Long-Acting Cerebral Stimulants and ADHD Medications
Effective 05/01/22

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)	
Mydayis® (amphetamine salts extended-release) (QL > 1 unit/day)	
Vyvanse® (lisdexamfetamine) > 2 units/day	Vyvanse® (lisdexamfetamine) ≤ 2 units/day
Long-acting Methylphenidate Cerebral Stimulants (oral, non-solution and transdermal	
Adhansia XR® (methylphenidate extended-release) (QL > 1 unit/day)	
Aptensio XR® (methylphenidate extended-release) (QL > 1 unit/day)**	
Azstarys® (serdexmethylphenidate/dexmethylphenidate) (QL > 1 unit/day)	

Drugs that require PA	No PA
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)
Mydayis® (amphetamine salts extended-release)

Prescriber provides documentation of **ALL** of the following:
1. Member has a diagnosis of attention deficit hyperactivity disorder (ADHD)
2. For **Mydayis®** requests, member is ≥13 years of age

3. Prescriber has provided documentation of an inadequate response, adverse reaction, or contraindication to Adderall XR® **and** Vyvanse
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

*** Authorized generic available. Both brand and authorized generic require PA.*

***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 stability, refer to Appendix*
- *If request documents risk of harm, refer to Appendix*
- *If request documents a swallowing disorder, refer to Appendix*

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. Appropriate diagnosis
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 Focalin XR® (dexmethylphenidate extended-release)
4. Clinical rationale for use of the requested agent instead of Daytrana® (methylphenidate transdermal)
5. **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 guideline)

If the request is for brand name Aptensio XR® prescriber must also provide medical records documenting an inadequate response or adverse reaction to the therapeutically equivalent generic

*** A-rated generic available, both brand and A-rated generic require PA*
*** Authorized generic available. Both brand and authorized generic require PA.*

***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 – Adverse reactions/Contraindications to Stimulants*
- *If request documents stability, refer to Appendix*
- *If request documents risk of harm, refer to Appendix*
- *If request documents a swallowing disorder, refer to Appendix*
- ***For examples of clinical rationale for Jornay PM® instead of Concerta®, Daytrana®, and Focalin XR®, please see Appendix.***

Methylphenidate extended-release 72 mg tablet‡

‡ A branded generic(s) is available in this formulation. Please review using the appropriate generic NDC

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

1. Appropriate diagnosis
2. Clinical rationale for use of the requested agent instead of two Concerta® (methylphenidate extended-release) 36 mg tablets
3. Clinical rationale for use of the requested agent instead of Focalin XR® (dexmethylphenidate extended-release)
4. Clinical rationale for use of the requested agent instead of 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 – Adverse reactions/Contraindications to Stimulants*
- *If request documents stability, refer to Appendix*
- *If request documents risk of harm, refer to Appendix*
- *If request documents a swallowing disorder, refer to Appendix*

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 preferred over generic 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 (Exceeding quantity limits-Stimulants)*

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:

I. Stability

Stability on a medication requiring a prior authorization is generally not a reason to bypass approval criteria. For members <18 years of age, all requests will be reviewed using the **MassHealth Pediatric Behavioral Health Medication Initiative** guideline.

Non-preferred Long Acting Stimulants

Clinical Situation	Decision	Notes
Member is **stabilized** and there is **severe** risk of harm (e.g., suicidal or homicidal ideations)	**Provisionally approve** for six months, regardless of missing trials.	N/A
Member is **stabilized** and there is documentation of risk of harm (e.g., aggression)	**Evaluate on a case-by-case** basis using clinical judgement taking into account the member's complexity and severity of the behaviors.	• Generally, requests should provide details regarding a current risk of harm; however, if compelling information is provided regarding a history of severe risk of harm (e.g., suicide attempt), request can be considered for approval. • If there is unspecific risk of harm documented, consider outreach to clarify specific risks. If denied, please notify the prescriber's office of the reason(s) for the denial and availability of emergency overrides. If questions arise regarding the severity of behaviors documented, Clinical Review may be consulted on a case-by-case basis.
Member is **stabilized** and made an attempt to transition from a non-preferred product to a preferred product on or after 11/6/2017 and experienced an adverse event, worsening of symptoms, or inadequate response.	**Approve** without a second preferred trial.	N/A
Member is **stabilized**, has **autism** and there is documentation the member may	**Forward** to Clinical Review. The decision to approve or deny should	N/A

have difficulty transitioning to a preferred product.	be case-by-case taking into account severity of the condition and alternatives tried.	

For other compelling clinical scenarios where the member does not meet criteria for approval, please outreach to the prescriber's office to inform them of the reason(s) for denial and availability of emergency overrides.

II. Grandfathering

Information is not applicable.

III. Requests for Members at Risk of Harm to Self or Others

If the member has started or has been **stabilized** on the requested medication → please refer to Appendix I.

Non-preferred Long Acting Stimulants

If a request states that the member is at risk of harm to self or others (regardless of severity), ***has not been stabilized*** on the requested non-preferred long acting stimulant and has not provided appropriate clinical rationale for use over preferred agents and/or Concerta® → please **deny** request and notify the prescriber's office of the reason(s) for denial and availability of emergency overrides.

If a request states that the member is at risk of harm to self or others and the member does not meet criteria for approval→ please outreach to the prescriber's office to inform them of the reason(s) for denial and availability of emergency overrides.

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 old
4. Alpha$_2$ agonist or cerebral stimulant pharmacy claim for pediatric members less than 3 years old

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.

Additional Information

IV. Classification/Duration of Action

Medication	Short /Intermediate Acting	Long Acting
Amphetamine products	Dexedrine® tablet, Evekeo®, Evekeo ODT®, Zenzedi® Duration: 4 to 6 hours Adderall®, Dexedrine® capsule Duration: 6 to 8 hours	Adderall XR®, Adzenys ER®, Adzenys XR-ODT®, Dyanavel XR®, Vyvanse® Duration: 10 to 12 hours Mydayis® Duration: 16 hours
Methylphenidate products	Focalin®, Methylin®, Ritalin® Duration: 3 to 5 hours Metadate ER® Duration: 3 to 8 hours	Aptensio XR®, Azstarys®, Concerta®, Cotempla® XR-ODT, Daytrana®, Focalin XR®, Jornay PM®, ®, methylphenidate extended-release CD®, methylphenidate 72 mg ER tablet, QuilliChew ER®, Quillivant XR®, Ritalin LA® Duration: 8 to 12 hours Adhansia XR® Duration: 16 hours

V. Adverse reactions/Contraindications to Stimulants

Weight Loss or Failure to Gain Weight
Weight loss is considered an adverse reaction to stimulants.

If PA request states that the member experienced weight loss, failure to gain weight or appetite suppression on stimulants (either class)→ **Approve**

Insomnia, Agitation, Increased Anger and Aggression
If PA request states that the member has experienced insomnia, agitation or increased anger and aggression on stimulants (either class)→**Approve**

Tic Disorder
If the member has a pre-existing tic disorder or developed tics on a stimulant → **Approve**

Seizures w/ ADHD
If request states that the patient has a pre-existing seizure disorder and stimulants should be avoided → **Approve**

Traumatic Brain Injury w/ ADHD
Trial of **both** a methylphenidate product and amphetamine product is required for approval

- Need rationale for not using stimulants
  - If rationale submitted is concern for seizures→ **Approve**
  - If rationale submitted is other than seizures → **Deny**

For members with an anxiety disorder and NO documentation of substance abuse disorder
Stimulants are still an appropriate option for these members (can be used with or without an SSRI) → Deny

If compelling case, please forward to clinical review. If clinical review/supervisor is not available and compliance is an issue, please approve or deny based on your professional clinical judgment and forward to clinical review for follow-up.

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.

VI. Cardiovascular Concerns with stimulants

In a large clinical trial published in the November 2011 issue of the *New England Journal of Medicine*, the researchers concluded that stimulant medications do not raise the risk of sudden death, heart attack or stroke in children and young adults. In December 2011, the *Journal of the American Medical Association* analyzed data on more than 150,000 young and middle-aged adults taking a stimulant and found no added risk of heart attack, sudden cardiac death or stroke, even among patients with a family history of heart disease.

If a prior authorization states they wish to bypass stimulants due to risk of cardiovascular events → **Deny**

Heart Disease w/ ADHD
Children
If request states "congenital heart disease" and stimulants should be avoided → **Deny**

- Ask for additional information regarding status/etiology of the congenital heart disease.
  - If heart disease is symptomatic (tachycardia or hypertension) → **Approve**
  - If heart disease is resolved/insignificant → **Deny**

Adults
If request states that the member has heart disease or the provider is concerned about heart disease and wishes to use a non-stimulant over a stimulant → **Deny**

- Ask for additional information regarding status/etiology of the congenital heart disease
  - If heart disease is symptomatic (tachycardia or hypertension) →There should be at least **1 failed trial** of another non-stimulant medication that may be used for ADHD such as bupropion.
    - If heart disease is resolved/insignificant → **Deny**

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.

VII. Exceeding Quantity Limits-Stimulants

Requests that exceed the quantity limit should be reviewed for possible dose consolidation

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. Subsequent requests that do not address the consolidation should be denied.

For scenarios where member is using high quantities of lower strength medications (long or short)

- If dose consolidation *is possible*: Approve request for 1 month and ask for consideration of dose consolidation.
- Subsequent requests that do not address the consolidation should be denied.

For scenarios where dose consolidation is NOT possible- please **approve.**

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) – please **approve**.

Note:
It is acceptable if consolidating the dose would cause the member to have to fill 2 scripts as opposed to 1 script.

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.

VIII. Non-Preferred Stimulants and Swallowing Disorders

If the member has started or has been **stabilized** on the requested medication → please refer to Appendix I.
If there is documentation of **risk of harm** → please refer to Appendix III

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]
- chewable products
  - QuilliChew ER® [methylphenidate extended-release chewable tablet])
- 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.**

IV. 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.

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 05/01/2022

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