicable.*
Approval Criteria: **Benzodiazepine polypharmacy** *(overlap of 60 days or more of ≥2 benzodiazepines [does not include hypnotic agents, nasal diazepam, rectal diazepam, or nasal midazolam] within a 90 day period)*	Prescriber provides documentation of **ONE** of the following: a. **If the member has a seizure diagnosis only,** then all requested benzodiazepine(s) may be approved without additional documentation b. **ALL** of the following: 1. Clinically appropriate diagnosis (e.g., anxiety, panic disorder, insomnia, agitation, skeletal muscle pain) 2. Treatment plan including names of current benzodiazepines and corresponding diagnoses 3. **ONE** of the following: a. Cross-titration/taper of benzodiazepine therapy b. Compelling rationale for use of ≥2 benzodiazepines of different chemical entities (e.g., lorazepam and clonazepam) c. ***** If above criteria is not met and prescriber documents a recent psychiatric hospitalization (within the last 3 months) OR history of severe risk of harm to self or others,** please APPROVE the benzodiazepine regimen (without any other requirements) for **3 months (or for duration requested if shorter)** *Notes:* • *Member needs to meet all criteria for the requested agent as specified in the respective medication class guideline, if applicable.* • *If the prescriber rationale for use of ≥2 benzodiazepines of different chemical*

	entities includes the need for a long-acting benzodiazepine to target insomnia, prescriber outreach to discuss use of non-benzodiazepine agents (e.g., melatonin [comorbid ADHD, insomnia without comorbid psychiatric diagnosis], clonidine [comorbid ADHD], trazodone) or treatment of the underlying comorbidity (e.g., anxiety, depression) will need to be attempted.
Approval Criteria: **Antidepressant, armodafinil, benzodiazepine, buspirone, donepezil, memantine, modafinil, mood stabilizer, or naltrexone (excluding anticonvulsants indicated for seizure only) in <u>member <6 years of age</u>**	Based on the diagnoses noted for the medication(s) requested, prescriber provides documentation of **ONE** of the following: a. **If the member has a seizure diagnosis only**, then the requested anticonvulsant and/or benzodiazepine may be approved b. **If the member has a psychiatric diagnosis**, then **ALL** of the following criteria must be met: 1. Treatment plan including names of current behavioral health medications and corresponding diagnoses 2. Prescriber is a psychiatrist or psychiatry consult was provided **Please document inadequate response or adverse reaction(s) to previous clinically relevant medication trial(s) along with dates and/or duration of use as noted on the request or in claims history, if available.* c. **If the member only has a diagnosis in which an antidepressant or a mood stabilizer may be clinically appropriate (e.g., migraine, neuropathic pain)**, then **ALL** of the following criteria for the requested antidepressant or mood stabilizer must be met: 1. Treatment plan including names of current behavioral health medications and corresponding diagnoses 2. Prescriber is a specialist (e.g., psychiatrist, neurologist) or clinically appropriate specialist consult was provided **Please document inadequate response or adverse reaction(s) to previous clinically relevant medication trial(s) along with dates and/or duration of use as noted on the request or in claims history, if available.* d. **If the member has multiple comorbid conditions**, then the member must meet the criteria outlined above (#1 - 4) depending on the diagnosis, as applicable e. ***** If above criteria is not met and prescriber documents a recent psychiatric hospitalization (within the last 3 months) OR history of severe risk of harm to self or others,** please APPROVE the behavioral health medication regimen (without any other requirements) for **3 months (or for duration requested if shorter)** *Notes:* • *Member needs to meet all criteria for the requested agent as specified in the respective medication class guideline, if applicable.* • *Benzodiazepine requests for other clinically appropriate diagnoses (e.g., nausea/vomiting) may be granted an approval. Please consult with a supervisor or clinical reviewer.* • *Benzodiazepine requests for use during medical or dental procedures may be granted an approval if dosing and duration requested is appropriate. Please see appendix for additional information.* • *Anticonvulsants indicated for seizure only excluded from PBHMI age restrictions are listed in Appendix Table I*

	• *If a request indicates that naltrexone is being utilized for substance use disorder, the request can be approved as requested.*
Approval Criteria: **New start therapy request for an antipsychotic in a <u>member <6 years of age</u>**	Prescriber provides of documentation of **ONE** of the following: a. **ALL** of the following: 1. Complete medication treatment plan including name, dose and frequency of all current behavioral health medications, associated target symptom(s), and behavioral health diagnoses **Please document inadequate response or adverse reaction(s) to previous clinically relevant medication trial(s) along with dates and/or duration of use as noted on the request or in claims history, if available.* 2. Comprehensive behavioral health treatment plan (i.e., non-pharmacological interventions) is in place 3. Member is in the **acute stage** of treatment which is defined as the initiation of antipsychotic treatment with likely subsequent dose adjustments to maximize response and minimize side effects 4. Prescriber is a specialist in one of the following areas or a consult from a specialist was provided: child psychiatry, pediatric neurology, or developmental/behavioral pediatrics b. ****If above criteria is not met and prescriber documents a recent psychiatric hospitalization (within the last 3 months) OR history of severe risk of harm to self or others,** please APPROVE the behavioral health medication regimen (without any other requirements) for **3 months (or for duration requested if shorter)** *Notes:* • *Member needs to meet all criteria for the requested agent as specified in the respective medication class guideline, if applicable.* • *New start defined as: antipsychotic naïve, antipsychotic for a new psychiatric episode, switch to a different antipsychotic therapy*
Approval Criteria: **Continuation of therapy request for an antipsychotic in a <u>member <6 years of age</u>**	Prescriber provides documentation of **ONE** of the following: a. **ALL** of the following: 1. Complete medication treatment plan including name, dose and frequency of all current behavioral health medications, associated target symptom(s), and behavioral health diagnoses **Please document inadequate response or adverse reaction(s) to previous clinically relevant medication trial(s) along with dates and/or duration of use as noted on the request or in claims history, if available.* 2. Comprehensive behavioral health treatment plan (i.e., non-pharmacological interventions) is in place 3. Prescriber is a specialist in one of the following areas or a consult from a specialist was provided: child psychiatry, pediatric neurology, or developmental/behavioral pediatrics 4. **ONE** of the following stages of treatment: a. **Maintenance:** response to antipsychotic treatment with goal of remission or recovery b. **Discontinuation:** clinically indicated that the antipsychotic can likely be tapered successfully

	5. **If maintenance stage**, regimen is effective, therapy benefits outweigh risks, and appropriate monitoring is in place. i. **If the member has been on the antipsychotic regimen for the past 12 months,** need clinical rationale for extended therapy to include at least **ONE** of the following: a. Previous efforts to reduce/simplify the antipsychotic regimen in the past 12 months resulted in symptom exacerbation b. Family/caregiver does not support antipsychotic regimen change at this time due to risk of exacerbation c. Other significant barrier for antipsychotic therapy discontinuation 6. **If discontinuation stage**, cross-titration or taper of antipsychotic therapy b. ****If above criteria is not met and prescriber documents a recent psychiatric hospitalization (within the last 3 months) OR history of severe risk of harm to self or others,** please APPROVE the behavioral health medication regimen (without any other requirements) for **3 months (or for duration requested if shorter)** *Notes:* • *Member needs to meet all criteria for the requested agent as specified in the respective medication class guideline, if applicable.* • *Continuation of therapy defined as: member new to MassHealth and continuing therapy from a previous insurer, extension of therapy past the acute phase of treatment*
Approval Criteria: **Atomoxetine in <u>member <6 years of age</u>**	Based on the diagnoses noted for the medication(s) requested, prescriber provides documentation of **ONE** of the following: a. **ALL** of the following: 1. Diagnosis of ADHD 2. Treatment plan including names of current behavioral health medications and corresponding diagnoses 3. **If the member is <3 years of age**, prescriber is a psychiatrist or psychiatry consult was provided b. ***** If above criteria is not met and prescriber documents a recent psychiatric hospitalization (within the last 3 months) OR history of severe risk of harm to self or others,** please APPROVE the behavioral health medication regimen (without any other requirements) for **3 months (or for duration requested if shorter)** *Notes:* • **Please document inadequate response or adverse reaction(s) to previous clinically relevant medication trial(s) along with dates and/or duration of use as noted on the request or in claims history, if available.*
Approval Criteria:	Prescriber provides documentation of **ONE** of the following: a. **If the member has a cardiovascular diagnosis only,** then the requested

Cerebral stimulant or alpha$_2$ agonist medication in <u>member <3 years of age</u>	alpha$_2$ agonist may be approved b. **ALL** of the following: 1. Diagnosis of ADHD, hyperactivity associated with ASD, or developmental/intellectual disability 2. Treatment including name(s) of current alpha$_2$ agonist(s) or cerebral stimulant(s) and corresponding diagnoses 3. Compelling clinical rationale for stimulant or alpha$_2$ agonist use in a member <3 years of age c. ***** If above criteria is not met and the prescriber documents recent psychiatric hospitalization (within last the 3 months) OR history of severe risk of harm to self or others,** please APPROVE the stimulant/alpha agonist regimen (without any other requirements) for **3 months (or for duration requested if shorter)** *Notes:* • *Member needs to meet all criteria for the requested agent as specified in the respective medication class guideline, if applicable* • *Please document inadequate response or adverse reaction(s) to previous clinically relevant medication trial(s) along with dates and/or duration of use as noted on the request or in claims history, if available.*
Approval Criteria: **Ambien® (zolpidem)* Ambien CR® (zolpidem extended-release tablet)*, estazolam, flurazepam, Halcion® (triazolam)*, Lunesta® (eszopiclone)*, Restoril® (temazepam)* 7.5 mg, 15 mg and 30 mg and Sonata® (zaleplon)* in members <u><6 years of age</u>** **Both brand and generic require PA*	Prescriber provides documentation of **ALL** of the following: 1. Member meets all criteria for the requested agent as specified in the Hypnotic Agents guideline, if applicable. 2. **ONE** of the following: a. Diagnosis of **insomnia along *with* other behavioral health comorbidities except ADHD** (e.g., anxiety disorders, depression) b. For diagnosis of **insomnia *without* behavioral health comorbidities**, inadequate response (defined by ≥10 days of therapy), adverse reaction, or contraindication to melatonin *(History of claims in POPS is sufficient)* c. For diagnosis of **insomnia *with concomitant* ADHD**, **ALL** of the following: 1. Inadequate response (defined by ≥10 days of therapy), adverse reaction, or contraindication to melatonin *(History of POPS claims is sufficient)* 2. Inadequate response (defined by ≥10 days of therapy), adverse reaction or contraindication to clonidine *(History of POPS claims is sufficient)* 3. Treatment plan including name of current hypnotic agent and corresponding diagnosis 4. Prescriber is a specialist (e.g., psychiatrist, neurologist) or consult was provided *Notes:* • *Melatonin tablets and solution are available without prior authorization with a written prescription in members ≤18 years old.* • *A melatonin trial may be bypassed in members with an autoimmune disorder (e.g.,*

	Addison's disease, Crohn's disease, Cushing's disease, Graves' disease) as melatonin may stimulate the immune system and exacerbate these conditions. • *A clonidine trial may be bypassed in members with depression, cardiovascular disease, coronary insufficiency, renal impairment, sinus node dysfunction, conduction disturbances, or history of bradycardia as it may not be clinically appropriate in these conditions.* • *Provisional one month approvals may be granted in clinically appropriate circumstances.*
Approval Criteria: **Other Hypnotic agents in members <6 years of age: doxepin tablet, Belsomra® (suvorexant), Dayvigo® (lemborexant), quazepam, Restoril® (temazepam) 22.5 mg, and other zolpidem formulations (Edluar SL®, Intermezzo®, and Zolpimist®*)** **Agent does not participate in the federal rebate program.*	Prescriber provides documentation of **ALL** of the following: 1. Member meets all criteria for the requested agent as specified in the Hypnotic Agents guideline, if applicable 2. Treatment plan including name of current hypnotic agent and corresponding diagnosis 3. Prescriber is a specialist (e.g., psychiatrist, neurologist) or consult was provided *Notes:* • *Rozerem® (ramelteon) is excluded from the Pediatric Behavioral Health Medication Initiative.* • *Provisional one month approvals may be granted in clinically appropriate circumstances.*
Approval Criteria: **Behavioral health medication regimen with ≥4 agents (e.g., antipsychotics, antidepressants, alpha agonists, armodafinil, benzodiazepines,**	Prescriber provides documentation of **ONE** of the following: a. **ALL** of the following: 1. Multiple and/or treatment-resistant behavioral health and other non-behavioral health diagnoses where use may be clinically appropriate (e.g., migraines [TCAs, venlafaxine], neuropathic pain [duloxetine, TCAs, venlafaxine], refractory enuresis [imipramine], hypertension [alpha agonists]) 2. Treatment plan including names of current behavioral health medications and corresponding diagnoses 3. Prescriber is a specialist (e.g., psychiatrist, neurologist) or consult was provided 4. **If the requested polypharmacy regimen includes ≥1 mood stabilizer,** then follow the criteria listed below:

donepezil, hypnotic agents, memantine, modafinil, mood stabilizers, naltrexone, and stimulants) *(claims for ≥4 behavioral health medications in the last 45 days)*	i. **If the member has a seizure diagnosis only,** then all requested mood stabilizer(s) may be approved ii. **If the member has a psychiatric diagnosis only,** then evaluate the total number of mood stabilizers in the regimen: 1. If the mood stabilizer total is ≤2, then the requested mood stabilizer(s) may be approved 2. If the mood stabilizer total is ≥3, then review the medication regimen with the criteria listed in section A below iii. **If the member has a diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain) only,** then evaluate the total number of mood stabilizers in the regimen: 1. If the mood stabilizer total is ≤2, then the requested mood stabilizer(s) may be approved 2. If the mood stabilizer total is ≥3, then review the medication regimen with the criteria listed in section B below iv. **If the member has a seizure diagnosis AND a psychiatric diagnosis**, then subtract one anticonvulsant* from the total mood stabilizer regimen if it is listed under the column "Seizure Indications" in Appendix Table I: 1. If the mood stabilizer total is ≤2, then all requested mood stabilizer(s) may be approved 2. If the mood stabilizer total is ≥3, then review the medication regimen with the criteria listed in section A below v. **If the member has a seizure diagnosis AND a diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain)**, then subtract one anticonvulsant* from the total mood stabilizer regimen if it is listed under the column "Seizure Indications" in Appendix Table I: 1. If the mood stabilizer total is ≤2, then the requested mood stabilizer(s) may be approved 2. If the mood stabilizer total is ≥3, then review the medication regimen with the criteria listed in section B below vi. **If the member has a psychiatric diagnosis AND a diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain)**, then evaluate the total number of mood stabilizers in the regimen: 1. If the mood stabilizer total is ≤2, then the requested mood stabilizer(s) may be approved 2. If the mood stabilizer total is ≥3, then review the medication regimen with the criteria listed in

sections A and B below

vii. **If the member has a seizure diagnosis AND a psychiatric diagnosis AND a diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain)**, then subtract one anticonvulsant* from the total mood stabilizer regimen if it is listed under the column "Seizure Indications" in Appendix Table I:
    1. If the mood stabilizer total is ≤2, then all requested mood stabilizer(s) may be approved
    2. If the mood stabilizer total is ≥3, then review the medication regimen with the criteria listed in sections A and B below

b. ***** If above criteria is not met and the prescriber documents a recent psychiatric hospitalization (within the last 3 months) OR history of severe risk of harm to self or others,** please APPROVE the behavioral health medication regimen (without any other requirements) for **3 months (or for duration requested if shorter)**

**This anticonvulsant will not be included in the behavioral health medication total, which identifies polypharmacy (claims for 4 or more psychotropic medications in the last 45 days).*

Section A: Criteria for psychiatric diagnoses

In addition to criteria listed above (#1a-1c), prescriber provides documentation of **ONE** of the following:

1. Cross-titration/taper of mood stabilizer therapy
2. Inadequate response or adverse reaction to two monotherapy and/or multiple combination therapy trials as clinically appropriate (include trial duration with dates of use as documented on request or in claims history, if available)

Section B: Criteria for diagnoses in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain)

In addition to criteria listed above (#1a-1c), prescriber provides documentation that other clinically relevant therapies for the diagnosis (migraine and/or neuropathic pain) has been tried and failed; therefore, multiple mood stabilizers are needed to treat the member's condition.

Notes:

- *If the member has a comorbid seizure diagnosis, and the prescriber documents that multiple mood stabilizers are specifically being used for seizure control, then the mood stabilizer regimen may be approved.*
- *If the member has a comorbid psychiatric diagnoses and other diagnoses in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain), the request may be approved if member meets requirements of section A or B above, if clinically appropriate. Please review these requests on a case-by -case*

	basis. *Additional Notes:* • *Member needs to meet all criteria for the requested agent as specified in the respective medication class guideline, if applicable.* • *If a request indicates that naltrexone is being utilized for substance use disorder, the request can be approved as requested.*
Denial Criteria:	Please refer to table/flowchart below for PBHMI clinical situations and the respective durations of approval, and denial scenarios
	Prescriber and pharmacy outreach via telephone will be attempted on all prior authorization denials to explain the decision and offer emergency supplies. Pharmacy outreach is based on clinical judgement (e.g., evidence of therapy stabilization).
	If a request is denied and the prescriber has additional clinical documentation, a new prior authorization request must be submitted.
Duration/ Quantity of Authorization	Please refer to table below for PBHMI clinical situations and the respective durations of approval and denial scenarios.

Special Cases	
Clinical Situation	**Duration of Approval**
• Requested regimen does not require PA but is rejecting at the pharmacy (e.g., due to past claims history for a discontinued medication)	3 months
• Member has TPL • TPL ≥ 60% and does NOT meet approval criteria	3 months
• Member has TPL • TPL ≥ 60% and meets approval criteria	Varies (see full criteria met)
• Member has TPL • TPL <60%	Varies (follow below guidance)
Full Criteria Met	
Clinical Situation	**Duration of Approval**
• No cross-taper planned	12 months
• No cross-taper planned • Regimen includes any of the following: o Antipsychotic polypharmacy o Regimen with ≥6 medications o Regimen includes clozapine o Antidepressant in age <6 o Mood stabilizer in age <6 (excluding seizures only) o Antipsychotic in age <8 o Member is <3 years of age	6 months
• Cross-taper planned that will result in a regimen that regimen **will NOT require PA** through PBHMI if successful	3 months
• Cross-taper planned that will result in a regimen that regimen **will require PA** through PBHMI if successful	3 months (cross-taper agent) 12 months (all others)
• Cross-taper planned that will result in a regimen that regimen **will require**	3 months (cross-taper agent)

PA through PBHMI if successful • Regimen includes any of the following: o Antipsychotic polypharmacy o Regimen with ≥6 medications o Regimen includes clozapine o Antidepressant in age <6 o Mood stabilizer in age <6 (excluding seizures only) o Antipsychotic in age <8 o Member is <3 years of age	6 months (all others)
Full Criteria *<u>NOT</u>* Met	
Clinical Situation	**Duration of Approval**
• Any ONE of the following: o Severe risk of harm to self or others o Recent psychiatric hospitalization (within the last 3 months) o Cross-taper planned that will result in a regimen that regimen **will NOT require PA** through PBHMI if successful	3 months
• No documentation of risk of harm • No documentation of recent hospitalization (within the past 3 months) • Any one of the following: o Cross-taper planned that will result in a regimen that regimen **will require PA** through PBHMI if successful o **Member is stable on requested regimen**	1 month
• No documentation of risk of harm • No documentation of recent hospitalization (within the past 3 months) • New start/no documentation that the member is stable or continuing therapy on the requested medication	Deny

In situations where drug criteria may indicate a shorter duration of approval, please approve for the more restrictive (shorter) duration.
Provisional approvals do not apply to new starts for medications that require prior authorization outside of PBHMI requirements (e.g., drug, quantity limits, brand name).

Appendix

Appendix Table I: List of mood stabilizers separated by clinical indications for seizure alone, behavioral health alone, and concomitant use for seizure and behavioral health indications

Behavioral Health Indications	Behavioral Health and Seizure Indications	Seizure Indications (Excluded from PBHMI Age restrictions)

Behavioral Health Indications	Behavioral Health and Seizure Indications	Seizure Indications (Excluded from PBHMI Age restrictions)
Lithobid® (**lithium**)	Tegretol®, Tegretol® XR, Carbatrol® ER, Epitol®, Equetro®, (**carbamazepine**)	Briviact® (**brivaracetam**)
		Epidiolex® (**cannabidiol**)
	Aptiom® (**eslicarbazepine**)	Xcopri® (**cenobamate**)
	Neurontin®, Horizant®, Gralise® (**gabapentin**)	ONFI® tablets and suspension Sympazan® film (**clobazam**)
	Lamictal®, Lamictal® CD, Lamictal® ODT, Lamictal® ODT Starter Kit, Lamictal® XR, Lamictal® XR Starter Kit, Lamictal® Starter Kit (**lamotrigine**)	Zarontin® (**ethosuximide**)
	Trileptal®, Oxtellar XR® (**oxcarbazepine**)	Peganone® (**ethotoin**)
	Lyrica®, Lyrica CR® (**pregabalin**)	Felbatol® (**felbamate**)
	Topamax®, Topamax® Sprinkle, Trokendi XR® (**topiramate**)	Vimpat® (**lacosamide**) solution, tablets, injection
	Depakene®, Depakote®, Depakote® ER, Depakote® Sprinkle (**valproic acid**)	Keppra®, Spritam® (**levetiracetam**)
		Celontin® (**methsuximide**)
		Fycompa® (**perampanel**)
		Dilantin®, Dilantin-125®, Dilantin Infatab (**phenytoin**), phenytoin 100 mg/4 mL unit dose suspension, Phenytek® (**phenytoin sodium**), phenytoin injection
		Mysoline® (**primidone**)
		Banzel® (**rufinamide**) tablets and suspension
		Diacomit® (**stiripentol**)
		Gabitril® (**tiagabine**)
		Sabril® (**vigabatrin**)
		Zonegran® (**zonisamide**)

Abbreviations: CD=chewable dispersible, ER=extended release, ODT= oral disintegrating tablet, XR=extended release.

Appendix Table II: List of stimulant agents considered immediate-release and extended-release formulations of the same chemical entity

Medication/ Chemical Entity	Immediate-Release (Short /Intermediate Acting) Agents	Extended-Release (Long Acting) Agents
Amphetamine products	Adderall® (mixed amphetamine salts) Evekeo® (amphetamine sulfate) Evekeo ODT® (amphetamine sulfate) Desoxyn® (methamphetamine) Dexedrine® (dextroamphetamine) Dexedrine® Spansule (dextroamphetamine)	Adderall XR® (amphetamine salts) Adzenys ER® (amphetamine) Adzenys XR-ODT® (amphetamine) Dyanavel XR® (amphetamine) Vyvanse® (lisdexamfetamine) Mydayis® (amphetamine salts)

Medication/ Chemical Entity	Immediate-Release (Short /Intermediate Acting) Agents	Extended-Release (Long Acting) Agents
	dextroamphetamine solution Dextrostat® (dextroamphetamine) Zenzedi® (dextroamphetamine)	
Methylphenidate products	Focalin®(dexmethylphenidate) Methylin®(methylphenidate) Metadate ER®(methylphenidate) Methylin ER®(methylphenidate) Methylin Solution®(methylphenidate) methylphenidate powder Ritalin® (methylphenidate) Ritalin SR®(methylphenidate)	Adhansia XR® (methylphenidate ER) Aptensio XR® (methylphenidate) Concerta® (methylphenidate ER) Daytrana® (methylphenidate) Focalin XR® (dexmethylphenidate) Jornay PM® (methylphenidate ER) Metadate CD® (methylphenidate) methylphenidate ER 72 mg tablet QuilliChew ER® (methylphenidate) Quillivant XR® (methylphenidate ER oral suspension) Ritalin LA® (methylphenidate) Cotempla XR ODT® (methylphenidate)

Stability

NOTE: If a medication requires PA outside of PBHMI, refer to the stability section in the applicable internal guideline for additional considerations

For requests that document stability, a 1 month provisional approval can be considered if there is no reason for a longer provisional approval (e.g., recent psychiatric hospitalization or severe risk of harm to self or others). The decision for a 1 month provisional approval should be based on the clinical judgment of the reviewer. POPS claims suggesting stability is generally a reason to provide a provisional approval.

For **cerebral stimulant polypharmacy** cases with documented stability or POPS claims suggesting stability, approval criteria may be bypassed (for cerebral stimulant polypharmacy only). Requests with stability may receive a standard approval (6 to 12 months based on TCM high risk algorithm). Other applicable criteria for PBHMI must be met (e.g., 4+ polypharmacy, age <3).

Prescriber Specialty and Acceptable Psychiatry Consults

For criteria where a psychiatrist (or other specific specialist) is required, mid-level practitioners such as nurse practitioners, physician assistants (including those with a psychiatry focus) will need to provide documentation of their collaborating physician or a consult with a specialist. Please processes based on the order below.

1. If the collaborating physician's specialty is not provided, please check the MA Board of Registration in Medicine website at http://profiles.ehs.state.ma.us/Profiles/Pages/FindAPhysician.aspx to verify the specialty and refer to steps below.

a. If the collaborating physician is a specialist (e.g., psychiatrist, neurologist) that is considered appropriate for the given criteria, the PBHMI criteria will be fulfilled and a full duration of approval may be granted if ALL other criteria is met.
b. If the collaborating physician is not a specialist (e.g., pediatrician, internal medicine), then a specialist consult will be required as outlined in the criteria and a provisional approval may be granted. Please consult a supervisor if there are any questions.

2. If the collaborating physician is NOT documented, please attempt outreach to the office to verify the collaborating physician for the mid-level practitioner. Clarification may be accepted over the phone.
3. If the office is unable to provide the collaborating physician's name or the mid-level practitioner does not have a collaborating physician, then a provisional approval should be issued (x3 months if risk of harm or recent hospitalization OR x1 month if stable on requested agent/regimen).
    a. A collaborating specialist or specialist consult will be required on resubmission. Please consult with the Plan Pharmacy Team if there has been a resubmission and this has not been addressed. A longer term approval may be required to allow the member to find a specialist.
    b. Prescriber outreach: YES
    c. Additional Messaging: "A prior authorization was submitted for a member who is affected by the Pediatric Behavioral Health Medication Initiative. Drug Utilization Review needs to verify the collaborating physician name and specialty for <mid-level practitioner name>."

A psychiatry consult will be acceptable if it is dated within the last year. If a specific consult date (within the past year) is provided with an appropriate specialist, medical records or notes from the consult are not required. Documentation of consultation with the Massachusetts Child Psychiatry Access Project (MCPAP) providers is acceptable. Provisional approvals may be considered if the consult date is not provided or is more than 1 year ago. Tailoring of the outgoing message and/or outreach to the prescriber should be considered. The following verbiage may be used: "A prior authorization was submitted for a member who is affected by the Pediatric Behavioral Health Medication Initiative. Drug Utilization Review needs to verify the consulting physician and date of consult."

Massachusetts Child Psychiatry Access Project (MCPAP)

The Massachusetts Child Psychiatry Access Project (MCPAP) is valuable resource for primary care providers for member cases in which psychiatry consultation would be appropriate. It is available free of charge to Massachusetts primary care providers who treat children. A primary care provider enrolled in MCPAP may call for a consultation with a child psychiatry specialist. Outreach to MCPAP typically results in a consult with a specialist within two weeks. If a primary care provider submits a prior authorization indicating difficulty obtaining a specialist consult, consultants should inform the prescriber that the MCPAP resource is available and that MassHealth would accept a MCPAP consult as a specialist consult. The MCPAP website address is http://www.mcpap.com and provides valuable information for prescribers and the details about the program.

Antidepressant Polypharmacy

In certain antidepressant regimens, the use of an antidepressant (e.g., SSRI, SNRI) in conjunction with bupropion, mirtazapine, or trazodone may be clinically appropriate and may not require prior authorization under the PBHMI. Please refer to the following examples:

1. If the member has a regimen with two antidepressant medications and one agent is bupropion, mirtazapine, or trazodone, the regimen will not require prior authorization for antidepressant polypharmacy.

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The following examples do not require PA for antidepressant polypharmacy under the PBHMI:
Example #1: Sertraline (for depression) and trazodone (for insomnia)
Example #2: Sertraline (for depression) and bupropion (for antidepressant augmentation)

2. If the member has a regimen with two antidepressant medications and both agents are bupropion, mirtazapine, or trazodone, the regimen will not require prior authorization for antidepressant polypharmacy.

The following examples do not require PA for antidepressant polypharmacy under the PBHMI:
Example #1: Bupropion (for depression) and trazodone (for insomnia)
Example #2: Trazodone (for depression) and mirtazapine (for antidepressant augmentation)

3. If the member has a regimen with ≥3 antidepressant medications, the regimen will require prior authorization for antidepressant polypharmacy.

○

The following examples **require PA** for antidepressant polypharmacy under the PBHMI:
Example #1: Sertraline (for depression), bupropion (for antidepressant augmentation), and trazodone (for insomnia)
Example #2: Bupropion (for depression), mirtazapine (for antidepressant augmentation), and trazodone (for insomnia)

Spravato® (esketamine nasal spray) is indicated for treatment-resistant depression in adult patients to be used in combination with an oral antidepressant. The use of an oral antidepressant in combination with Spravato® (esketamine nasal spray) is appropriate. Spravato® (esketamine) is only approved for adult patients, and requests for pediatric patients <18 years of age should be reviewed on a case-by-case basis.

Use of antidepressant and anticonvulsant agents for migraine prophylaxis

The American Academy of Neurology (AAN) practice parameters for the pharmacological treatment of migraine headache in children and adolescents was last updated in 2004. At that time, there was insufficient evidence to make recommendations for the use of agents such as cyproheptadine, amitriptyline, divalproex sodium, topiramate, or levetiracetam in pediatric patients. There was conflicting evidence for the use of propranolol or trazodone and agents such as nimodipine and clonidine lacked efficacy. In March 2014, topiramate gained FDA-approval for migraine prevention in pediatric patients 12 to 17 years of age.

In 2012, the AAN published updated evidence-based guidelines for the pharmacologic treatment for episodic migraine prevention in adults. Medications identified with established efficacy (Level A recommendations) based on clinical trial evidence include divalproex sodium, sodium valproate, topiramate, metoprolol, propranolol, timolol, and frovatriptan. Medications identified as probably effective (Level B recommendations), include amitriptyline, venlafaxine, atenolol, nadolol, naratriptan, and zolmitriptan. Frovatriptan, naratriptan, and zolmitriptan are recommended for use in short-term prophylaxis of menstrual-related migraine.

There is limited literature supporting the use of migraine prophylactic agents in the pediatric population; however, there are AAN Level A and B recommendations for adult patients. As the approach to therapy for both patient populations is

similar, anticonvulsants (e.g., divalproex sodium, sodium valproate, topiramate) and antidepressants (e.g., amitriptyline, venlafaxine) for migraine prophylaxis may be considered to be clinically appropriate in the pediatric population.

Use of antidepressant and anticonvulsant agents for neuropathic pain

Neuropathic pain is generally uncommon in the pediatric population. Underlying causes for neuropathic pain among pediatric patients may include complex pain syndromes, phantom limb pain, spinal cord injury, trauma, postoperative neuropathic pain, autoimmune and degenerative neuropathies, and the effects of malignancies and treatment. As there is limited literature about the treatment of neuropathic pain in children and adolescents, the approach to care is generally extrapolated from adult management. Non-pharmacologic treatment strategies include transcutaneous electric nerve stimulation, thermal feedback, and physical therapy. Pharmacologic treatments include sympathetic blockade, anticonvulsants (e.g., gabapentin), tricyclic antidepressants (e.g., amitriptyline), immunoglobulin, non-steroidal anti-inflammatories, and opioids.

Treatment-resistant Obsessive Compulsive Disorder (OCD) and antidepressant polypharmacy with clomipramine

Selective serotonin reuptake inhibitors (SSRIs) are first-line therapy options for children with OCD. Severe cases may require medication augmentation strategies including antidepressant polypharmacy (e.g., 2 SSRIs or one SSRI and clomipramine). Failure of these augmentation strategies would constitute treatment resistance. As antidepressant polypharmacy with clomipramine is defined in treatment guidelines, use of this regimen would be clinically appropriate in pediatric members who were refractory to first-line therapies (e.g., SSRI monotherapy).

Tricyclic antidepressants for refractory nocturnal enuresis

Nocturnal enuresis, also known a bed-wetting, is a common urinary incontinence symptom reported in children and may have significant psychosocial impacts. Non-pharmacologic treatments are generally first-line (e.g., bladder training, bed-wetting alarms) and second-line treatment includes desmopressin. Imipramine, a tricyclic antidepressant traditionally dosed at 1.0 to 2.5 mg/kg, is a third-line option due to concerns with adverse effects in the pediatric population. In general, tricyclic antidepressants are only recommended for refractory cases. The 2010 NICE guidelines note any tricyclic drugs should be used as a second-line therapy, should not be used in combination with an anticholinergic, and imipramine should be the tricyclic of choice.

Behavioral health medications for sleep disturbance in very young children (e.g., <6 years of age)

There is limited evidence and clinical guidance for the use of behavioral health medications (e.g., trazodone, tricyclic antidepressants, alpha agonists, benzodiazepines, antipsychotics, hypnotics, anticonvulsants) for the treatment of sleep disturbance in very young children. Underlying etiologies, comorbid diagnoses, concomitant medications, and environmental factors should be evaluated if sleep disturbance has been identified. Behavioral therapy is the mainstay of treatment and should be implemented prior to pharmacologic treatment. Pharmacotherapy should be initiated for the shortest duration possible, combined with behavioral interventions, and reassessed frequently. Requests for hypnotics (e.g., zolpidem, eszopiclone) in members <6 years of age should be reviewed with the PBHMI guideline criteria. All other requests should be reviewed for the following information:

1. Clear treatment plan (medication, dose, frequency)
2. Severity of sleep disturbance (e.g., child and/or family impairment)

3. Intended treatment duration and prescriber follow-up plan
4. Previous therapy trials (e.g., melatonin, other agents targeting sleep disturbance)
5. Documentation if psychosocial interventions (e.g., sleep hygiene techniques, behavioral intervention) have been implemented or considered
6. Specialist involvement or consultation

Use of benzodiazepines for medical and dental procedures

Benzodiazepine requests for use during medical or dental procedures may be granted an approval if dosing and duration requested is appropriate. Approved quantities should generally not exceed the quantity being requested for the procedure. If the date of the procedure is not provided, please provide an approval duration of **1 month**.

Based on limited data, appropriate dosing for pediatric benzodiazepines for procedural use may include:

diazepam	Sedation, anxiolysis, and amnesia prior to procedure	Infants ≥6 months: 0.2 to 0.3 mg/kg 45 to 60 minutes prior to procedure; maximum dose: 10 mg/dose Children: 0.2 to 0.5 mg/kg 45 to 60 minutes prior to procedure; maximum dose: 10 mg/dose Adolescents: 0.2 to 0.3 mg/kg 45 to 60 minutes prior to procedure; maximum dose: 10 mg/dose
lorazepam	Sedation (preprocedure)	Children and adolescents: 0.05 mg/kg 45 to 60 minutes prior to procedure; range reported in literature: 0.02 to 0.09 mg/kg

For requests for other benzodiazepines or requests exceeding recommended dosing, please consult with a supervisor or clinical reviewer of the day.

Alzheimer's Agents in Pediatric Patients

There is some evidence available that supports the use of Alzheimer's agents for the management of certain psychiatric conditions in pediatric members. Requests for agents or regimens requiring PA may be considered for approval if there is specialty involvement (psychiatry or neurology) and the requested agent is medically necessary.

<u>Behavioral Symptoms in Autism Spectrum Disorder (ASD) and Pervasive Developmental Disorder</u>
All Alzheimer's agents have been studied in the management of behavioral symptoms associated with ASD and/or PDD. Studies have shown numerical as well as statistically significant improvements in various outcomes such as memory function, language, and behavioral symptoms (hyperactivity, irritability, attention). Clinical studies evaluated these agents in combination with other psychiatric medications, most often antipsychotics (memantine immediate-release [up to 30 mg/day] and donepezil [up to 10 mg/day]). Memantine IR is considered relatively safe in pediatric patients. Memantine, along with the other Alzheimer's agents, at the doses noted have shown mostly mild adverse events; however, behavioral regression, tremor, distractibility and seizures have also been reported. There is limited information regarding the safety of memantine ER, and a single study of memantine extended-release plus risperidone has shown no benefit.

ASD with Limited Rapid Eye Movement (REM) Sleep

Donepezil (2.5 to 3.5 mg/day) has also been evaluated as monotherapy in pediatric patients who have limited rapid eye movement sleep. In these patients, donepezil was shown to normalize sleep percentages and decrease REM latency.

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

Memantine IR monotherapy (10 to 20 mg/day) has been shown to provide a dose-dependent benefit in both the inattention and the hyperactivity/impulsivity domains of pediatric patients with combined ADHD. The response was minimal at 10 mg/day and significantly better on the 20 mg/day dosage in pediatric patients with ADD/ADHD. No studies of memantine in combination with other agents used for the treatment of ADD/ADHD (stimulants, alpha agonists, atomoxetine) were identified. Donepezil has only been evaluated in combination with other agents. In patients with ADHD, donepezil (up to 10 mg/day) plus a stimulant was not well tolerated and did not appear useful for the treatment of residual ADHD.

Tics associated with ADHD

Donepezil (up to 10 mg/day) has been studied in pediatric patients with ADHD and tics in combination with other agents (e.g., neuroleptics, stimulants, antidepressants, anxiolytics). Although donepezil did not show any improvement in ADHD symptoms, tics were reduced in these children and adolescents.

Obsessive-Compulsive Disorder (OCD)

There is limited clinical data to support the use of Alzheimer's agents in the treatment of OCD. A single case report noted improvement of OCD symptoms in a child treated with memantine IR (up to 10 mg/day) in combination with citalopram. Additional studies of memantine (unclear doses) as add-on therapy to an SSRI and/or cognitive-behavioral therapy in adults have shown positive responses. Generally, OCD is managed with cognitive behavioral therapy. Selective-serotonin reuptake inhibitors (SSRIs), clomipramine or augmentation of an SSRI/clomipramine with an atypical antipsychotic. Given the safety profile of memantine IR that has been established in children and adolescents, prescribers may wish to avoid the adverse events associated with atypical antipsychotics and clomipramine.

Other Psychiatric Conditions

Alzheimer's agents have not been evaluated in pediatric patients for other psychiatric conditions such as schizophrenia, major depressive disorder, bipolar disorder or generalized anxiety disorder. In adults, memantine IR has been evaluated for these indications and there have been mixed results. Because safety and efficacy of many therapeutic alternatives for these diagnoses have been established in children, use of these agents is generally not recommended.

Modafinil Agents in Pediatric Patients

Treatment of ADHD in pediatric patients with modafinil has been studied in clinical trials and was shown to be safe and effective at doses ranging from 100 mg to 300 or 400 mg daily (depending on body weight <30 kg or ≥30 kg) in pediatric patients older than six years of age. Modafinil was well tolerated and significantly improved symptoms of ADHD in several double-blind, placebo-controlled, randomized controlled trials.

There is limited data available to support the use of modafinil and armodafinil in psychiatric disorders (depression, bipolar disorder) and there are many available FDA-approved therapies. Although it is not considered the standard of care for depression, evidence suggests there may be some benefit to modafinil, particularly if used to augment an antidepressant.

The FDA's Pediatrics Advisory Committee previously recommended that the label include language that specifically warns against its use in children for any indication due to post-marketing reports of serious dermatologic and psychiatric

reactions; as such, the prescribing information for Provigil® (modafinil) includes warning for Stevens-Johnson syndrome. However, recent data suggests modafinil agents are safe and effective in children for several indications and clinical guidelines recommend modafinil agents as a potential treatment option.

Naltrexone in Pediatric Patients with Self-Injurious Behaviors

Naltrexone has been studied for its behavioral health effects primarily in pediatric patients with autistic disorder with self-injurious behaviors (SIBs). Naltrexone is currently not FDA-approved for use in treating the symptoms of autism spectrum disorder; however, a number of case reports and small clinical studies had been published prior to 2000. It is theorized that naltrexone may stimulate release of endogenous endorphins that may deter some of the observed repetitive behaviors.

The typical doses assessed in these reports range from 0.5 to 2 mg/kg at various administration times (i.e., per day, weekly, intermittently). In one double-blind, placebo-controlled trial of adult patients (N=33), naltrexone did not demonstrate benefit compared with placebo. In a separate cross-over study of six male patients, treatment naltrexone 50 mg/day (0.6 to 1.5 mg/kg for three weeks) resulted in significant reductions in the frequency of SIBs in two patients and a trend toward benefit in a third. Lastly, one case report of a 12-year-old female with autism and SIBs who was treated with naltrexone resulted in a no SIBs for 22 months. Overall, the recent evidence for use of naltrexone is minimal and conflicting.

Requests for naltrexone for the treatment of substance use disorder (SUD) should be approved as requested.

Compelling cases - Clinical and/or Supervisor Review

If clinical review or supervisor is not available and compliance is an issue, please approve or deny based on professional clinical judgment and forward to clinical review for follow-up. A provisional approval may also be granted if clinically appropriate. If necessary, please attempt to contact the pharmacy for an emergency supply.

Next Review Date

2021

Other Applicable Policies

Quantity Limitation Policy
Antidepressants Policy
Insomnia Agents Policy
Anticonvulsants Policy
Antipsychotics Policy
ADHD Medications Policy

Reference Table: Pediatric Behavioral Health Medication Initiative Drug list[1]

Pediatric Behavioral Health Medication Initiative Medication List[1]			
Antidepressants		**Mood Stabilizers**	
amitriptyline	maprotiline	brivaracetam[3]	lithium
amoxapine	mirtazapine	cannabidiol[3]	methsuximide[3]
bupropion	nefazodone	carbamazepine	oxcarbazepine
citalopram	nortriptyline	cenobamate[3]	perampanel[3]
clomipramine	paroxetine	clobazam[3]	phenytoin[3]
desipramine	phenelzine	divalproex	pregabalin
desvenlafaxine	protriptyline	eslicarbazepine	primidone[3]
doxepin	selegiline[2]	ethosuximide[3]	rufinamide[3]
duloxetine	sertraline	ethotoin[3]	stiripentol[3]
escitalopram	tranylcypromine	felbamate[3]	tiagabine[3]
esketamine	trazodone	gabapentin	topiramate
fluoxetine	trimipramine	lacosamide[3]	valproic acid
fluvoxamine	venlafaxine	lamotrigine	vigabatrin[3]
imipramine	vilazodone	levetiracetam[3]	zonisamide[3]
isocarboxazid	vortioxetine	**Antianxiety Agents**	
levomilnacipran		alprazolam	diazepam[4]
Stimulants		buspirone	lorazepam
amphetamine	dextroamphetamine/amphetamine	chlordiazepoxide	meprobamate
amphetamine sulfate	lisdexamfetamine	chlordiazepoxide/ amitriptyline	midazolam[4]
dextroamphetamine	methamphetamine	clonazepam	oxazepam
dexmethylphenidate	methylphenidate	clorazepate	
Antipsychotics		**Hypnotics**	
aripiprazole	olanzapine	doxepin[5]	suvorexant
asenapine	olanzapine/fluoxetine	estazolam	temazepam
brexpiprazole	paliperidone	eszopiclone	triazolam
cariprazine	perphenazine	flurazepam	zaleplon
chlorpromazine	perphenazine/amitriptyline	lemborexant	zolpidem
clozapine	pimozide	quazepam	
fluphenazine	quetiapine		
haloperidol	risperidone	**Alpha$_2$ Agonists**	
iloperidone	thioridazine	clonidine	guanfacine
loxapine	thiothixene	**Miscellaneous**	
lumateperone	trifluoperazine	armodafinil	memantine
lurasidone	ziprasidone	atomoxetine	modafinil
molindone		donepezil	naltrexone[6]

[1] Short-acting intramuscular injectable and intravenous formulations are not included.
[2] Emsam® (selegiline) is the only selegiline formulation included.
[3] Agent is considered to be used only for seizure diagnoses and is excluded from age restriction for members less than six years of age
[4] Nasal and rectal diazepam and nasal midazolam formulations are not included.
[5] Doxepin tablet is classified as a hypnotic agent and not included in the antidepressant restrictions.
[6] Injectable naltrexone (Vivitrol) is not included.

Original Approval Date	Original Effective Date	Policy Owner	Approved by

2/11/2021	6/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
2/11/2021	9.058 PBHMI Policy retired, new policy created; Policy adjusted to mirror PUF Policy	6/1/2021	P&T Committee

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.