Long-Acting Cerebral Stimulants and ADHD Medications
Effective 03/01/2023

Plan	☐ MassHealth ☒ MH UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit (NLX)		
Specialty Limitations	N/A		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview
Attention deficit hyperactivity disorder medications and cerebral stimulants

Reference Table:

Drugs that require PA	No PA
Long-acting Amphetamine Cerebral Stimulants (oral, non-solution and transdermal	
Adderall XR® (amphetamine salts extended-release)† > 2 units/day ††	Adderall XR® (amphetamine salts extended-release) ≤ 2 units/day ††
Adzenys XR-ODT® (amphetamine extended-release orally disintegrating tablet) (QL > 1 unit/day)	
Dyanavel XR® (amphetamine extended-release chewable tablet)	
Mydayis® (amphetamine salts extended-release) (QL > 1 unit/day)	
Vyvanse® (lisdexamfetamine capsule) > 2 units/day	Vyvanse® (lisdexamfetamine capsule) ≤ 2 units/day
Vyvanse® (lisdexamfetamine chewable tablet) (QL >2 units/day)	
Long-acting Methylphenidate Cerebral Stimulants (oral, non-solution and transdermal	
Adhansia XR® (methylphenidate extended-release) (QL > 1 unit/day)	

Drugs that require PA	No PA
Aptensio XR® (methylphenidate extended-release) (QL > 1 unit/day)*	
Azstarys® (serdexmethylphenidate/dexmethylphenidate) (QL > 1 unit/day)	
Concerta® (methylphenidate extended release) > 2 units/day † ††	Concerta® (methylphenidate extended-release) ≤ 2 units/day ††
Cotempla XR-ODT® (methylphenidate extended-release orally disintegrating tablet) (QL > 1 unit/day)	
Daytrana® (methylphenidate transdermal) > 1 unit/day† ††	Daytrana® (methylphenidate transdermal) ≤ 1 unit/day††
Focalin XR® (dexmethylphenidate extended-release)† PD > 2 units/day ††	Focalin XR® (dexmethylphenidate extended-release)PD ≤ 2 units/day ††
Jornay PM® (methylphenidate extended-release) (QL > 1 unit/day)	
methylphenidate extended-release, CD (QL > 2 units/day)	
methylphenidate extended-release 72 mg tablet‡ (QL > 1 unit/day)	
QuilliChew ER® (methylphenidate extended-release chewable tablet) (QL > 2 units/day)	
Ritalin LA® (methylphenidate)* (QL > 2 units/day)	
Cerebral Stimulant Liquid	
Adzenys ER® (amphetamine extended-release 1.25 mg/mL oral suspension)§ **	
Dyanavel XR® (amphetamine extended-release 2.5 mg/mL oral suspension)§	
Quillivant XR® (methylphenidate extended-release oral suspension)§	

† A-rated generic available. Both brand and A-rated generic require PA at these quantities, if applicable.
†† Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent
* A-rated generic available. Both brand and A-rated generic require PA.
** Authorized generic available. Both brand and authorized generic require PA.
‡ A branded generic(s) is available in this formulation.
§ Quantity limits do not apply to this agent, singly or in combination with other cerebral stimulants.
PD Preferred Drug. In general, a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.

Coverage Guidelines

Long-Acting Amphetamine Cerebral Stimulants:
Adzenys ER® (amphetamine extended-release 1.25 mg/mL oral suspension)
Adzenys XR-ODT® (amphetamine extended-release orally disintegrating tablet)
Dyanavel XR® (amphetamine extended-release 2.5 mg/mL oral suspension, chewable tablet)

Mydayis® (amphetamine salts extended-release)
Vyvanse® (lisdexamfetamine chewable tablet)
Prescriber provides documentation of **ALL** of the following:

1. Member has a diagnosis of **ONE** of the following (*see Appendix G for additional approvable diagnoses):*
    a. Attention deficit hyperactivity disorder (ADHD)
    b. Narcolepsy
    c. Binge eating disorder (Vyvanse only)
2. For **Mydayis®** requests, member is ≥13 years of age
3. Clinical rationale for use of the requested agent instead of **BOTH** of the following:
    a. Adderall XR® (amphetamine salts extended-release)
    b. Vyvanse® (lisdexamfetamine) capsule
4. **If the request is for brand name Adzenys ER® suspension** prescriber must also provide medical records documenting an inadequate response or adverse reaction to the therapeutically equivalent generic

***Please note**: Additional criteria may apply for members under the age of 18. Please refer to the MassHealth Pediatric Behavioral Health Medication Initiative guideline for criteria.*

- *Quantity limits do not apply to Adzenys ER® or Dyanavel XR®, singly or in combination with other cerebral stimulants.*
- *If request documents a swallowing disorder, refer to Appendix D*

Long-Acting Methylphenidate Cerebral Stimulants
Adhansia XR® (methylphenidate extended-release)
Aptensio XR® (methylphenidate extended-release)
Azstarys® (serdexmethylphenidate/ dexmethylphenidate)
Cotempla XR-ODT® (methylphenidate extended-release orally disintegrating tablet)
Jornay PM® (methylphenidate extended-release) methylphenidate extended-release, CD
QuilliChew ER® (methylphenidate extended-release chewable tablet)
Quillivant XR® (methylphenidate extended-release oral suspension)
Ritalin LA® (methylphenidate)
Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of **ONE** of the following (*see Appendix G for additional approvable diagnoses):*
    a. ADHD
    b. Narcolepsy
2. **ONE** of the following:
    a. Clinical rationale for use of the requested agent instead of Concerta® (methylphenidate extended-release)
    b. Clinical rationale for requested formulation instead of solid oral formulations (e.g., swallowing disorder, dysphagia)
3. Clinical rationale for use of the requested agent instead of **BOTH** of the following:
    a. Focalin XR® (dexmethylphenidate extended-release)
    b. Daytrana® (methylphenidate transdermal)
4. **If the request is for brand name Ritalin LA®** prescriber must also provide medical records documenting an inadequate response or adverse reaction to the generic equivalent being requested (as per the Brand Name and Non-Preferred Generic Drugs guideline)

5. **If the request is for brand name Aptensio XR®** prescriber must also provide medical records documenting an inadequate response or adverse reaction to the generic equivalent being requested (as per the Brand Name and Non-Preferred Generic Drugs guideline)

***Please note**: Additional criteria may apply for members under the age of 18. Please refer to the MassHealth Pediatric Behavioral Health Medication Initiative guideline for criteria.*

Notes:

- *Quantity limits do not apply to Quillivant®, singly or in combination with other cerebral stimulants.*
- *See Appendix B – Adverse reactions/Contraindications to Stimulants*
- *If request documents a swallowing disorder, refer to Appendix D*
- ***For examples of clinical rationale for Jornay PM® instead of Concerta®, Daytrana®, and Focalin XR®, please see Appendix E.***

Methylphenidate extended-release 72 mg tablet
Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of **ONE** of the following (*see Appendix G for additional approvable diagnoses):*
    a. ADHD
    b. Narcolepsy
2. Clinical rationale for use of the requested agent instead of **ALL** of the following:
    a. two Concerta® (methylphenidate extended-release) 36 mg tablets
    b. Focalin XR® (dexmethylphenidate extended-release)
    c. Daytrana® (methylphenidate transdermal)

***Please note**: Additional criteria may apply for members under the age of 18. Please refer to the MassHealth Pediatric Behavioral Health Medication Initiative guideline for criteria.*

- *See Appendix B– Adverse reactions/Contraindications to Stimulants*
- *If request documents a swallowing disorder, refer to Appendix D*

Cerebral Stimulant Quantity Limits (per month)

- > 1 unit/day for Adhansia XR® (methylphenidate ER), Adzenys XR-ODT® (amphetamine ER ODT), Aptensio XR® (methylphenidate ER), Azstarys® (serdexmethylphenidate/ dexmethylphenidate) Cotempla XR-ODT® (methylphenidate ER ODT), Daytrana® (methylphenidate transdermal), Jornay PM® (methylphenidate ER), and Mydayis®
- Long acting agents > 2 combined units per month total

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

1. Individual drug PA criteria must be met first where applicable
2. Medical necessity for an increased dosage that results in requiring quantities that exceed the determined limits
3. **If request is for a brand name medication with an A-rated generic**, prescriber must also provide medical records documenting an inadequate response or adverse reaction to the generic equivalent being requested (as per the Brand Name and Non-Preferred Generic Drugs guideline)

Notes:

- *Please refer to the **MassHealth Pediatric Behavioral Health Medication Initiative** guideline regarding the review of requests for members <18 years of age.*
- *See Appendix F for Stimulants Exceeding quantity limits*

Continuation of Therapy
Reauthorization require physician attestation that indicates a positive response to therapy.

Limitations
1. Initial and reauthorization approvals may be granted for up to 1 year
2. Limitations may apply singly or in combination with other cerebral stimulants
3. Quantity limits apply. Please see reference grid above

Appendix
A. MassHealth Pediatric Behavioral Health Medication Initiative

The Pediatric Behavioral Health Medication Initiative requires prior authorization for members <18 years of age for behavioral health medication classes and/or specific medication combinations (i.e., polypharmacy) that have limited evidence for safety and efficacy in the pediatric population. The aspects of the **MassHealth Pediatric Behavioral Health Medication Initiative** that may apply to the cerebral stimulants and ADHD guideline include the following:

1. Behavioral health medication polypharmacy (pharmacy claims for 4 or more behavioral health medications [i.e., alpha$_2$ agonists, antidepressants, antipsychotics, atomoxetine, benzodiazepines, buspirone, cerebral stimulants, hypnotic agents, and mood stabilizers] filled within a 45 day period)
2. Cerebral stimulant polypharmacy (overlapping pharmacy claims for 2 or more stimulants for ≥60 days within a 90 day period). *Immediate-release and extended-release formulations of the same chemical entity are not included. Stimulant polypharmacy would only apply if an amphetamine-related product is used in combination with a methylphenidate-related product.*
3. Atomoxetine pharmacy claim for pediatric members less than 6 years of age
4. Alpha$_2$ agonist or cerebral stimulant pharmacy claim for pediatric members less than 3 years of age

Please refer to the **MassHealth Pediatric Behavioral Health Medication Initiative** guideline to assess appropriateness of therapy when reviewing prior authorization requests for pediatric members <18 years of age.

B. Adverse reactions/Contraindications to Stimulants

The following may be considered:

1. Weight loss or failure to gain weight or appetite suppression
2. Insomnia, agitation, increased anger and aggression
3. Tic disorder (pre-existing or developed tics on a stimulant)
4. Seizures with ADHD
5. Traumatic brain injury with ADHD
    a. Trial of both a methylphenidate product and amphetamine product is required or clinical rationale for not using stimulants due to concern for seizures

For members <18 years of age, all requests for stimulants will also be reviewed using additional criteria in the **MassHealth Pediatric Behavioral Health Medication Initiative** guideline.

C. Cardiovascular Concerns with stimulants

The following may be considered heart disease with ADHD in children:

1. Symptomatic tachycardia or hypertension

For members <18 years of age, all requests for ADHD agents will also be reviewed using additional criteria in the **MassHealth Pediatric Behavioral Health Medication Initiative** guideline.

D. Non-Preferred Stimulants and Swallowing Disorders

Swallowing disorders
Select non-preferred products may offer a therapeutic option for children or those with swallowing disorders including:

- capsules that may be opened and sprinkled on food
  - Adderall XR® [amphetamine salts extended-release]
  - Adhansia XR® [methylphenidate extended-release]
  - Aptensio XR® [methylphenidate extended-release]
  - Jornay PM® [methylphenidate extended-release]
  - Metadate CD® [methylphenidate extended-release]
  - Ritalin LA® [methylphenidate extended-release]
  - Vyvanse® [lisdexamfetamine capsule]
- chewable products
  - QuilliChew ER® [methylphenidate extended-release chewable tablet])
  - Vyvanse® [lisdexamfetamine chewabletablet]
- orally disintegrating tablets
  - Adzenys XR-ODT® [amphetamine extended-release orally disintegrating tablet]
  - Cotempla XR-ODT® [methylphenidate extended-release orally disintegrating tablet]
- oral suspensions
  - Adzenys ER® [amphetamine extended-release suspension]
  - Dyanavel XR® [amphetamine extended-release suspension]
  - Quillivant XR® [methylphenidate extended-release suspension]
- transdermal products
  - Daytrana® [methylphenidate transdermal]

Adderall XR® (amphetamine salts extended-release), Focalin XR® (dexmethylphenidate extended-release) and Vyvanse® (lisdexamfetamine) may also be opened and sprinkled on food or in liquid and would be a reasonable treatment option in patients who cannot swallow tablets. Additionally, Daytrana® (methylphenidate) is applied transdermally and would not be affected by swallowing disorders. Therefore, trials with these agents would be required when reviewing requests for a non-preferred long-acting stimulant in a member unable to swallow tablets. If there is a specific need for a chewable tablet, ODT, or suspension vs. opening a capsule or use of a transdermal product (for non-preferred methylphenidate extended release products), this should be evaluated on a case by case basis. Concerta® (methylphenidate

extended-release) tablets must be swallowed whole. Therefore, this trial will not be required if the prescriber documents that the member is unable to swallow tablets.

Abuse Deterrence
Although serdexmethylphenidate alone has been shown to provide less abuse potential than other stimulants, the combination Azstarys® (serdexmethylphenidate/dexmethylphenidate) has not been evaluated. The FDA-determined that the combination, which includes dexmethylphenidate (a CII) would have the same potential for abuse as other stimulants and did not allow abuse-deterrent labeling to be included with Azstarys®. As such, **requests documenting reduced potential for abuse and/or dependence with Azstarys®, or any other non-preferred formulation, would not be compelling to bypass preferred alternatives.**

E. Clinical Rationale for Jornay PM over Preferred Alternatives

Jornay PM® (methylphenidate extended-release) is a methylphenidate extended-release (ER) product FDA-approved for the treatment of ADHD. Jornay PM® is unique from other extended-release methylphenidate products in that it is the first product to be administered once-daily in the evening (recommended administration administration between 6:30 PM and 9:30 PM), whereas other ER products are administered once daily in the morning. Jornay PM® is formulated using a unique delayed- and extended-release drug-delivery system which prevents release of the drug until the morning after a night of sleep, eliminating the need to administer medication in the morning. The initial absorption of methylphenidate into the plasma is delayed such that no more than 5% of total drug is available within the first 10 hours after dosing.

Clinical rationale for bypassing trials of the preferred alternative methylphenidate ER products for the use of Jornay PM® (e.g., Focalin XR®, Daytrana®, and Concerta®) should include that the member experiences significant ADHD symptoms and functional impairment upon wakening, which has not been resolved with other stimulant trials including other methylphenidate ER products. If the request indicates inadequate response with adequate trials at optimized doses of all preferred alternatives but does not include the above rationale, the request can be approved. Requests that do not include this rationale and do not include trials of the preferred alternative methylphenidate ER products should be denied and compelling cases may be reviewed with the clinical reviewer.

F. Exceeding Quantity Limits

Requests that exceed the quantity limit should be reviewed for possible dose consolidation. The following situations are considered approvable:

For short acting agents without a long acting agent:
- If dose consolidation *is possible*: Approve request for 1 month and ask for consideration of dose consolidation.

For scenarios where member is using high quantities of lower strength medications (long or short)
- If dose consolidation *is possible*: request may be granted for **1 month**

For scenarios where dose consolidation is NOT possible.

For requests for dextroamphetamine 5 mg and 10 mg tablets where further dose consolidation is not possible using only the 5 mg or 10 mg tablets (i.e., without using the 2.5 mg, 7.5 mg, 15 mg, 20 mg or 30 mg tablets).

G. Diagnoses Considered Appropriate for Stimulant Use

If a prescriber documents one of the diagnoses below on requests for non-preferred stimulants and all other criteria have been met (i.e., trials with preferred agents, quantity limits), the request may be approved.

The various CNS stimulants are currently FDA-approved for indications including ADHD, narcolepsy, and binge eating disorder (lisdexamfetamine). However, stimulants may be considered first-line or adjunctive therapy in a number of off-label conditions, including but not limited to:

- Sleep disorders, such as: obstructive sleep apnea, hypersomnia, Shift Work Disorder
- Autism Spectrum Disorder related symptoms
- Binge eating disorder (all other agents)
- Traumatic Brain Injury
- Depressive condition (as adjunctive treatment)
- Excessive sleepiness or fatigue associated with a chronic medical condition, such as: ○ Multiple sclerosis
- Parkinson's Disease
- Cancer-related fatigue

Review History

11/17/2021 – Created and reviewed at P&T: Updated to be in compliance with MassHealth Uniform formulary
03/16/2022 – Reviewed and Updated for March P&T; Guideline updated to reflect the removal of preferred drug designation of Adderall XR and Vyvanse from reference table. Updated Non-Preferred Stimulants and Swallowing Disorders appendix and clarified verbiage in Jornay PM appendix for acceptable clinical rationale; remove PA from Daytrana for QL 1 patch per day. Effective 05/01/22.
05/18/2022 – Reviewed and Updated for May P&T; Guideline updated to require PA for Vyvanse (lisdexamfetamine) chewable tablet. Guideline updated for A rated generic of Aptensio XR. Effective 06/01/22.
06/22/2022 – Reviewed and Updated for June P&T; matched MH UPPL. Guideline updated to require brand Daytrana® to be preferred over generic. Effective 08/01/22.
11/16/2022 – Reviewed and updated for Nov P&T; matched MH UPPL. Updated Reference table to reflect availability of new A-rated generic for Daytrana (methylphenidate transdermal). Added new formulation, Dyanavel XR® (amphetamine extended-release chewable tablet). Effective 11/01/2022
01/11/2023 – Reviewed and updated for Jan P&T. Clarified diagnoses throughout. Added appendices on approvable diagnoses and quantity limits exceeded. Effective 3/1/23.

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